PPRB
PUBLIC PROCUREMENT REVIEW BOARD

SPECIAL TELEPHONIC MEETING MINUTES
Thursday, September 9, 2021

Location:
E.T. Woolfolk State Office Building
501 North West Street, Room 1302
Jackson, Mississippi

Board Members Attending Via Teleconference:

Billy Morehead, Chair
Norman McLeod, Interim Vice Chair
Rita Wray
David Russell
Liz Welch, Department of Finance and Administration

DFA Staff Members Present:
Aubrey Leigh Goodwin
Ross Campbell
Brittney Thompson
Suzanne Hudson
Liz DeRouen
Kevin Griffin

DFA Staff Members Attending Via Teleconference:

Catoria Martin, Special Assistant Attorney General
Liz Bolin, Special Assistant Attorney General

Guest Attending Via Teleconference:

Matt Dry, PEER

HemoCue America (HemoCue/Protestor)
- Orlando "Rod" Richmond, Esq., Butler Snow LLP
- Mark Garriga, Esq., Butler Snow LLP
- Hunter Bennett, Esq., Covington & Burling LLP
- Evan Sherwood, Esq., Covington & Burling LLP

Mississippi State Department of Health (MSDH/Agency)
- Jennifer Dotson, Director of Procurement
- Kevin Pearson, Project Director
- Sharon Dowdy, Chief Financial Officer

Teselyn Funches, Procurement Coordinator
Laura Tucker, Director of Public Health Nursing
LaTeshya Martin, Special Assistant Attorney General for MSDH

EKF Diagnostics, Inc. (EKF/Intended Awardee):
John Lassiter, Burr Forman LLP
Josh Stover, Burr Forman LLP
Pat Breheny, Public Health Sales Specialist
Jami Meeks, Vice President, Strategic Business Development

Ms. Goodwin identified all participants, both present and those attending via teleconference.

I. Call to Order

The meeting was called to order by Chair Billy Morehead.

II. Consideration of Protest

A. Protest; HemoCue America (HemoCue) v. Mississippi State Department of Health (MSDH); Contract for Hemoglobin Analyzers and Microcuvettes (RFx # 3140002081)

1. HemoCue (Protestor)

- Mr. Richmond presented arguments on behalf of the Protestor. He reserved five (5) minutes for rebuttal.

2. Mississippi State Department of Health (Agency)

- Ms. Martin presented arguments on behalf of the Agency.

3. EFK Diagnostics (EKF)

- Mr. Lassiter presented EKF's response to the protest.

4. HemoCue Rebuttal

- Mr. Richmond presented rebuttal for the Protestor.

Following rebuttal, questions from the Board were addressed.

B. Record on Appeal

i. HemoCue Protest to MSDH dated April 26, 2021
ii. MSDH Response dated June 22, 2021
iii. HemoCue's Appeal to PPRB dated July 1, 2021
iv. EKF's Response to HemoCue's Appeal dated July 30, 2021

The Protest documents are attached to these Minutes as **Attachment A.I, A.II, A.III, and A.IV.**

Action: A motion was made by Mr. McLeod to close the meeting to determine whether or not to declare an executive session. The motion was seconded by Mr. Russell and unanimously approved by all members present.

Mr. Morehead announced the meeting would close while the public was excused from the meeting so that the Board could determine whether to into Executive Session. Only DFA staff and Board members would remain on the teleconference while the Board members determined whether an Executive Session was appropriate.

Ms. Goodwin outlined the procedure for participants to reenter the meeting after the conference line was muted for the Board to discuss whether Executive Session would be entered or not.

Action: Mr. McLeod made a motion to go into Executive Session in accordance with Mississippi Code Section 25-41-7(4)(b) for the purpose of strategy sessions or negotiations with respect to issuance of an appealable order when an open meeting would have a detrimental effect on the litigating position of the PPRB. The motion was seconded by Mr. Russell and unanimously approved by all members present.

After the conference line was unmuted, Mr. Morehead announced to the public that the Board was entering Executive Session in accordance with Mississippi Code Section 25-41-7(4)(b) for the purpose of strategy sessions or negotiations with respect to issuance of an appealable order when an open meeting would have a detrimental effect on the litigating position of the PPRB. Everyone except the Board members and DFA staff was excused until the Board concluded its Executive Session.

Ms. Goodwin outlined the procedure for participants to reenter the meeting when the Board exits Executive Session.

III. Executive Session

While the public was excused from the teleconference, only discussion of the protest was had.

Motion: A motion was made by Ms. Wray to find in favor of the Protestor and direct the agency to either award a contract to HemoCue for the 301 product or reissue the procurement, after researching the product and revising the specifications to clarify the minimum requirements and specifically, determine whether the B.7 "30 seconds or less" is a must or whether there are acceptable qualifiers. The motion was seconded by Mr. McLeod and unanimously approved by all members present.

Ms. Goodwin identified all participants as they rejoined the Open Session of the teleconference meeting which reconvened at 10:15 a.m.

Mr. Morehead announced that during Executive Session the Board conducted strategy sessions and negotiations regarding an appealable order. Mr. Morehead reported that the Board unanimously found in favor of the Protestor, and directs the agency to either award a contract to HemoCue for the 301 product or reissue the procurement. Furthermore, if the agency chooses to reissue the procurement, then the Board recommends the agency research the product and revise specifications to clarify the minimum requirements and specifically, determine whether the B.7 "30 seconds or less" is a must or whether there are acceptable qualifiers. Counsel for the Board was directed to prepare a written Order in conformance therewith, which will be sent to all parties.

IV. Other Business

A. Ms. Goodwin gave an update on the Department of Education (MDE). She stated that as of Wednesday, September 8, 2021, MDE notified DFA staff that they will not request a Special PPRB Meeting for emergency procurements. MDE has determined there is time to issue those procurements following nonemergency procurement procedures and regulations.

B. Next Regular PPRB Meeting is October 6, 2021 at 9:00 a.m.

V. Adjournment

Action: A motion was made by Mr. Russell to adjourn. The motion was seconded by Mr. McLeod and unanimously approved by all members present.

These Minutes of the Public Procurement Review Board were approved by the members on the 3rd of November, 2021.

W Morehead

Billy Morehead, Chair

11/5/21

Date

PPRB
PUBLIC PROCUREMENT REVIEW BOARD

STATE OF MISSISSIPPI
GOVERNOR TATE REEVES

DEPARTMENT OF FINANCE AND ADMINISTRATION

LIZ WELCH
EXECUTIVE DIRECTOR

NOTICE

A Special Meeting of the

PUBLIC PROCUREMENT REVIEW BOARD

will be held Thursday, September 9, 2021
9:00 a.m.

**This Meeting will be via teleconference.*
Public access to the meeting will be provided telephonically.
*For access to the call, please send a request to PPRB@dfa.ms.gov**

PUBLIC PROCUREMENT REVIEW BOARD

PUBLIC PROCUREMENT REVIEW BOARD

Telephonic Regular Meeting
September 9, 2021
9:00 a.m.

BOARD MEMBERS ATTENDING VIA TELECONFERENCE

Billy Morehead

Norman McLeod

Rita Wray

David Russell

Liz Welch

PUBLIC PROCUREMENT REVIEW BOARD

PUBLIC PROCUREMENT REVIEW BOARD

Telephonic Special Meeting
September 9, 2021
9:00 a.m.

PPRB STAFF ATTENDANCE SHEET

NAME AND TITLE	AGENCY/COMPANY
Ross Campbell	DFA/OPTFM
Aubrey Leigh Goodwin	Executive
Brittney Thompson	DFA/OPSCR
Suzanne Hudson	DFA/OPSCR
Kevin Griffin	DFA/OIT
Liz DeRouen	DFA/OPC

PUBLIC PROCUREMENT REVIEW BOARD

Telephonic Special Meeting
September 9, 2021
9:00 a.m.

STAFF ATTENDING VIA TELECONFERENCE

NAME	AGENCY/COMPANY
Torri Martin	Special Assistant Attorney General
Liz Bolin	Special Assistant Attorney General

PPRB
PUBLIC PROCUREMENT REVIEW BOARD

PUBLIC PROCUREMENT REVIEW BOARD

Telephonic Special Meeting
September 9, 2021
9:00 a.m.

GUESTS ATTENDING VIA TELECONFERENCE

NAME	AGENCY/COMPANY
Matthew Dry	PEER
Jennifer Dotson	Mississippi State Department of Health
Sharon Dowdy	Mississippi State Department of Health
Teselyn Funches	Mississippi State Department of Health
Laura Tucker	Mississippi State Department of Health
Kevin Pearson	Mississippi State Department of Health
LaTeshya Martin	Mississippi State Department of Health

HemoCue America:

Orlando "Rod" Richmond, Butler Snow LLP
Mark Garriga, Butler Snow LLP
Hunter Bennett, Covington & Burling LLP
Evan Sherwood, Covington & Burling LLP

EKF Diagnostics, Inc.:

John Lassiter, Burr Forman LLP
Josh Stover, Burr Forman LLP
Pat Breheny, Public Health Sales Specialist
Jami Meeks, Strategic Business Development

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PUBLIC PROCUREMENT REVIEW BOARD

SPECIAL TELEPHONIC MEETING AGENDA
Thursday, September 9, 2021
9:00 a.m.

This Meeting will be via teleconference. Public access to the meeting will be provided telephonically. For access to the call, please send a request to PPRB@dfa.ms.gov

I. Call to Order

II. Consideration of Protest

A. Protest; HemoCue America (HemoCue) v. Mississippi State Department of Health (MSDH); Contract for Hemoglobin Analyzers and Microcuvettes (RFx # 3140002081)

1. Protestor will have 20 minutes to present; may reserve 5 minutes for rebuttal
2. Agency will have 20 minutes to present
3. Intended Awardee will have 10 minutes to present
4. Protestor will have 5 minutes for rebuttal

Representatives for HemoCue (Protestor):
Orlando "Rod" Richmond, Esq., Butler Snow LLP, Counsel for HemoCue America
Mark Garriga, Esq., Butler Snow LLP, Counsel for HemoCue America
Hunter Bennett, Esq., Covington & Burling LLP, Counsel for HemoCue America
Evan Sherwood, Esq., Covington & Burling LLP, Counsel for HemoCue America

Representatives for MSDH (Agency):
Jennifer Dotson, Director of Procurement
Kevin Pearson, Project Director
Sharon Dowdy, Chief Finance Officer
Teselyn Funches, Procurement Coordinator
Laura Tucker, Director of Public Health Nursing
LaTeshya Martin, Special Assistant Attorney General for MSDH

Representatives for EKF Diagnostics, Inc. (EKF)(Intended Awardee):
John Lassiter, Counsel for EKF
Josh Stover, Counsel for EKF
Pat Breheny, Public Health Sales Specialist, EKF
Jami Meeks, Vice President of Strategic Business Development, EKF
Ralph Guetlein, Global Director, Devices and Instrumentation, EKF

B. Record on Appeal

i. HemoCue Protest to MSDH dated April 26, 2021
ii. MSDH Response dated June 22, 2021
iii. HemoCue's Appeal to PPRB dated July 1, 2021
iv. EKF's Response to HemoCue's Appeal dated July 30, 2021

III. Other Business

A. Next Regular PPRB Meeting October 6, 2021 at 9:00 a.m.

IV. Adjournment

Attachment A

Record on Appeal

I. HemoCue Protest to MSDH
   - Dated April 26, 2021

II. MSDH Response
   - Dated June 22, 2021

III. HemoCue's Appeal to PPRB
   - Dated July 1, 2021

IV. EKF's Response to HemoCue's Appeal
   - Dated July 30, 2021

Attachment A.I

Record on Appeal

HemoCue Protest to MSDH

Dated April 26, 2021

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CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION WHICH MAY NOT BE RELEASED WITHOUT THE PRIOR WRITTEN PERMISSION OF HEMOCUE AMERICA

26 April, 2021

Dr. Thomas Dobbs, State Health Officer
&
Chief Procurement Officer
Mississippi State Department of Health
Purchasing Department
Room 137A
The Underwood Building
570 E. Woodrow Wilson
Jackson, MS 39216

Ref: **REQUEST FOR QUOTES-FORMAL (RFQF) REVERSE AUCTION**
RFx #3140002081 for Hemoglobin Analyzers and Microcuvettes

Dear Dr. Dobbs and Chief Procurement Officer,

This letter serves as HemoCue America, a division of Radiometer America Inc's ("HCAM") formal protest of the award made by the Mississippi State Department of Health ("MSDH") under for RFQF RFx#**3140002081** ("RFQF"). As the posting of the award notice was on April 20, 2021, this protest is timely filed and meets the requirements of the Mississippi Procurement Manual Chapter 6 Legal and Contractual Remedies, which we were instructed by the agency to follow.

Based on publicly available information, and given that the specifications established in the RFQF clearly do not include non-invasive technologies, HCAM is the only company that offers a product that meets the agency's needs. Indeed, only two other companies make invasive analyzers — EKF Diagnostics Inc., dba Stanbio Laboratory ("EKF") and Immunostics, Inc. ("Immunostics") — but neither has a product that can meet the solicitation's requirements. The agency's decision not to make award to HCAM was thus unreasonable and contrary to the solicitation's terms.

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Radiometer America Inc.

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I. The Agency's Award Decision Is Improper, Because HCAM's Hb 301 Analyzer Was the Only Product that Could Meet the Agency's Minimum Requirements

MSDH's solicitation sought a hemoglobin analyzer that had several key features. In particular, the solicitation's Specification Sheet required the following:

- Section B.5: "Testing sample size must be 10µl or less."
- Section B.6: "Measuring range must be Hgb: 0-25.6 g/dL."
- Section B.7: "Measuring time must be 30 seconds or less."

Exhibit A. In its question-and-answer session, MSDH explained that compliance with these standards was "mandatory," because they were "the minimum required" features to meet "the needs of the agency." *See* Exhibit B. The solicitation reiterated this point, stating that "[n]on-responsive bids will not be considered. A non-responsive bid is . . . a bid that does not comply with the minimum provisions of the specification." Exhibit. C, § 19.

Measured against that standard, it is clear that none of EKF's or Immunostic's products can comply. Indeed, only HCAM's Hb 301 product meets these standards.

Immunostic's hemochroma PLUS System Does Not Comply with the Solicitation

In the 510K Substantial Equivalence Determination Decision Summary for the hemochroma PLUS System (#K182298 Attached) (Exhibit D), the hemochroma PLUS System has a stated measuring range of 5.0-25.6 g/dL and a stated sample volume of 15 microliters. Immunostic's hemochroma PLUS System, therefore, cannot meet the requirements established in #B.5 nor #B.6.

Differences		
Item	Device hemochroma PLUS System K182298	Predicate HemoCue Hb 301 System K061047
Test Principle	Dual wavelengths for Hgb measurement and reference absorption.	Dual wavelengths for Hgb measurement and turbidity compensation.
Wavelength	Dual wavelengths 530 and 850 nm	Dual wavelengths 506 and 880 nm
Measuring Range	5.0–25.6 g/dL	0–25.6 g/dL
Sample Type	Capillary and venous whole blood	Capillary, venous, and arterial whole blood
Sample Volume	15µL	10µL
Test time	3 seconds	10 seconds
Parameter(s)	Estimation of hematocrit (HCT)	No estimation of HCT

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EKF's DiaSpect Tm System Does Not Comply with the Solicitation

In 2018, EKF was awarded 510K approval for their DiaSpect Tm System (#K172173 Attached) (Exhibit E) and CBER clearance of this product was established in 2020 (#BK200520 Attached) (Exhibit F). This device utilizes a reagentless cuvette and has a stated measuring range of 1.2 – 25.5 g/dL. Therefore, it does not meet the Mandatory Specification established in #B.6.

Performance	Predicate Device HemoPoint H2 Measurement System (K081719)	Candidate Device DiaSpect Tm system (K172173)
Method of detection (Test methodology)	Azide methemoglobin	Optical absorbance
Sample type	Capillary, arterial or venous	Capillary or venous
Sample volume	8 µL	< 10µL
Cuvette reagent components	Azide methemoglobin reagent	None
Cuvette storage	15 – 30°C	0 – 50°C
Cuvette components	2 canisters of 50 or 4 canisters of 50	5 packs of 100
Control Kit components	Two concentration levels of controls (3 vials of each)	Three concentration levels of controls (1 vial of each)
Quality Control	Requires two buffer based controls to validate the calibration	Requires three buffer based controls to validate the calibration
Measurement Range	0.0 – 25.6 g/dL	1.2 – 25.5 g/dL
Measuring Time	30-60 seconds	1 second

EKF's HemoPoint H2/HemoControl System Does Not Comply with the Solicitation

In the FDA 510K approval letter for the HemoPoint H2 product (#K032482 attached) (Exhibit G), EKF used the HemoCue B-Hemoglobin testing system (an old discontinued system) as a predicate device and it's measuring time is the same as that discontinued HCAM system "approximately 30-60 seconds" (highlighted below). It is also noted that "measuring time depends on the concentration." The system is based on an Azide methemoglobin method. Reagent in the microcuvette interacts with the sample and absorption is measured. This absorption is proportional to the tHb (total hemoglobin) concentration. Therefore, the measuring

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time is always to be expressed as a range and can never meet the mandatory specification as written in #B.7 — "Measuring time must be 30 seconds or less."

Comparison to Predicate Device:

Specification	HemoPoint® H2	HemoCue	Comments
Instrument :	No. 1	No. 2	No.1 ↔ No. 2
Measurement range	0 – 25.6 g/dL	0 – 25.6 g/dL	equivalent
Specified range	0 – 25.6 g/dL	0 – 23.5 g/dL	equivalent
Specified accuracy	± 0.3 g/dL at ≈14 g/dL	± 0.3 g/dL at ≈14 g/dL	equivalent
Sample material	venous, arterial or capillary human blood	venous, arterial or capillary human blood	equivalent
Measuring time	Approximately 30 – 60 sec	Approximately 30 – 60 sec	measuring time depends on the concentration
Measuring units	mol/L, g/dL, g/L	mol/L, g/dL, g/L	equivalent
Calibration	against NCCLS reference method	against ICSH reference method	NCCLS is current version of the method
Method	Azidemethemoglobin method (Vanzetti)	Azidemethemoglobin method (Vanzetti)	equivalent

Conclusion / Substantial Equivalence:
The HemoPoint® H2 Hemoglobin Photometer and HemoPoint® H2 Cuvettes and the predicate devices, HemoCue B-Hemoglobin System with microcuvette are substantially equivalent based on design and function.

OCT 2 4 2003

K032482

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

(As required by 21 CFR 807.92)

Trade Name: HemoPoint® H2 Hemoglobin Measurement System

Common/Classification Name: Automated Hemoglobin System

Device Classification:
Class: II
CFR: 21 CFR 864.5620
Product Code: GKR

Manufacturer:
Stanbio Laboratory
1261 North Main Street
Boerne, Texas 78006

Device Description / Procedure Principle:
The HemoPoint® H2 Hemoglobin Measurement System is comprised of a HemoPoint® H2 Hemoglobin Photometer and HemoPoint® H2 Cuvettes.

The recognized reference method for tHb determination (tHb = total hemoglobin) is the cyanmethemoglobin method, which is also known as the cyanhemoglobin method. The blood sample is diluted 1:251 with a reagent buffering solution. Here the erythrocytes are hemolysed and the bivalent iron in oxy- and desoxyhemoglobin are oxidised by the reagent potassium hexacyanoferrate (III) to trivalent iron and so converted to methemoglobin. Together with cyanide ions, which are also contained in the reagents, the methemoglobin forms a stable, colored complex, namely cyanmethemoglobin. This has a wide absorption maximum at 540 nm. This absorption is proportional to the tHb concentration.

In 1966, Vanzetti suggested to replace KCN by NaN_3 and thus was able to reduce the toxicity of the reagent mixture considerably.

Vanzetti's method is also known as the azide methemogobin method. A modified azide methemoglobin method is used in the HemoPoint® H2 system.

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Additionally, when the EKF cuvettes were updated in 2008 and a new 510K approval was received (#K081719 attached) (Exhibit H), this measuring time was reaffirmed and reapproved as "Approximately 30-60 sec". While the predicate device is now noted as the previous version of the H2 cuvette, the measuring time and Azide methemoglobin methodology do not change.

Comparison to Predicate Device:

Specification	HemoPoint® H2 (current cuvette)	HemoPoint® H2 (modified cuvette)	Comments
Instrument	No 1	No 2	No 1 ⟺ No 2
Measurement range	0 – 25.6 g/dL	0 – 25.6 g/dL	equivalent
Specified range	0 – 25.6 g/dL	0 – 25.6 g/dL	equivalent
Specified accuracy	± 0.3 g/dL at ≈ 14 g/dL	± 0.3 g/dL at ≈ 14 g/dL	equivalent
Sample material	venous, arterial or capillary human blood	venous, arterial or capillary human blood	equivalent
Measuring time	Approximately 30 – 60 sec	Approximately 30 – 60 sec	equivalent
Measuring units	mol/L, g/dL, g/L	mol/L, g/dL, g/L	equivalent
Calibration	against NCCLS reference method	against NCCLS reference method	equivalent
Method	Azidemethemoglobin method (Vanzetti)	Azidemethemoglobin method (Vanzetti)	equivalent

Finally, in 2003 and updated in 2020, EKF submitted and was granted FDA approval — (#K031898) (Exhibit I Attached) and (#K200909 Attached) (Exhibit J) — for their HemoControl device. While these approvals were data based, the measuring time is not changed and the methodology remains reagent based on Azide methemoglobin.

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Around the time of the release of the RFQF, EKF Diagnostics started making changes to the "measuring time definition" publicly attainable on their https://www.ekfusa.com/ website. The screenshot below was taken on 2/1/21, after the publication of the RFQF but before the State reached a final decision on which analyzers to include in the Reverse Auction.

EKF's website makes clear that it can take up to 60 seconds to take a measurement, even though it may be able to perform in "just 30 seconds" or "from 25 seconds." At best, EKF offers a range of time from "25-60" seconds, which does not meet the solicitation's mandatory standard.

Thus, HCAM's Hb 301 Analyzer is the only analyzer that could meet the agency's requirements. MSDH should have disqualified the other analyzers and made award to HCAM.

II. MSDH Engaged in Unequal Treatment by Disqualifying HCAM's Hb 201 Analyzer

On April 8, 2021, MSDH disqualified HCAM's Hb 201 analyzer from the competition, because it cannot measure hemoglobin in 30 seconds or less. Despite that, and for the reasons discussed in Section I, it is clear that the agency selected a hemoglobin analyzer that also cannot comply with the solicitation's minimum requirements. Thus, the agency engaged in unequal and irrational treatment — MSDH relaxed the solicitation standards for the awardee's product, but then applied a strict standard to disqualify HCAM's Hb 201 analyzer. But for that error, there is a substantial chance that the agency would have selected the Hb 201 analyzer, because of its combined competitive price and technical merits. That is a classic example of unequal treatment, and this protest should be sustained.

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III. Conclusion

For the above reasons, MSDH's award decision was contrary to the solicitation's standards and prejudiced HCAM. As the only eligible offeror, there is a substantial chance that HCAM would have been selected for award, but-for the agency's evaluation error. To remedy this error, the agency should direct an award to HCAM, as the only offeror whose product meets solicitation requirements. Thank you for your time and consideration.

Respectfully,

Mark Bellwood
Director of Sales, Specialty Markets
HemoCue America
(214) 412-8900
mark@hemocue.com

- EXHIBIT A -

MSDH-RFx # 3140002081 SPECIFICATION SHEET

Hemoglobin Analyzer and Microcuvettes

A.
A.1 Prospective device must be CLIA Waived.

B. General Specifications-Analyzer
B.1 All devices purchased must be new and model currently in production. Refurbished or demonstrator units are not acceptable. Instrument name and model must be listed.
B.2 The vendor must guarantee manufacturer replacement units for defective units for first 5 years.
B.3 All units must include a physical set of operating manual and brochures.
B.4 All units must include training and education program to all sites as well as refresher trainings at no cost.
B. 5 Testing sample size must be 10µl or less.
B. 6 Measuring range must be Hgb: 0-25.6 g/dL.
B.7 Measuring time must be 30 seconds or less.
B. 8 Unit must provide memory for no less than 100 test results.
B. 9 Unit must include AC adapters and DC battery options.
B. 10 Unit must have internal self check no less than each time unit is powered on.
B. 11 Units will be delivered to WIC Central Office, Ridgeland, MS with no shipping cost.

C. General Specifications-Microcuvettes
C.1 Expiration date at time of shipment must be greater than 18 months.
C.2 Expiration date after opening must be greater than or equal to 90 days.
C. 3 Guaranteed pricing of microcuvette supplies for 5 years.

The specifications listed are the minimum required for this RFQ-F Reverse Auction. They are not intended to limit competition nor specify any particular bidder/respondent, but to ensure that the MSDH receives a quality product meeting the needs of the agency.

— EXHIBIT B —

MISSISSIPPI STATE DEPARTMENT OF HEALTH

MISSISSIPPI STATE DEPARTMENT OF HEALTH
MAGIC RFx#3140002081
for
Hemoglobin Analyzers and Microcuvettes

AMENDMENT #3 - ATTACHMENT A
Solicitation Questions and Answers

	QUESTIONS	ANSWERS
1.	Are the specifications listed in the MSDh0RFX #3140002081(in section AA 1; section B.B. 1 – B10 and section C.C1 = C3) mandatory specifications?	Yes
2.	What is the process for protesting after the award for MSDH -RFX 3140002081?	This is reverse auction request. The vendors submit quotes and the program reviews if they meet the requirements. We then do open auction on or around Wednesday, March 10, 2021. The vendor with the lowest bid will win the auction.
3.	Can a responding supplier to MSDH RFX 3140002081 submit two unique bid responses? If so, please explain the process to do so.	This is up to the vendor.

— EXHIBIT C —

MSDH Request for Quotes-Formal (RFQF) Reverse Auction
RFx #3140002081

GENERAL CONDITIONS- REVERSE AUCTIONS

ALL BIDS SUBMITTED SHALL BE IN COMPLIANCE WITH ALL CONDITIONS SET FORTH HEREIN. THE BID PROCEDURES FOLLOWED BY THIS OFFICE WILL BE IN ACCORDANCE WITH THESE CONDITIONS. THEREFORE, ALL BIDDERS ARE URGED TO READ AND UNDERSTAND THESE CONDITIONS PRIOR TO SUBMITTING A BID.

1. DEFINITIONS

The use of the word "agency" in any Bid Invitation solicitation or specification shall be intended to mean state agencies only. The words "governing authority" when used shall be intended as meaning city, county or other local entities.

2. PREPARATION OF BIDS

2.1 Responding suppliers must provide a Quote with the initial response. Quotes are utilized by the Purchasing Agent to determine market pricing and set the auction parameters (e.g., start price). Bids and/or Quotes may be submitted through the State of Mississippi's e-procurement system (MAGIC), or in person to the Mississippi State Department of Health, Office of Purchasing ("MSDH" or "the State"). Paper bids are allowed. All prices and notations must be printed in ink or typewritten. No erasures permitted. Errors may be crossed out and corrections printed in ink or typewritten adjacent and must be initialed, in ink, by the person signing bid.

2.2 To submit bids electronically, bidders must ensure they are registered in the MAGIC system and have received a login, password, and supplier number and that all technical requirements have been met.

2.3 If a bidder is unwilling or unable to participate through MAGIC, an MSDH representative can enter the Vendor's bid(s) manually (i.e. Surrogate bidding).

2.4 Bidders participating in person by surrogate bidding must so indicate in their response to the initial Request for Quote-Formal (RFQF).

2.5 Failure to examine any drawings, specifications, and instructions will be at bidder's risk.

2.6 Price each item separately. Unit prices shall be shown. Bid prices must be net.

2.7 It is understood that reference to available specifications shall be sufficient to make the terms of such specifications binding on the bidder.

2.8 Bidders must furnish all information requested in the bid specifications. Further, when required, each bidder must submit for bid evaluation cuts, sketches, descriptive literature and technical specifications covering the product offered. Reference to literature submitted with a previous bid or on file with MSDH will not satisfy this provision.

2.9 Samples of items, when requested, must be furnished free of expense, and if not destroyed in testing will, upon request, be returned at the bidder's expense. Request for the return of samples must be made within ten (10) days following opening bids. Each individual sample must be labeled with bidder's name, manufacturer's brand name and number, State of Mississippi commodity number, bid number and item reference.

2.10 Time of performance. The number of calendar days in which delivery will be made after receipt of order shall be indicated in the bid specifications.

3. BID SUBMISSION

3.1 When submitting a bid electronically, the authorized signature may be typed or be an electronic signature.

3.2 Bids and modifications or corrections received after the closing time specified will not be considered.

3.3 When submitting the response to the RFQF in MAGIC, bidder must ensure all questions have been answered within the RFQF and all proposed items in bid have a response.

3.4 Bidders submitting paper responses should submit responses to the MSDH by the response deadline.

4. ACCEPTANCE OF BIDS

MSDH reserves the right to reject any and all bids, to waive any informality in bids and unless otherwise specified by the bidders, to accept any items on the bid. The State reserves the right to modify or cancel in whole or in part its Invitation for Bids.

If a bidder fails to state the time within which a submitted response will expire, it is understood and agreed that the MSDH shall have 60 days to accept.

5. ERROR IN BID

If a vendor is participating in a Live Auction, the vendor can notify MSDH in the event of an erroneous bid via the chat message feature. Erroneous bids, where the mistake is apparent to MSDH, may be deleted during the live auction.

6. SPECIAL DISCOUNT PERIOD

Time in connection with a special discount offered will be computed from date of delivery at destination or from the date correct invoices are received, if the latter date is later than the date of delivery. Cash discounts will not be considered in the award process.

7. AWARD

7.1 Contracts and purchases will be made or entered into with the lowest responsible bidder meeting specifications, except as otherwise specified in the bid specifications. Where more than one item is specified in the specifications, the State reserves the right to determine the low bidder either on the basis of the individual item(s) or on the basis of all items included in its Invitation for Bids, or as expressly provided in the State's Invitation for Bids.

7.2 Unless the bidder specified otherwise in the bid, the State may accept any item or group of items of any kind.

7.3 A written purchase order or contract award furnished to the successful bidder within the time of acceptance specified in the Invitation for Bid results in a binding contract without further action by either party. The contract shall consist solely of these General Conditions, the Instructions and Special Conditions, the successful bidder's bid, and the written purchase order or contract award. The contract shall not be assignable in whole or in part without the written consent of the State.

8. INSPECTION

Final inspection and acceptance or rejection may be made at delivery destination, but all materials and workmanship shall be subject to inspection and test at all times and places, and when practicable. During manufacture, the right is reserved to reject articles which contain defective material and workmanship. Rejected material shall be removed by and at the expense of the contractor promptly after notification or rejection. Final inspection and acceptance or rejection of the materials or supplies shall be made as promptly as practicable, but failure to inspect and accept or reject materials or supplies shall not impose liability on the State or any subdivision thereof for such materials or supplies as are not in accordance with the specification. In the event necessity requires the use of materials or supplies not conforming to the specification, payment therefore may be made at a proper reduction in price.

9. TAXES

The State is exempt from federal excise taxes and state and local sales or use taxes and bidders must quote prices which do not include such taxes. Exemption certificates will be furnished upon request. Contractors making improvements to, additions to or repair work on real property on behalf of the State are liable for any applicable sales or use tax on purchase of tangible personal property for use in connection with the contracts. Contractors are likewise liable for any applicable use tax on tangible personal property furnished to them by the State for use in connection with their contracts.

10. GIFTS, REBATE, GRATUITIES

10.1 Acceptance of gifts from bidders is prohibited. No officer or employee of the MSDH, nor any head of any state department, institution or agency, nor any employee of any state department, institution or agency charged with responsibility of initiating requisitions, shall accept or receive, directly or indirectly, from any person, firm or corporation to whom any contract for the purchase of materials, supplies, or equipment for the State of Mississippi may be awarded, by rebate, gifts, or otherwise, any money or anything of value whatsoever, or any promise, obligation or contract for future rewards or compensation.

10.2 Bidding by state employees is prohibited. It is unlawful for any state official or employee to bid on, or sell, or offer for sale, any merchandise equipment or material, or similar commodity to the State during the tenure of his or her office or employment, or for the period prescribed by law thereafter, or to have any interest in the selling of the same to the State.

11. BID INFORMATION

Bid information and documents may be examined pursuant to the Mississippi Public Records Act of 1983, MS Code 25-61-1 et seq.

12. PRECEDENCE

Bids shall be made and the contract shall be entered into in accordance with the General Conditions as hereinafter amended and modified. Should a conflict exist between the General Conditions and the Instructions and Special Conditions, the Instructions and Special Conditions shall take precedence.

13. COMPETITION

There are no federal or state laws that prohibit bidders from submitting a bid lower than a price or bid given to the U.S. Government. Bidders may bid lower than U.S. Government contract price without any liability as

the State is exempt from the provisions of the Robinson-Patman Act and other related laws. In addition, the U.S. Government has no provisions in any of its purchasing arrangements with bidders whereby a lower price to the State must automatically be given to the U.S. Government.

14. WAIVER

MSDH reserves the right to waive any General Condition, Special Condition, or minor specification deviation when considered to be in the best interest of the State.

15. CANCELLATION

Any contract or item award may be canceled with or without cause by the State with the giving of 30 days written notice of intent to cancel. Cause for the State to cancel may include, but is not limited to, cost exceeding current market prices for comparable purchases; request for increase in prices during the period of the contract; or failure to perform to contract conditions. The Contractor will be required to honor all purchase orders that were prepared and dated prior to the date of expiration or cancellation if received by the Contractor within a period of 30 days following the date of expiration or cancellation. Cancellation by the State does not relieve the Contractor of any liability arising out of a default or nonperformance. If a contract is canceled by the State due to a Contractor's request for increase in prices or failure to perform, that Contractor will be disqualified from bidding for a period of 24 months. The Contractor may cancel a contract for cause with the giving of 30 days written notice of intent to cancel. Cause for the Contractor to cancel may include, but is not limited to the item(s) being discontinued and/or unavailable from the manufacturer.

16. SUBSTITUTIONS DURING CONTRACT

During the term of a contract, if adequate documentation is provided that supports the claim that the contract item(s) are not available, items which meet the minimum specifications may be substituted if approved by MSDH and the substitutions are deemed to be in the best interest of the State.

17. APPLICATION

It is understood and agreed by the bidder that any contract entered into as a result of this Invitation for Bids is established for use by MSDH and all purchases made by MSDH for products included under the provisions of the contract shall be purchased from the bidder receiving the award unless exempt by special authorization from the state Office of Purchasing, Travel and Fleet Management.

Under the provisions of Section 31-7-7 Mississippi Code of 1972, Annotated, the prices offered herein shall be extended to the governing authorities. However, the governing authorities, by provisions of Section 31-7-12 Mississippi Code, may purchase products covered by state contracts from any source offering an identical product at a price that does not exceed the state contract price.

18. ADDENDA

Addenda modifying plans and/or specifications may be issued if time permits. No addendum will be issued within a period of two (2) working days prior to the time and date set for the bid opening. Should it become necessary to issue an addendum within the two (2) day period prior to the bid opening, the bid date will be reset to a date not less than five (5) working days after the date of the addendum, giving bidders ample time

to comply with the addendum. When replying to a bid request on which an addendum has been issued, and the specifications require acknowledgement, the bid shall indicate that provisions of the addendum have been noted and that the bid is being offered in compliance therewith. Failure to make this statement may result in the bid being rejected as not being in accordance with the revised specifications or plans.

19. NONRESPONSIVE BIDS

Nonresponsive bids will not be considered. A non-responsive bid is considered to be a bid that does not comply with the minimum provisions of the specification. Any bidder found to repeatedly offer alternated products that are not compliant with specifications in an attempt to obtain a contract on the basis of pricing only will be disqualified from bidding for a period of 24 months.

20. SPECIFICATION CLARIFICATION

It shall be incumbent upon all bidders to understand the provisions of the specifications and to obtain clarification prior to the time and date set for the live auction or bid opening. Such clarification will be answered only in response to a written request submitted in the specified amount of time set by the MSDH. TheMSDH reserves the right to specify a time frame in which clarification request shall be made.

21. Omitted

22. PRE-QUALIFICATION PROCESS

22.1 The purpose of the RFQF is to advertise the competitive procurement for solicitation of formal quotes from potential bidders to participate in the Reverse Auction. The MSDH will be responsible for defining product categories, adding bidders, and publishing all bid related documents to the procurement portal. Once the responses have been received and the Opening Date has been reached, the MSDH will review the submissions to qualify bidders and determine a starting price for reverse auction items.

22.2 The Invitation for Bids/RFQF shall be advertised in accordance with Section 3.106.05.4 of the Mississippi Procurement Manual. Minimum due date for responses to the RFQF will be on the 8th working day after the last day of advertisement.

22.3 Responses to the RFQF will be reviewed by the MSDH for responsiveness to specifications. Price quotes received will be evaluated in conjunction with other market research to determine the starting price for the Auction.

22.4 The MSDH will accept bidder responses in MAGIC who have qualified meeting RFx specifications. Bidders not meeting specifications will not be allowed to participate in the Auction.

22.5 Once qualified, the MSDH will notify the vendor of Qualification and the date of the Live Auction via email. After receiving the confirmation email, bidders should review/ensure technical requirements for MAGIC have been met or confirm participation in person.

22.6 It is requested that bids be submitted on the basis of statewide distribution. Contractors must maintain adequate distribution capabilities and adequate stock of all items to insure prompt delivery.

23. **FIRM BID PRICE**

Prices accepted from bidder submissions shall be firm for the term of the contract except that the State shall receive the benefit of any price decrease in excess of five (5) percent. The contractor must provide written price reduction information within ten (10) days of its effective date.

24. CONTRACT EXTENSION

24.1 Automatic contract renewals or extensions are not allowed. Contracts must be extended or renewed with the proper documents signed or approved by the MSDH.

24.2 The MSDH reserves the right to extend the term of a contract, when necessary, to continue a source of supply whenever new or replacement contracts are not completed prior to the expiration date. Such extensions are dependent upon the agreement of the Contractor and shall not exceed three (3) months.

25. SUSPENSION AND DEBARMENT

By submitting a bid, the bidder is certifying that neither the bidder nor any potential subcontractors are debarred or suspended or are otherwise excluded from or ineligible for participation in federal assistance programs.

26. ASSIGNMENT

The Contractor shall not assign or subcontract in whole or in part, its right or obligations under this agreement without prior written consent of the MSDH.

27. INDEMINIFICATION

Contractor shall Indemnify, defend, save and hold harmless, protect, and exonerate the State of Mississippi, its Commissioners, Board Members, officers, employees, agents, and representatives from and against all claims, demands, liabilities, suits, actions, damages, losses, and costs of every kind and nature whatsoever, including, without limitation, court costs, investigative fees and expenses, and attorneys' fees, arising out of or caused by Contractor's and/or its partners, principals, agents, employees, and/or subcontractors in the performance of or failure to perform this Agreement. In the State's sole discretion, Contractor may be allowed to control the defense of any such claim, suit, etc. In the event Contractor defends said claim, suit, etc., Contractor shall use legal counsel acceptable to the State; Contractor shall be solely liable for all reasonable costs and/or expenses associated with such defense and the State shall be entitled to participate in said defense. Contractor shall not settle any claim, suit, etc., without the State's concurrence, which the State shall not unreasonably withhold.

28. LIVE AUCTION

28.1 Notification of Auction Start date and time will be sent via email to qualifying bidders. If a bidder is unwilling or unable to participate through MAGIC, a representative from the MSDH can enter the Vendor's bid(s) manually (i.e. Surrogate Bidding). If a bidder elects to participate via Surrogate Bidding, the bidder must be physically present at the public bidding location, with the means to submit written bids for each offer made and signed by an authorized agent of the Vendor. A Bid Form will be provided to the Vendor at the start of the auction. This form will not be returned to the bidder but will become a part of the Bid Documentation for Evaluation by the MSDH.

28.2 The Auction time may be extended at the discretion of the MSDH. Examples of reasons to extend an auction include, but are not limited to, technical difficulties experienced by the MSDH or bidder, the need to pause the Auction, or bids placed within the last few moments of bidding.

28.3 Communication with bidders participating electronically during the Auction may be done via the Live Chat Feature. The MSDH has the ability to send messages to particular bidders or broadcast to all bidders. Bidders can ONLY communicate with the MSDH, not other bidders.

28.4 Bidders may be removed from a Live Auction for improper conduct, including but not limited to profanity, threats, consistently entering erroneous or extremely low bids, or other disruptive behavior.

28.5 Bidders/Suppliers should be advised that no award will automatically result from a reverse auction, and that the MSDH will review the results of the auction and make a determination in a timely manner.

29. **FORCE MAJEURE**

If the MSDH is closed for any reason, including but not limited to: acts of God, strikes, lockouts, riots, acts of war, epidemics, governmental regulations superimposed after the fact, fire, earthquakes, floods, or other natural disasters (the "Force Majeure Events"), which closure prevents the opening of bids at the advertised date and time, all bids received shall be publicly opened and read aloud on the next business day that the agency shall be open and at the previously advertised time. The new date and time of the bid opening, as determined in accordance with this paragraph, shall not be advertised, and all bidders, upon submission of a bid proposal, shall be deemed to have knowledge of and shall have agreed to the provisions of this paragraph. Bids shall be received by the agency until the new date and time of the bid opening as set forth herein. The MSDH shall not be held responsible for the receipt of any bids for which the delivery was attempted and failed due to the closure of the MSDH as a result of a Force Majeure Event. Each bidder shall be required to ensure the delivery and receipt of its bid by the MSDH prior to the new date and time of the live auction or bid opening.

MSDH Request for Quotes-Formal (RFQF) Reverse Auction

RFx# 3140002081

INSTRUCTIONS AND SPECIAL CONDITIONS

The Mississippi State Department of Health plans to purchase the following and invites your quote/participation:

Hemoglobin Analyzers and Microcuvettes for use in clinics/locations Statewide

The Purpose of this RFQF is to advertise this competitive procurement for solicitation of formal quotes from potential bidders to participate in a Reverse Auction.

The initial response to the RFQF shall include a proposed product, including specifications and/or sample, for the MSDH to evaluate and determine responsiveness to requirements/specifications. Once a supplier's/bidder's product is determined to be responsive, the supplier/bidder may participate in the reverse auction.

Responding suppliers/bidders must provide a quote with the initial response. Quotes are utilized by the purchasing agent to determine market pricing and set the auction parameters (e.g., Start Price).

Valid quotes will be accepted until 3:00 PM, CST, February 19, 2021

Qualified bidders will be notified approx. 7 working days prior to the auction via email if selected to participate. Once notification has been received, bidders should logon to MAGIC to validate technical requirements prior to the Live Auction.

The anticipated time for this reverse auction, for this procurement, is scheduled to be held on Wednesday, March 10, 2021, beginning at 2:00 PM CST and end at 2:30 PM CST. All bids must be entered into the eProcurement system during the allotted timeframe to be considered however, the MSDH reserves the right to extend the auction date if necessary to complete prequalifications. In addition, no vendor/supplier may be prohibited from participating in the reverse auction in person by paper through surrogate bidding.

Suppliers should be advised that no award will automatically result from a reverse auction, and that the MSDH will review the results of the auction and make a determination in a timely manner.

Vendors/bidders must be registered in MAGIC in order to receive a User ID and Password to log in. Vendors who are new to MAGIC may visit the Vendor information page on State of MS, Department of Finance and Administration's web site, or register online, Vendor Registration.

To Log into MAGIC, open the following URL: https://portal.magic.ms.gov/irj/portal. Enter User ID and Password. The password is case sensitive.

Vendors/bidders are responsible for ensuring Technical Requirements are met for participating in the reverse auction, etc. Technical Requirements are listed below:

Technical Requirements

Bidders are responsible for ensuring technical requirements are met.

Acceptable Internet Browser(s)

- Microsoft Internet Explorer (IE) version 11
- Microsoft Edge
- Google Chrome versions 49 and above

Unsupported Internet Browser(s)

- Microsoft Internet Explorer (IE) version 10 or below
- Safari
- Firefox

Note: Pop-up blocker must be turned off.

MISSISSIPPI STATE DEPARTMENT OF HEALTH

REQUEST FOR QUOTES-FORMAL (RFQF)
REVERSE AUCTION
RFx # 3140002081

The Mississippi State Department of Health (MSDH) will purchase Hemoglobin Analyzers and Microcuvettes for use in clinics/locations Statewide and invites your participation in accordance with the terms and conditions of this RFQF Reverse Auction. Once award of the bid has been made, the terms and conditions as set forth in this RFQF Reverse Auction shall become a contract binding on the successful bidder. Any documents submitted to satisfy a requirement of this request and any assurances made by the successful bidder in satisfaction of this request shall become a part of the agreement between the Mississippi State Department of Health and the successful bidder. The Mississippi State Department of Health shall have the right to rely upon the documents and assurances submitted by the successful bidder.

This RFQF Reverse Auction is for an estimated initial quantity/purchase of (230 Each) Hemoglobin Analyzers and related supplies (Microcuvettes). Estimated quantity of Microcuvettes, for a five year period, is 4500 Boxes of 200. Orders for Microcuvettes will be placed approx. (3) times per year for approx. 300 Boxes.

Pricing for Microcuvettes shall be guaranteed for a five-year period.

Pricing is also requested, and shall be guaranteed for a five-year period, for any New/Additional Analyzers purchased after the initial order.

This RFQF Reverse Auction/Award will be for a five-year period.

Pricing to include all shipping charges.

E-Verify Compliance - Contractor/Seller represent and warrants that it will ensure its compliance with the Mississippi Employment Protection Act (Senate Bill 2988 from the 2008 Regular Legislative Session) and will register and participate in the status verification system for all newly hired employees. The term "employee" as used herein means any person that is hired to perform work within the State of Mississippi. As used herein "status verification system" means the Illegal Immigration Reform and Immigration Responsibility Act of 1996 that is operated by the United States Department of Homeland Security, also known as the E-Verify Program, or any other successor electronic verification system replacing the E-Verify Program. Contractor/Seller agrees to maintain records of such compliance and , upon request of the State, to provide a copy of each such verification to the State. Contractor/Seller further represents and warrants that any person assigned to perform services hereunder meets the employment eligibility requirements of all immigration laws of the State of Mississippi. Contractor/Seller understands and agrees that any breach of these warranties may subject Contract/Seller to the following: (a) termination of this Agreement and Ineligibility for any state or public contract in Mississippi for up to three (3) years, with notice of such (b) the loss of any license, permit, certification or other document granted to Contractor/Seller by an agency, department or governmental entity for the right to do business in Mississippi for up to one (1) year, or (c) both. In the event of such termination/cancellation, Contractor/Seller would also be liable for any additional costs incurred by the State due to contract cancellation or loss of license or permit.

E-Payments – Payments by the Mississippi State Department of Health shall be made and remittance information provided electronically as directed by the State of Mississippi. These payments shall be deposited into the bank account of the Contractor's choice. The state may, at its sole discretion, require the Contractor to submit invoices and supporting documentation electronically at any time during the terms of this agreement. Contractor understands and agrees that the State is exempt from the payment of taxes. All payments shall be in United States currency.

Applicable Law – This purchase(s) shall be governed by and construed in accordance with the laws of the State of Mississippi, excluding its conflicts of law provisions, and any litigation with respect thereto shall be brought in the courts of the State of Mississippi. The vendor shall comply with applicable federal, state and local laws and regulations.

Payment Terms – MS Code Section 31-7-305(3) allows a state entity to pay invoices within 45 days without penalty.

Bid terms are welcome, however, they will not be used as criteria for awarding the bid.

Items will be purchased from the RFQF Reverse Auction by the Mississippi State Department of Health in accordance with the terms and conditions set out in this request and the attachments hereto.

State and Federal law requires that the Mississippi State Department of Health not be liable should federal or state funds not be available to make the purchases. Should federal or state funds be reduced or eliminated, the State of Mississippi, the Mississippi State Department of Health, its agents, servants and employees would have no obligation to purchase any quantity of

goods or services covered by this request for bid. The bidder agrees to hold the above enumerated entities and individuals harmless in that event.

The bidder/prospective vendor must further give assurances in writing that it can provide and deliver the items as ordered on a schedule agreeable to the Mississippi State Department of Health. The contractor shall not assign, sell or subcontract in whole or in part, its rights or obligations under this agreement without prior written consent of the MSDH. Any attempt assignment or sale of the contract without said consent shall be void and of no-effect.

The MSDH reserves the right to refuse any items not meeting the specifications of this bid.

Prospective bidders are to contact Cynthia Brasher, Purchasing Director in writing if there are any questions regarding this RFQF Reverse Auction, either by email cynthia.brasher@msdh.ms.gov or by writing to P. O. Box 1700, Jackson, MS 39215-1700. Questions are to be received no later than the close of business on February 12, 2021. MSDH answers/responses will be posted on the State of MS Transparency website and on the MSDH website within 1-2 days.

Sealed quotes/responses will be accepted/received until 3:00 PM, CST, Friday, February 12, 2021, either hand delivered or by mail to **Mississippi State Department of Health, Purchasing Department, Room 137A, The Underwood Building, 570 E. Woodrow Wilson, Jackson, Mississippi 39216 or Post Office Box 1700, Jackson, MS 39215-1700.** The quotes/responses must be received before and be dated and time stamped by the submission deadline. All bids must be properly stamped. No quotes/responses will be accepted after the established submission deadline.

Currently, due to the continuing Covid-19 pandemic, the Mississippi State Department of Health remains closed to the public.

Prior to the quote/response due date and time, quotes/responses may be Hand Delivered to the agency between the hours of 8:00 a.m. and 5:00 p.m., CST. Entry may be obtained at the Visitor's entrance to the Mississippi State Department of Health, Osborne Building, 570 E Woodrow Wilson, Jackson, MS 39216. A receptionist will be on duty to receive the bid responses and forward to the addressee on the envelope/package.

No facsimile (FAX) quotes/responses will be accepted.

Quote/response BID FORM must be signed by a person with authority to bind the bidder, and must accompany your submission. Failure to comply with this provision, any other provision of this RFQF Reverse Auction, or any provision of state or federal law or regulation regarding the submission of bids may cause the bid to be rejected.

In addition, it is requested that bidders also submit a quote/response on-line in the State of Mississippi electronic procurement system, MAGIC, however, it is not mandatory. In order to submit quotes/responses bidders must be registered as a vendor in MAGIC system and have an I.D. number and password assigned at the time of registration. Technical assistance may be found at http://www.dfa.ms.gov/dfa-offices/mmrs/mississippi-suppliers-vendors/. If a bidder submits both a paper quote/response and an on-line quote/response, the paper quote/response will take precedence if there is a discrepancy between the two.

The Mississippi State Department of Health reserves the right to waive minor informalities, which are matters of form rather than substance, or insignificant mistakes or to allow the bidder to correct them if other bidders are not prejudiced.

The bid will be awarded to the lowest and best responder/participant of this RFQF Reverse Auction as determined by the agency. The awardee will perform the terms and conditions of the bid and any contract awarded hereunder. No assignment of subcontracting of the award or any contract awarded there under shall be allowed without prior written approval of the State Health Officer.

PLEASE MARK YOUR ENVELOPES EXTERNALLY:

RFx #3140002081 Submission Deadline: 3:00 PM, CST, February 19, 2021

MSDH-RFx # 3140002081 SPECIFICATION SHEET

Hemoglobin Analyzer and Microcuvettes

A.
A.1 Prospective device must be CLIA Waived

B. General Specifications-Analyzer
B.1 All devices purchased must be new and model currently in production. Refurbished or demonstrator units are not acceptable. Instrument name and model must be listed.
B.2 The vendor must guarantee manufacturer replacement units for defective units for first 5 years.
B.3 All units must include a physical set of operating manual and brochures.
B.4 All units must include training and education program to all sites as well as refresher trainings at no cost.
B. 5 Testing sample size must be 10µl or less
B. 6 Measuring range must be Hgb: 0-25.6 g/dL
B.7 Measuring time must be 30 seconds or less
B. 8 Unit must provide memory for no less than 100 test results.
B. 9 Unit must include AC adapters and DC battery options
B. 10 Unit must have internal self check no less than each time unit is powered on.

C. General Specifications-Microcuvettes
C.1 Expiration date at time of shipment must be greater than 18 months.
C.2 Expiration date after opening must be greater than or equal to 90 days.
C. 3 Guaranteed pricing of microcuvette supplies for 5 years.

The specifications listed are the minimum required for this RFQ-F Reverse Auction. They are not intended to limit competition nor specify any particular bidder/respondent, but to ensure that the MSDH receives a quality product meeting the needs of the agency.

Response/Quote

BID FORM

RFx 3140002081

Hemoglobin Analyzer - Name and Model # _____

Estimated Quantity – Initial Purchase: 230 Each $_____/EA

Guaranteed Pricing for any NEW/Additional units purchased during a five year period: $_____/EA

Microcuvettes - Name and Product # _____

Estimated Quantity – Five Year Period: 4500 Boxes/200 PER Box $_____/BOX

(Orders to be placed approx. (3) times per year for approx. 300 Boxes)

Name of Company_____

Quoted By_____

Signature_____

Email_____

Telephone_____

By signing this Bid Form, the company representative certifies that he/she has authority to bind the company and has thoroughly read and understands this RFQF Reverse Auction and the attachments herein and that the company meets all requirements/specifications and agrees to all provisions of this solicitation and any issued addenda.

MSDH Anticipated Initial Shipping List for Analyzers: RFx 3140002081

	Nutritionist	Quantity	Address				
Northern Region 1	"	25	Yalobusha County Health Dept.	645 S. Main Street	Water Valley	MS	38965
	"	22	Northern Region I Office	532 S. Church Street	Tupelo	MS	38802
	"	21	Northern Region I Annex	2600 Browning Rd.	Greenwood	MS	38930
Central Region 2	"	20	Starkville Food Center	1203 Louisville St	Starkville	MS	39759
	"	19	Lauderdale County Health Dept.	5224 Valley Street	Meridian	MS	39304
	"	22	Central Region 2 Office	4800 McWillie Circle	Jackson	MS	39206
Southern Region 3	"	23	Adams County Health Dept.	415 Hwy 61 N	Natchez	MS	39120
	"	14	Southern Region - Hattiesburg	208 W. Pine Street, Suite 100	Hattiesburg	MS	39401
	"	14	Southern Region 3 Office	1141 Bayview Ave., Suite 102	Biloxi	MS	39530
WIC Shipping & Receiving	Percy Catchings	50	WIC Central Warehouse	249 West Mitchell Street	Jackson	MS	39213
Total		230					

– EXHIBIT D –

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K182298

B. Purpose for Submission:

Expansion of target patient population – addition of pediatric claim

C. Measurand:

Hemoglobin

D. Type of Test:

Quantitative determination of hemoglobin

E. Applicant:

Immunostics, Inc.

F. Proprietary and Established Names:

hemochroma PLUS System
hemochroma PLUS Controls

G. Regulatory Information:

1. Regulation section:

   21 CFR 864.5620, Automated hemoglobin system
   21 CFR 864.8625, Hematology quality control mixture

2. Classification:

   Class II

3. Product code:

   GKR, System, hemoglobin, automated
   GGM, Control, hemoglobin

4. Panel:

Hematology (81)

H. Intended Use:

1. Intended use(s):

   The hemochroma PLUS System is for the quantitative determination of hemoglobin concentration in non-anticoagulated capillary (finger-stick) whole blood or venous whole blood (K_2-EDTA, K_3-EDTA, sodium citrate, lithium heparin, or sodium heparin). The testing system is designed for point-of-care settings, hospitals, and medical lab facilities.

   Estimation of hematocrit, as a function, is only for normal hemoglobin values, 12.0 to 18.0 g/dL (120 to 180 g/dL) and in patients $\geq$ 6 months old.

   The hemochroma PLUS Controls are intended for use as quality control material to assure the validity and performance of the hemochroma PLUS system in measuring the human hemoglobin concentration.

   The hemochroma PLUS Microcuvettes are only used with hemochroma PLUS Analyzer. The hemochroma PLUS System is for *in vitro* diagnostic only.

   The hemochroma PLUS Analyzer calculates the test result automatically and displays hemoglobin concentration in terms of g/dL.

2. Indication(s) for use:

   Same as intended use

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   hemochroma Plus Analyzer

I. Device Description:

The hemochroma PLUS System consists of a hemochroma PLUS Analyzer, single-use hemochroma PLUS Microcuvettes, hemochroma PLUS ID Chip, optical System Check Microcuvette and hemochroma PLUS Controls.

1. hemochroma PLUS Analyzer

   The hemochroma PLUS Analyzer is a battery powered, hand-held device used to

measure total hemoglobin concentration in human whole blood. Whole blood may be collected by fingerstick (capillary) or venipuncture and analyzed without pre-processing. The hemochroma PLUS Analyzer uses hemochroma PLUS Microcuvettes with dual ports where the user applies samples either through capillary action or direct volume pipetting. The hemochroma PLUS Analyzer determines hemoglobin concentration in whole blood samples using a dual wavelength photo-absorption method and measures the degree of light absorption with a spectrophotometer. The optical distance between the hemochroma PLUS Microcuvette walls is fixed and permits photometric determination of hemoglobin in undiluted blood samples. The computed end result is displayed on a LCD display and can be printed on an external printer (optional).

2. hemochroma PLUS Microcuvette

   The hemochroma PLUS Microcuvettes are specially designed for use with the hemochroma PLUS Analyzer. The microcuvettes function as measuring devices specifically holding 15 µL of blood and are inserted into the hemochroma PLUS Analyzer by placing it into the cuvette holder. The optical distance between the hemochroma PLUS Microcuvette walls is fixed and by measuring the degree of light absorption permits photometric determination of the hemoglobin in undiluted blood samples.

3. hemochroma PLUS ID Chip

   The hemochroma PLUS ID chip contains encoded memory with the calibration data/information of the Microcuvette lot. With the ID chip inserted in the designated port, the hemochroma PLUS Analyzer reads and utilizes the calibration data regarding the lot under consideration and applies appropriate correction to the conversion formula while computing the test result.

4. hemochroma PLUS Optical System Check Microcuvette

   hemochroma PLUS Optical System Check Microcuvette is designed for use with the hemochroma PLUS Analyzer only. The Optical System Check Microcuvette is a special glass filter used to measure the degree of light absorption with the spectrophotometric method. If the result is between 11.7–12.3 g/dL, the optic system is working properly according to specification.

5. hemochroma PLUS Controls

   The hemochroma PLUS Controls: Level 1 (Low), Level 2 (Middle), and Level 3 (High), are external quality controls designed for use with hemochroma PLUS Analyzer only.

J. Substantial Equivalence Information:

1. Predicate device name(s):

HemoCue Hb 301 System

2. Predicate 510(k) number(s):

   K061047

3. Comparison with predicate:

Similarities		
Item	Device Hemochroma PLUS System K182298	Predicate HemoCue Hb 301 System K061047
Intended Use/ Indications for Use	The hemochroma PLUS System is for the quantitative determination of hemoglobin concentration in non-anticoagulated capillary (finger-stick) whole blood or venous whole blood (K_2-EDTA, K_3-EDTA, sodium citrate, lithium heparin, or sodium heparin). The testing system is designed for point-of-care settings, hospitals, and medical lab facilities. Estimation of hematocrit, as a function, is only for normal hemoglobin values, 12.0 to 18.0 g/dL (120 to 180 g/dL) and in patients ≥ 6 months old. The hemochroma PLUS Controls are intended for use as quality control material to assure the validity and performance of the hemochroma PLUS system in measuring the human hemoglobin concentration. The hemochroma PLUS Microcuvettes are only used with hemochroma PLUS Analyzer. The hemochroma PLUS System is for *in vitro* diagnostic only. The hemochroma PLUS	The HemoCue Hb 301 System is designed for quantitative point-of-care whole blood hemoglobin determination in primary care using a specially designed analyzer, the HemoCue Hb 301 Analyzer, and specially designed microcuvettes, the HemoCue Hb 301 Microcuvettes. The HemoCue Hb 301 system is for in vitro diagnostic use only. The HemoCue Hb 301 Analyzer is only to be used with HemoCue Hb 301 Microcuvettes.

Similarities		
Item	Device Hemochroma PLUS System K182298	Predicate HemoCue Hb 301 System K061047
	Analyzer calculates the test result automatically and displays hemoglobin concentration in terms of g/dL.	
Parameter(s)	Hemoglobin (Hgb)	Same

Differences		
Item	Device hemochroma PLUS System K182298	Predicate HemoCue Hb 301 System K061047
Test Principle	Dual wavelengths for Hgb measurement and reference absorption.	Dual wavelengths for Hgb measurement and turbidity compensation.
Wavelength	Dual wavelengths 530 and 850 nm	Dual wavelengths 506 and 880 nm
Measuring Range	5.0–25.6 g/dL	0–25.6 g/dL
Sample Type	Capillary and venous whole blood	Capillary, venous, and arterial whole blood
Sample Volume	15µL	10µL
Test time	3 seconds	10 seconds
Parameter(s)	Estimation of hematocrit (HCT)	No estimation of HCT

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP28-A3C: Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition

L. Test Principle:

The hemochroma PLUS Analyzer utilizes a dual wavelength LED light source by which the hemoglobin absorbance is detected and converted into an electrical signal. The signal is directly proportional to the amount of hemoglobin present in the sample. The concentration of hemoglobin is calculated based on a pre-programmed calibration. The hemochroma PLUS Microcuvette is specifically designed for the hemochroma PLUS Analyzer. Approximately 15 µL of capillary or venous blood is taken up by capillary action using the tip of the hemochroma PLUS Microcuvette or by direct volume pipetting of the sample. The blood filled Microcuvette is inserted onto the microcuvette holder, and the hemochroma PLUS Analyzer measures the degree of light absorption with a spectrophotometer. The absorbance of the light from the hemochroma PLUS Microcuvette is converted into an electrical signal. The optical distance between the hemochroma PLUS Microcuvette walls is fixed and permits

photometric determination of the hemoglobin in undiluted blood samples.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

In premarket notification K163465 the following studies were performed for the hemochroma PLUS System: method comparison to the HemoCue Hb 301 System, precision/reproducibility, linearity, detection limit, stability, and interference studies. The established performance and technological characteristics cleared in K163465 remain unchanged; therefore, additional performance studies were not required to support substantial equivalence in this premarket notification.

a. Precision/Reproducibility:

Refer to K163465

b. Linearity/assay reportable range:

Refer to K163465

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Refer to K163465

d. Detection limit:

Refer to K163465

e. Analytical specificity:

Refer to K163465

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Refer to K163465

b. Matrix comparison:

Refer to K163465

3. Clinical studies:

   a. *Clinical Sensitivity:*

      Not applicable

   b. *Clinical specificity:*

      Not applicable

   c. *Other clinical supportive data (when a. and b. are not applicable):*

4. Clinical cut-off:

   Not applicable

5. Expected values/Reference range:

   Adult references ranges were based on existing medically accepted published reference ranges[1].

Group	Cited Reference Range
Adult Male	14.0 – 18.0 g/dL
Adult Female	12.0 – 16.0 g/dL

   Pediatric reference ranges were based on existing medically accepted published references ranges[2].

Group	Cited Reference Range
2–6 months	9.5 – 13.5 g/dL
7 months – 2 years	10.5 – 14.0 g/dL
3–6 years	11.5 – 14.5 g/dL
7–12 years	11.5 – 15.5 g/dL
13–18 years male	13.0 – 16.0 g/dL
13–18 years female	12.0 – 16.0 g/dL

N. Instrument Name:

[1] Billett, H.H. Hemoglobin and Hematocrit. Clinical Methods: The History, Physical, and Laboratory Examinations. Boston: Butterworths, 3rd Edition, 1990: Chapter 51.
[2] Andropoulos, D.B., and Gregory, G.A. Gregory's Pediatric Anesthesia. Wiley-Blackwell, 5th Edition, 2012: Appendix B.

hemochroma PLUS Analyzer

O. System Descriptions:

1. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes _____ or No ___X____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No ___X____

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes __X___ or No _____

3. Specimen Identification:

   There is no sample identification function for the hemochroma PLUS Analyzer. Samples are applied directly to the microcuvettes as they are collected. The end user must develop a manual system to identify patients that are tested with the hemochroma PLUS Analyzer.

4. Specimen Sampling and Handling:

   Capillary or venous whole blood is directly applied from the finger or blood tube (using a disposable pipette) to the Microcuvette. Wipe off excess blood from the surface of the microcuvette using a piece of soft gauze. The blood-filled Microcuvette is then inserted into the hemochroma PLUS Analyzer.

5. Calibration:

   The hemochroma PLUS ID chip contains encoded memory with the calibration data/information of the Microcuvette lot. With the ID chip inserted in the designated port, the hemochroma PLUS Analyzer reads and utilizes the calibration data regarding the lot under consideration and applies appropriate correction to the conversion formula while computing the test result.

6. Quality Control:

The hemochroma PLUS Controls (low, middle, and high hemoglobin) are intended for use as quality control material to assure the validity and performance of the hemochroma PLUS System in measuring the human hemoglobin concentration. The hemochroma PLUS Controls should be assayed according to the manufacturer's instructions and following the local and state guidelines. If controls do not perform as expected, the test results should not be used.

The hemochroma PLUS Optical System Check is used to assure the performance of the Optic System of the hemochroma PLUS. The Optical System Check Microcuvette is a special glass filter used to measure the degree of light absorption with the spectrophotometric method. If the result is between 11.7–12.3 g/dL, the optic system is working properly according to specification.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Not applicable

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

— EXHIBIT E —

U.S. FOOD & DRUG ADMINISTRATION

April 06, 2018

EKF-diagnostic GmbH
Mick Fenton
Head of Global QA/RA
Ebendorfer Chaussee 3
39179 Barleben
Germany

Re: K172173
Trade/Device Name: DiaSpect Tm system
Regulation Number: 21 CFR 864.5620
Regulation Name: Automated hemoglobin system
Regulatory Class: Class II
Product Code: GKR
Dated: February 20, 2018
Received: March 05, 2018

Dear Mick Fenton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR

803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Leonthena R. Carrington -S

Lea Carrington
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172173

Device Name
DiaSpect Tm system

Indications for Use *(Describe)*
The DiaSpect Tm system is intended for the in vitro quantitative measurement of total hemoglobin in non-anticoagulated capillary whole blood and venous whole blood drawn in K2EDTA or lithium heparin tubes. The DiaSpect Tm system consists of the DiaSpect Tm analyzer and specifically designed disposable cuvettes, the DiaSpect Tm Cuvettes. The device is intended for use in point-of-care settings. The DiaSpect Tm analyzer is only to be used with DiaSpect Tm Cuvettes.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5 510(k) Summary

510k Number

K172173

Introduction

In accordance with the requirements of 21CFR807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

I. Submitter

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Germany

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Phone: +44 0290705274
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Email: karengolomb@ekfdiagnostics.com

Date prepared: 10th July 2017

II. Device Name

Proprietary names:	DiaSpect Tm system
Common names:	As above
Classification:	21 CFR 864.5620 – Automated hemoglobin system Class II Hematology Product Code: GKR

III. Predicate Device

The DiaSpect Tm system is substantially equivalent to the currently marketed HemoPoint® H2 Measurement System (K081719).

IV. Device Description

The DiaSpect Tm system consists of an analyzer and cuvettes. The DiaSpect Tm analyzer is a spectrophotometric instrument for the total hemoglobin concentration in unaltered human blood. The DiaSpect Tm Cuvette is injection-molded of poly methyl methacrylate (PMMA) and contains a cavity of 10 µL volume. The cavity is empty.

V. Indications for Use

The DiaSpect Tm system is intended for the in vitro quantitative measurement of total hemoglobin in non-anticoagulated capillary whole blood and venous whole blood drawn in K_2EDTA or lithium heparin tubes. The DiaSpect Tm system consists of the DiaSpect Tm analyzer and specifically designed disposable cuvettes, the DiaSpect Tm Cuvettes. The device is intended for use in point-of-care settings. The DiaSpect Tm analyzer is only to be used with DiaSpect Tm Cuvettes.

Rx only.

VI. Comparison with Predicate

1. Predicate device name(s):
   HemoPoint® H2 Measurement System

2. Predicate 510(k) number(s):
   K081719

Similarities compared to the chosen (FDA cleared; marketed) predicate device (k081719)

Performance	**Predicate Device HemoPoint H2 Measurement System (K081719)**	**Candidate Device DiaSpect Tm system (K172173)**
Indications for use	Determine hemoglobin content of whole blood	Same
Analyte	Hemoglobin	Same
Sample preparation (pre-treatment)	None	Same
Automation	Fully automated assay	Same
Calibration procedure	Factory calibrated	Same
Built in Quality Control	Auto self-check between measurements	same

Differences compared to the chosen (FDA cleared; marketed) predicate device (k081719)

Performance	Predicate Device HemoPoint H2 Measurement System (K081719)	Candidate Device DiaSpect Tm system (K172173)
Intended Use	The HemoPoint H2 system is intended for the quantitative determination of hemoglobin (Hgb) in whole blood of adults, infants, and children in a professional point-of-care setting. It consists of a dedicated photometer and individual, single-use microcuvettes filled with reagents.	The DiaSpect Tm system is intended for the in vitro quantitative measurement of total hemoglobin in non-anticoagulated capillary whole blood and venous whole blood drawn in K_2EDTA or lithium heparin tubes. The DiaSpect Tm system consists of the DiaSpect Tm analyzer and specifically designed disposable cuvettes, the DiaSpect Tm Cuvettes. The device is intended for use in point-of-care settings. The DiaSpect Tm analyzer is only to be used with DiaSpect Tm Cuvettes. RX only
Method of detection (Test methodology)	Azide methemoglobin	Optical absorbance
Sample type	Capillary, arterial or venous	Capillary or venous
Sample volume	8 µL	< 10µL
Cuvette reagent components	Azide methemoglobin reagent	None
Cuvette storage	15 – 30°C	0 – 50°C
Cuvette components	2 canisters of 50 or 4 canisters of 50	5 packs of 100
Control Kit components	Two concentration levels of controls (3 vials of each)	Three concentration levels of controls (1 vial of each)
Quality Control	Requires two buffer based controls to validate the calibration	Requires three buffer based controls to validate the calibration
Measurement Range	0.0 – 25.6 g/dL	1.2 – 25.5 g/dL
Measuring Time	30-60 seconds	1 second

VII. Performance Characteristics

1. Analytical Performance

a. Precision/Reproducibility:

Precision was determined in accordance with CLSI EP5-A2, "Evaluation of Precision Performance of Quantitative Measurement Methods". Two precision studies were performed at the clinical sites per protocol EKF-PS-01. One study was a 20-Day multi-site study using

three levels of external control material, and the other study was a single-day, single-site precision study with 5 levels of natural and manipulated K2EDTA venous blood.

20-Day Precision

The 20-Day precision was performed by running external controls in duplicate twice per day by two operators at each of three sites (a 20 x 2 x 2 x 3 format with 6 operators, 3 lots, 3 instruments and 3 sites). Lots and instruments were nested with sites. The study was performed by six of the same operators who performed the Method Comparison studies. The 20-Day precision data met the criteria of <7% CV.

20-Day Precision Summary

Sample	N	Mean	Within-Run (SD, %CV)	Between-Run (SD, %CV)	Between-Day (SD, %CV)	Between-Operator (SD, %CV)	Between-Site (SD, %CV)	Total (SD, %CV)
Level 1	240	7.99	(0.085, 1.06%)	(0.05, 0.59%)	(0.04, 0.47%)	(0, 0%)	(0.04, 0.45%)	(0.11, 1.38%)
Level 2	240	12.58	(0.11, 0.88%)	(0.05, 0.38%)	(0.03, 0.22%)	(0, 0%)	(0.06, 0.47%)	(0.14, 1.09%)
Level 3	240	15.82	(0.15, 0.92%)	(0.06, 0.36%)	(0.04, 0.27%)	(0, 0%)	(0.15, 0.97%)	(0.22, 1.41%)

Single-Day Precision

Single-Day precision was performed at a single site using K_2EDTA venous whole blood. Five donors provided 5 samples, some of which were manipulated by removing plasma to increase hemoglobin, or diluting with the same donor's plasma to decrease hemoglobin. The study was performed at a new single site using 3 instruments, 3 lots and 3 untrained operators who had no prior experience running the DiaSpect Tm, and self-trained on the system. Each of 3 operators ran duplicate tests on all 5 levels with 3 lots of cuvettes in each of 3 instruments, providing 54 measurements for each level. The higher %CV found for Level 5 may be due to the increased viscosity of the abnormally high hematocrit for the samples. The Single-Day precision study met the criteria of <7% CV.

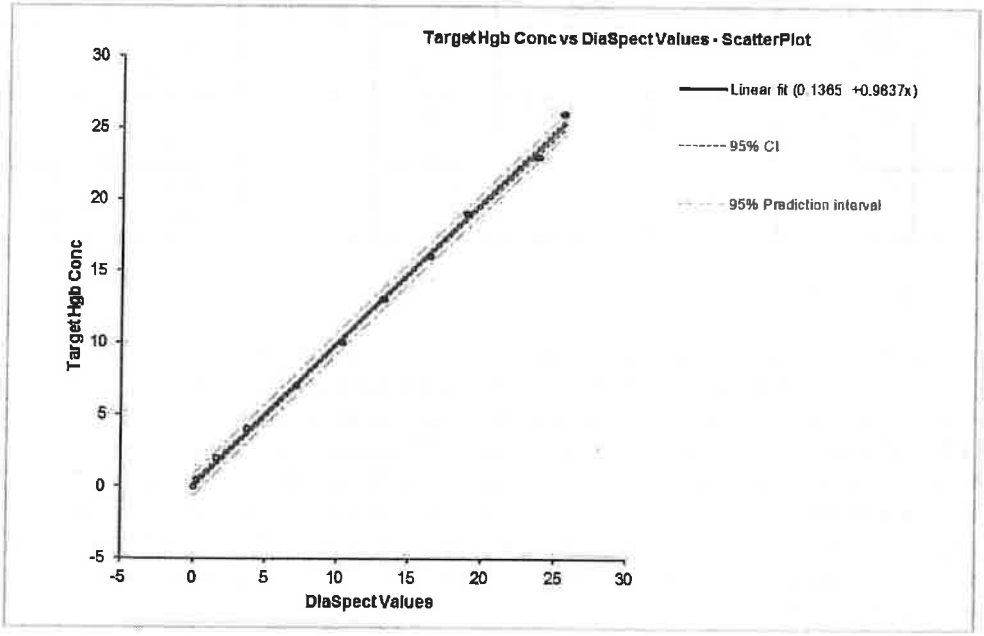
Single-Day Precision Summary

Sample	N	Mean	Within-Run (SD, %CV)	Between-lot (SD, %CV)	Between-Operator (SD, %CV)	Between-Analyzer (SD, %CV)	Total (SD, %CV)
Level 1	54	4.87	(0.05, 0.97%)	(0.04, 0.82%)	(0.02, 0.42%)	(0.11, 2.19%)	(0.13, 2.57%)
Level 2	54	10.19	(0.19, 1.87%)	(0, 0%)	(0.06, 0.6%)	(0.12, 1.17%)	(0.23, 2.29%)
Level 3	54	13.75	(0.38, 2.77%)	(0.07, 0.48%)	(0.21, 1.5%)	(0, 0%)	(0.44, 3.19%)

Level 4	*54*	*17.46*	*(0.69, 3.93%)*	*(0, 0%)*	*(0.08, 0.48%)*	*(0.37, 2.14%)*	*(0.79, 4.5%)*
Level 5	*54*	*22.93*	*(1.45, 6.33%)*	*(0, 0%)*	*(0.3, 1.32%)*	*(0, 0%)*	*(1.48, 6.47%)*

b. Linearity

A linearity study was conducted based on CLSI EP6-A. Specimens having eleven hemoglobin levels were prepared from venous whole blood. Each level was tested in triplicate on one DiaSpect Tm analyzer. Average results were plotted against results obtained from a HemoPoint® H2 analyzer, which was used as the reference method. Summarized results are presented in the following diagram. The correlation coefficient was greater than 0.95 and the slope of the linear equation was within 1.0±0.1 which met acceptance criteria.



d. Detection Limit:

<u>LoB</u>

Plasma samples were obtained from (5) individual whole blood donors. The five (5) plasma "blank" samples were tested for 3 days on one (1) DiaSpect Tm meter in quadruplicate (x4) using two (2) different lots of DiaSpect Tm cuvettes.

<u>LoD</u>

Four (4) whole blood samples (K_2EDTA) were collected from different donors. Four (4) independent samples covering Hgb concentrations 0.1 to 0.4 g/dL were prepared. Each sample was tested sixty (60) times on (1) DiaSpect Tm device using two (2) different lots of DiaSpect Tm cuvettes for 3 days.

LoQ

Nine (9) unique donor whole blood samples were used to prepare concentrations from 0.7-1.5 g/dL. Each sample was tested using two lots of DiaSpect Tm cuvettes on one DiaSpect Tm analyzer at least ten times for each lot for three days to achieve variability. The mean and SD for each sample concentration for each cuvette lot was determined and the bias for each of the nine levels calculated. LoQ was determined from the specified Total Error to be 1.2g\dL.

Sensitivity	Concentration
LoB	0.0 g/dL
LoD	0.3 g/dL
LoQ	1.2 g/dL

e. Analytical specificity:

Interference and cross-reactivity studies were performed in accordance with the CLSI guidance EP7-A2 "Interference testing in clinical chemistry".

Whole venous blood was collected with K_2EDTA tubes and was manipulated to create 3 hemoglobin concentrations of 11.0, 14.0, and 18.0 g/dL. Each hemoglobin concentration was spiked with potential interferent at the test concentrations listed below.

For Disease Conditions K_2EDTA venous blood specimens from up to five (5) donors with the following conditions were collected: Polycythemia, Hypochromia, High WBC Count and Sickle Cell. The predicate device HemoPoint(H2) was used as the reference method to obtain the Hgb concentration. Each sample was tested in duplicate on the H2 and five times on the DiaSpect Tm device. The predicate HemoPoint(H2) average was used to calculate the bias against each individual DiaSpect Tm result.

Potential interferent	Test Concentration	Design acceptance criteria	Result
Bilirubin	20.0 mg/dL	≤ 7%	Passed
Cholesterol	500 mg/dL	≤ 7%	Passed
Creatinine	5 mg/dL	≤ 7%	Passed
Protein	12 mg/dL	≤ 7%	Passed
Triglyceride	1000 mg/dL	≤ 7%	Passed
Urea	258 mg/dL	≤ 7%	Passed
Uric Acid	24 mg/dL	≤ 7%	Passed
Acetaminophen	2 mg/dL	≤ 7%	Passed
Ascorbic Acid	6 mg/dL	≤ 7%	Passed
Dopamine	0.1 mg/dL	≤ 7%	Passed
Ibuprofen	55 mg/dL	≤ 7%	Passed
Tetracycline	1.5 mg/dL	≤ 7%	Passed
Ferrous Sulfate	22 mg/dL	≤ 7%	Passed
Ammonium Ferric Citrate	30 mg/dL	≤ 7%	Passed
Ferrous Fumarate	30 mg/dL	≤ 7%	Passed

Iron Dextran	284 mg/dL	≤ 7%	Passed
Folic Acid	1000 ng/mL	≤ 7%	Passed
Vitamin B12	2500 ng/mL	≤ 7%	Passed
Lithium Carbonate	23 mg/dL	≤ 7%	Passed
Immunoglobin	500 mg/dL	≤ 7%	Passed
Methyldopa	1.7 mg/dL	≤ 7%	Passed
Salicylic Acid	100 mg/dL	≤ 7%	Passed
5x EDTA	Tube filled to 1/5 volume	≤ 7%	Passed
Hypochromia	Disease state	≤ 7%	Passed
High WBC Count	Disease state	≤ 7%	Passed
Polycythemia	Disease state	≤ 7%	Passed
Sickle Cell	Disease state	≤ 7%	Passed

All potential interferants tested within the acceptance criteria.

f. Assay cut-off:

Not applicable

g. Stability

Cuvettes from 12 different lots produced between December 2008 and July 2011 were tested in July 2011. Four cuvettes from each lot were tested by measuring the medium level of the DiaSpect Control HB, target value 12.6 g/dL, on the DiaSpect device.

The mean value of the measurements from all lots is 12.59 g/dL, with a total CV 0.75%. The results of measurements are summarized in the following Table.

Cuvette Lot	Production Date	Mean Hb g/dL
D080205	2008-12-18	12.53
D090001	2009-01-20	12.40
D090002	2009-05-26	12.50
D090007	2009-08-31	12.50
D090020	2009-12-08	12.60
D100009	2010-03-31	12.70
D100019	2010-05-03	12.65
D100034	2010-08-05	12.70
D100045	2010-11-28	12.60
D110007	2011-02-28	12.58
D110013	2011-05-02	12.70
D110022	2011-07-11	12.60
Mean Hb g/dL		12.59

SD	0.09
CV %	0.75
Min - Max, Hb g/dL	12.4 - 12.7

Conclusion: The DiaSpect Tm cuvette has a shelf life of at least 2.5 years.

h. Calibration

The DiaSpect Tm analyzer is factory calibrated and is not user adjustable.

i. Quality Control

The DiaSpect Tm system includes 3 levels of control solutions with known hemoglobin concentration. The DiaSpect Control HBT is produced in three concentrations that correspond to three levels of human hemoglobin. Each vial contains 1.9 mL of a solution of a red dye (Rhodamine) in purified water. The reagent does not contain any material of human or animal origin.

The DiaSpect Control HBT is 510(k) exempt.

2. Method Comparison Studies

Method comparison:

Method comparison studies were performed across four sites to support the substantial equivalence of the DiaSpect Tm Hemoglobin System with the predicate device. Finger stick capillary, K_2EDTA and lithium heparin venous whole blood specimens from a total of 399 subjects across four point-of-care clinical sites were tested on-site with both the DiaSpect Tm system (in singlicate) and in the HemoPoint® H2 Hemoglobin Analyzer (comparative method, in duplicate). IRB approval was obtained prior to initiating the studies.

A total of 364 male and female subjects, ranging from 9 months to 89 years of age, provided 363 capillary samples ranging from 8.5 to 20.1 g/dL, 349 EDTA venous samples ranging from 6.5 to 19.9 g/dL and 120 heparin venous samples ranging from 10.4 to 20.0 g/dL when tested in the DiaSpect Tm system. An additional 35 contrived EDTA venous samples were divided between three sites and tested to challenge the full measuring range of the DiaSpect Tm system. Of the 349 EDTA venous samples, five samples with hemoglobin values of 6–7 g/dL were tested in comparison with the predicate at one additional internal site to demonstrate the performance of the device around these levels.

Testing was performed over a 5-week period by 9 operators using four DiaSpect Tm analyzers and three lots of DiaSpect Tm Cuvettes. A single lot of tri-level DiaSpect Control HBT external controls were run each day specimens were tested. Clinical Study sites were required to have a current Certificate of Waiver and all operators were untrained, intended use operators. Operators were full time employees of the Certificate of Waiver test sites used in the study, who normally perform phlebotomy and/or participate in patient testing. Capillary whole blood and K_2EDTA venous whole blood were tested at the four sites by 9 operators. Lithium heparin was tested at one site by two operators. The results for all natural and contrived samples combined are summarized in Table below.

Table Overall Results Summary, Natural and Contrived, Samples All Sites

Site #	Blood Type	N (Clinical)	N (Contrived)	Slope	95% CI Slope	Intercept	95% CI Intercept	R
1	EDTA Venous	100	12	0.9805	0.947 - 1.014	0.5607	0.099 - 1.022	0.984
	Capillary	101	N/A	0.9628	0.928 - 1.008	0.3985	-0.167 - 0.964	0.977
2	EDTA Venous	120	11	1.0067	0.980 - 1.032	-0.1795	-0.558 - 0.199	0.989
	Heparin Venous	120	11	1.0229	1.004 - 1.042	-0.3606	-0.643 - 0.079	0.994
	Capillary	119	N/A	1.0129	0.951 - 1.075	0.0958	-0.989 - 0.798	0.943
3	EDTA Venous	119	12	0.9944	0.963 - 1.011	-0.0547	-0.295 - 0.382	0.992
	Capillary	120	N/A	0.9889	0.952 - 1.026	0.0772	-0.454 - 0.698	0.978
4	EDTA Venous	5	N/A	0.9487	0.642 - 1.255	0.7755	-3.518 - 5.069	0.985
	Capillary	23	N/A	1.0145	0.743 - 1.286	-0.3496	-4.109 - 3.410	0.861
TOTAL	EDTA Venous	349*	35	0.9858	0.969 - 1.002	0.2130	-0-029 - 0.455	0.986
	Capillary	363	N/A	0.9903	0.963 - 1.018	0.1164	-0.276 - .509	0.963

* See introductory study description.

Passing-Bablok Regression All Sites

		Passing-Bablok Regression	R
All results	Capillary	y = -0.1198 + 1.011x	0.965
	EDTA Venous	Y = 0.4867 + 0.9637x	0.986

Matrix Comparison

120 paired natural EDTA and heparin samples, ranging from 10.4 – 19.9 g/dL (EDTA) or 10.4 – 20.0 g/dL (heparin) Hgb, agreed closely and can be used interchangeably in the DiaSpect Tm system. Agreement between capillary and EDTA samples in the DiaSpect was favourable to that of the predicate system, and thus the DiaSpect Tm and predicate are substantially equivalent.

Comparison	Slope	Intercept	R
DiaSpect EDTA vs Heparin	0.9981	0.0644	0.9812
DiaSpect, Venous vs Capillary	0.9702	0.4634	0.8839
HemoPoint (predicate), Venous vs Capillary	0.8964	1.4695	0.8926

Expected Values/reference Range

Reference interval calculations were performed to verify that the results obtained for a normal reference population using the DiaSpect Tm Hemoglobin Measuring System are equivalent to published ranges (Dacie and Lewis, *Practical Haematology, Twelfth Edition*, Elsevier Limited 2017). Prospective fingerstick and venous EDTA DiaSpect Tm values from normal, healthy individuals enrolled in the method comparison studies were pooled and used. The interval between the 2.5th and 97.5th percentiles was taken as the reference interval. Results for subjects with no medications, capillary and EDTA venous samples combined.

Population	Age Range	Cited Reference Range
Adult Male	≥ 22 years	13.0 – 17.0 g/dL
Adult Female	≥ 22 years	12.0 – 15.0 g/dL
Child/Adolescent	> 2 years to 21 years	11.0 – 15.5 g/dL
Infant	1 month to 2 years	9.4 – 16.5 g/dL

VII. Conclusion

The DiaSpect Tm system data presented and provided is complete and supports the basis for substantial equivalence to the predicate device.

-EXHIBIT F-

Section 5 - 510(k) Summary

510k Number
BK200520

A. Introduction
In accordance with the requirements of 21CFR807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

I. Submitter
EKF-diagnostic GmbH
Ebendorfer Chaussee 3
Barleben, Germany 39179

Primary Contact: Karen Golomb
Phone: +1 (830) 249-0772
Fax: +1 (830) 249-0851
Email: karengolomb@ekfdiagnostics.com

Date prepared: October 21, 2020

II. Device Name

Proprietary names:	DiaSpect Tm DiaSpect Tm Cuvettes
Common names:	As above
Classification:	21 CFR 864.5620 – Automated hemoglobin system Class II Hematology
Product Code:	GKR

III. Predicate Device
The DiaSpect Tm system is substantially equivalent to the currently marketed HemoCue Hb 301 System (BK060048, K061047).

IV. Device Description
The DiaSpect Tm system consists of an analyzer and cuvettes. The DiaSpect Tm analyzer is a spectrophotometric instrument for the measurement of total hemoglobin concentration in unaltered human blood. The DiaSpect Tm Cuvette is injection-molded of poly methyl methacrylate (PMMA) and contains a cavity of 10 µL volume. The cavity is empty.

V. Indications for Use
The DiaSpect Tm system is intended for the *in vitro* quantitative measurement of total hemoglobin in non-anticoagulated capillary whole blood and venous whole blood drawn in K2-EDTA or lithium heparin tubes in point-of-care settings and in non-anticoagulated capillary whole blood and venous whole blood drawn in K2-EDTA tubes in blood bank settings. The DiaSpect Tm system consists of the DiaSpect Tm analyzer and specifically designed disposable cuvettes. The DiaSpect Tm analyzer is only to be used with DiaSpect Tm Cuvettes. Rx only.

Section 5 - 510(k) Summary

VI. Comparison with Predicate

Predicate device name(s): HemoCue Hb 301 System

Predicate 510(k) number(s): BK060048, K061047

Similarities compared to the predicate device (BK060048,K061047)

Performance	Predicate Device HemoCue Hb 301 System (*BK060048, K061047*)	Candidate Device DiaSpect Tm system (*K172173*)
Indications for use	Determine hemoglobin content of whole blood	Same
Analyte	Hemoglobin	Same
Sample preparation	None	Same
Automation	Fully automated assay	Same
Calibration procedure	Factory calibrated	Same
Test methodology	Optical absorbance	Same
Sample volume	10 µL	Same
Cuvette reagent components	None	Same
Result memory	No	Same
Quality Control	Quality control materials are available	Same

Differences compared to the predicate device (BK060048, K061047)

Performance	Predicate Device HemoCue Hb 301 System (*BK060048, K061047*)	Candidate Device DiaSpect Tm system (*K172173*)
Intended Use	The HemoCue Hb 301 System is designed for quantitative point-of-care whole blood hemoglobin determination in primary care or blood donation settings using a specially designed analyzer, the HemoCue Hb 301 Analyzer, and specially designed microcuvettes, the HemoCue Hb 301 Microcuvettes. The HemoCue Hb 301 System is for In Vitro Diagnostic use only. The HemoCue Hb 301 Analyzer is only to be used with HemoCue Hb 301 Microcuvettes.	The DiaSpect Tm system is intended for the *in vitro* quantitative measurement of total hemoglobin in non-anticoagulated capillary whole blood and venous whole blood drawn in K2-EDTA or lithium heparin tubes in point-of-care settings and in non-anticoagulated capillary whole blood and venous whole blood drawn in K2-EDTA tubes in blood bank settings. The DiaSpect Tm system consists of the DiaSpect Tm analyzer and specifically designed disposable cuvettes. The DiaSpect Tm analyzer is only to be used with DiaSpect Tm Cuvettes. Rx only.
Sample type	Capillary, arterial or venous whole blood	Capillary or venous whole blood
Built-In Quality Control	Auto self-check at start and at regular time intervals	Auto self-check confirms each measurement
Expected values Adult Males Adult Females Children Infants	 13.0 – 18.0 g/dL 11.0 – 16.0 g/dL 2 yrs to teenage: 11.0 – 16.0 g/dL Post-natal: 10.0 – 14.0 g/dL	 13.0 – 17.0 g/dL 12.0 – 15.0 g/dL >2 yrs to 21: 11.0 – 15.5 g/dL 1 mo. to 2 yrs: 9.4 – 16.5 g/dL
Operating temperature	10 to 40°C (50 to 104°F)	10 to 42°C (50 to 107°F)
Cuvette storage	10 – 40°C (50 to 104 °C)	0 – 50°C (32 to 122 °F)
Cuvette composition	Composed of polystyrene	Composed of poly methyl methacrylate (PMMA)

Section 5 - 510(k) Summary

Performance	Predicate Device HemoCue Hb 301 System (*BK060048, K061047*)	Candidate Device DiaSpect Tm system (*K172173*)
Control Kit components	Two concentration levels of liquid controls	Three concentration levels of liquid controls
Measurement Range	0.0 – 25.6 g/dL	1.2 – 25.5 g/dL
Connectivity	Serial port	• Wireless Bluetooth Low Energy • USB
Measuring Time	3 seconds	1 second
User Interface	• Display • Beeper • One button	• Display • Beeper • Cuvette holder
Microcuvette Insertion Technique	Place on a tray	Slot in
Power Sources	• AC adapter • 4 x AA batteries	• 3.6 V integrated lithium ion rechargeable batteries • USB Adaptor
Dimensions	6.3x5.5x2.8 inch	6x3.5x1.6 inch

VII. Performance Characteristics

1. Analytical Performance

Analytical studies to determine the substantial equivalence of the DiaSpect Tm system in point-of-care settings have been previously cleared under K172173. Precision study summaries from K172173 are included as follows:

a. Precision/Reproducibility:

20-Day Precision

Reproducibility was conducted at three intended use sites over 20 operating days using three DiaSpect Cuvette lots (one lot per site), three DiaSpect Tm Analyzers (one instrument per site), and one lot of DiaSpect Controls at three levels (low, medium and high). Each control set was run in duplicate twice daily for 20 days, by two operators at each site. A total of 160 test results were generated for each control level at each site. SD and %CV for within-run, between-run, between-day, between-operator, and between-site were calculated for each site and all sites combined. Reproducibility results at all test sites were within the defined acceptance criteria.

Table 1 20-Day precision data met the criteria of <7% CV.

Sample	N	Mean	Within-Run SD, %CV	Between-Run SD, %CV	Between-Day SD, %CV	Between-Operator SD, %CV	Between-Site SD, %CV	Total SD, %CV
Low	240	7.99	0.085, 1.06%	0.05, 0.59%	0.04, 0.47%	0, 0%	0.04, 0.45%	0.11, 1.38%
Medium	240	12.58	0.11, 0.8%	0.05, 0.38%	0.03, 0.22%	0, 0%	0.05, 0.47%	0.14, 1.09%
High	240	15.82	0.15, 0.92%	0.06, 0.36%	0.04, 0.27%	0, 0%	0.15, 0.97%	0.22, 1.41%

Section 5 - 510(k) Summary

Single-Day Precision
Single-day precision was performed at a single site using K2-EDTA venous whole blood. Five donors provided five samples (one sample each), some of which were manipulated to increase or decrease hemoglobin levels. The study was performed at a single site using three instruments, three lots of cuvettes, and three operators. Each of three operators ran duplicate tests on all five levels, providing 54 measurements for each level. Single-day precision results were within the defined acceptance criteria.

Table 2 Single-Day precision data met the criteria of <7% CV.

Sample	N	Mean	Within-Run (SD, %CV)	Between-Lot (SD, %CV)	Between-Operator (SD, %CV)	Between-Analyzer (SD, %CV)	Total (SD, %CV)
Level 1	54	4.87	(0.05, 0.97%)	(0.04,0.82%)	(0.02, 0.42%)	(0.11, 2.19%)	(0.13, 2.57%)
Level 2	54	10.19	(0.19, 1.87%)	(0, 0%)	(0.06, .06%)	(0.12, 1.17%)	(0.23, 2.29%)
Level 3	54	13.75	(0.38, 2.77%)	(0.07, 0.48%)	(0.21, 1.5%)	(0, 0%)	(0.44, 3.19%)
Level 4	54	17.46	(0.69, 3.93%)	(0, 0%)	(0.08,0.48%)	(0.37, 2.14%)	(0.79, 4.5%)
Level 5	54	22.93	(1.45, 6.33%)	(0, 0%)	(0.3, 1.32%)	(0, 0%)	(1.48, 6.47%)

b. Linearity
Please refer to submission K172173.

c. Traceability, Stability, Expected values (Controls, Calibrators)
The DiaSpect Control HBT is produced in three concentrations that correspond to three levels of human hemoglobin.

d. Detection Limit:
Please refer to submission K172173.

e. Analytical specificity:
Please refer to submission K172173.

f. Assay cut-off:
Not applicable

g. Stability
Please refer to submission K172173.

h. Calibration
The DiaSpect Tm analyzer is factory calibrated and requires no further calibration.

i. Quality Control
DiaSpect control solutions are available to facilitate compliance with local, state and/or federal regulations or accreditation requirements. The DiaSpect Control HBT is produced in three concentrations that correspond to three known levels of human hemoglobin. Each vial contains 1.9 mL of a solution of a red dye (Rhodamine) in purified water. The reagent does not contain any material of human or animal origin. The DiaSpect Control HBT is 510(k) exempt.

Section 5 - 510(k) Summary

2. Method Comparison Studies

Method comparison studies were conducted with finger stick capillary whole blood and paired K2-EDTA venous whole blood at blood bank settings. A total of 150 capillary and 147 venous blood donors were tested with the DiaSpect Tm and HemoCue Hb 301 at two sites.

DiaSpect Tm vs HemoCue Hb 301 (linear regression)

Site	Matrix	N	Slope (95% CI)	Intercept (95% CI)	r
1	Capillary	75	0.9644 (0.8911 ~ 1.0377)	0.1086 (-1.011 ~ 1.228)	0.951
	Venous	72	1.1521 (1.0967 ~ 1.2074)	-2.8551 (-3.7028 ~ -2.0074)	0.980
2	Capillary	75	0.9472 (0.8988 ~ 0.9957)	0.3588 (-0.3555 ~ 1.0731)	0.977
	Venous	75	1.1784 (1.1341 ~ 1.2227)	-2.7653 (-3.4184 ~ -2.1121)	0.987
Total	Capillary	150	0.9541 (0.9134 ~ 0.9948)	0.2619 (-0.3496 ~ 0.8733)	0.967
	Venous	147	1.1465 (1.1068 ~ 1.1863)	-2.5299 (-3.4183 ~ -2.1122)	0.978

DiaSpect Tm vs HemoCue Hb 301 (Passing-Bablok regression)

Site #	Matrix	N	Slope (95% CI)	Intercept (95% CI)	r
ALL	Capillary	150	1.000 (0.9512 ~ 1.032)	-0.45 (-1.011 ~ 0.2805)	0.967
ALL	Venous	147	1.140 (1.100 ~ 1.179)	-2.477 (-3.067 ~ -1.895	0.978

The bias of the DiaSpect Tm at hemoglobin acceptance levels for donors was calculated from the regression curves using the Hb 301 as the reference method.

Donor Cutoff vs Hb 301	DiaSpect Tm Capillary		DiaSpect Tm Venous	
	Hb Level	% Bias	Hb Level	% Bias
Adult Female, 12.5 g/dL	12.2 g/dL	-2.4%	11.8	-5.6%
Adult Male, 13 g/dL	12.7 g/dL	-2.3%	12.4	-4.8%

Using the Hb 301 as the reference method, the agreements for blood donor acceptance at these cutoff levels are as follows:

Capillary All Donors	Hb 301 ≥Cutoff	Hb 301 <Cutoff
DiaSpect Tm ≥Cutoff	127	2
DiaSpect Tm <Cutoff	7	14

Agreement (Score 95% CI)
Accept = 127/134 = 94.8% (89.6~97.4%)
Reject = 14/16 = 87.5% (64.0~96.5%)

Venous All Donors	Hb 301 ≥Cutoff	Hb 301 <Cutoff
DiaSpect Tm ≥Cutoff	120	1
DiaSpect Tm <Cutoff	13	13

Agreement (Score 95% CI)
Accept = 120/133 = 90.2% (84.0~94.2%)
Reject = 13/14 = 92.9% (68.5~98.7%)

Section 5 - 510(k) Summary

The negative bias observed for the DiaSpect Tm was resolved by comparing both test methods to a laboratory reference method. In a separate study conducted at one site, 100 capillary and 100 venous samples were tested with the DiaSpect Tm and HemoCue Hb 301 and compared with the same venous samples that were also tested with the Sysmex XP-300. The DiaSpect Tm was found to be substantially equivalent to the Sysmex XP-300 (calibrated to the hemiglobincyanide method, HiCN), while the HemoCue Hb 301 consistently provided results that are higher by approximately 0.6 g/dL. The results are summarized below.

The bias of the DiaSpect Tm at hemoglobin acceptance levels for donors was calculated from the regression curves using the Sysmex XP-300 as the reference method.

Donor Cutoff vs XP-300	DiaSpect Tm Capillary		DiaSpect Tm Venous	
	Hb Level	% Bias	Hb Level	% Bias
Adult Female, 12.5 g/dL	12.56	0.5%	12.53	0.2%
Adult Male, 13 g/dL	13.05	0.4%	13.07	0.7%

The bias of the Hb 301 at hemoglobin acceptance levels for donors was calculated from the regression curves using the Sysmex XP-300 as the reference method.

Donor Cutoff vs XP-300	Hb 301 Capillary		Hb 301 Venous	
	Hb Level	% Bias	Hb Level	% Bias
Adult Female, 12.5 g/dL	13.12	5.0%	13.03	4.2%
Adult Male, 13 g/dL	13.62	4.8%	13.55	4.2%

Using the Sysmex-XP-300 as the reference method, the agreements for blood donor acceptance at these cutoff levels are as follows:

Capillary All Donors	Sysmex XP-300 ≥Cutoff	Sysmex XP-300 <Cutoff
DiaSpect Tm ≥Cutoff	75	3
DiaSpect Tm <Cutoff	6	16

Agreement (Score 95% CI)
Accept = 75/81 = 92.6% (84.8~96.6%)
Reject = 16/19 = 84.2% (62.4~94.5%)

Venous All Donors	Sysmex XP-300 ≥Cutoff	Sysmex XP-300 <Cutoff
DiaSpect Tm ≥Cutoff	77	0
DiaSpect Tm <Cutoff	4	19

Agreement (Score 95% CI)
Accept = 77/81 = 95.1% (88.0~98.1%)
Reject = 19/19 = 100.0% (83.2~100.0%)

Matrix Comparison
Please refer to submission K172173.

VII. Conclusion
The DiaSpect Tm data presented and provided is complete and supports the basis for substantial equivalence to the predicate device for use in blood bank settings.

— EXHIBIT G —

OCT 2 4 2003

K032482

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

(As required by 21 CFR 807.92)

Trade Name:	HemoPoint® H2 Hemoglobin Measurement System
Common/Classification Name:	Automated Hemoglobin System
Device Classification:	Class: II CFR: 21 CFR 864.5620 Product Code: GKR
Manufacturer:	Stanbio Laboratory 1261 North Main Street Boerne, Texas 78006

Device Description / Procedure Principle:
The HemoPoint® H2 Hemoglobin Measurement System is comprised of a HemoPoint® H2 Hemoglobin Photometer and HemoPoint® H2 Cuvettes.

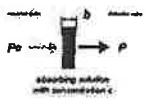
The recognized reference method for tHb determination (tHb = total hemoglobin) is the cyanmethemoglobin method, which is also known as the cyanhemoglobin method. The blood sample is diluted 1:251 with a reagent buffering solution. Here the erythrocytes are hemolysed and the bivalent iron in oxy- and desoxyhemoglobin are oxidised by the reagent potassium hexacyanoferrate (III) to trivalent iron and so converted to methemoglobin. Together with cyanide ions, which are also contained in the reagents, the methemoglobin forms a stable, colored complex, namely cyanmethemoglobin. This has a wide absorption maximum at 540 nm. This absorption is proportional to the tHb concentration.

In 1966, Vanzetti suggested to replace KCN by NaN_3 and thus was able to reduce the toxicity of the reagent mixture considerably.

Vanzetti's method is also known as the azide methemogobin method. A modified azide methemoglobin method is used in the HemoPoint® H2 system.

In the *HemoPoint® H2*, however, the use of microcuvettes with short light pathways makes it possible to analyze undiluted blood. The filled cuvette is inserted into the *HemoPoint® H2* photometer, the color produced by the chemical reaction in the cuvette is measured, and the Hb level is calculated and displayed.

In the *HemoPoint® H2* photometer the light transmitted through the cuvette sample is measured.



Principle of photometric transmitted light measurement.

P_0: 100 % - light intensity, P: remaining light intensity, b: distance through the solution

For this purpose, light is directed through the blood sample and the transmission T is measured. From the amount of light absorbed by the sample, the concentration of the hemoglobin in the cuvette can be calculated using Lambert-Beers Law.

Light emitting diodes (LED's) are used as light sources and a photodiode to detect the light. The light emitting diodes utilize the central wavelengths 570 nm (for measurement) and 880 nm (for turbidity compensation).

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS CONT'D

Intended Use:

The HemoPoint H2 Hemoglobin Measurement System is indicated for the quantitative determination of hemoglobin in arterial, venous, or capillary blood.

The microcuvettes part number 3010-100 are indicated for use in the HemoPoint® H2 Hemoglobin Measurement System and the Hemocue® measurement system. The microcuvettes are intended to be used only once and must be disposed of after use as potentially infectious waste.

Estimation of hematocrit as a function of Hemoglobin is performed for normal hemoglobin ranges only (120 to 180 g/L or 12.0 to 18.0 g/dL). The estimated hematocrit is not indicative of disease states such as anemia and abnormal values and will not be reported.

For In Vitro Diagnostic Use Only

Comparison To Predicate Device:

Precision:

Within-run imprecision HemoPoint® H2 System and HemoPoint® H2 Cuvettes on HemoCue Device ≤ 2%

	HemoPoint® H2 cuvette measured in HemoPoint® H2 device	**HemoPoint® H2 measured in HemoCue device**
Hemoglobin/high (17.3 g/dL): Within-Run Precision (NCCLS EP5-A):	S_{wr} 0.111 g/dL, CV 0.6 %	S_{wr} 0.103 g/dL, CV 0.6 %
Total Precision (NCCLS EP5-A):	S_T 0.207 g/dL, , CV 1.2 %	S_T 0.162 g/dL, CV 0.9 %
Hemoglobin/low (10.7 g/dL) Within-Run Precision (NCCLS EP5-A):	S_{wr} 0.095 g/dL, CV 0,9 %	S_{wr} 0.068 g/dL, CV 0,6 %
Total Precision (NCCLS EP5-A):	S_T 0.114 g/dL, CV 1.1 %	S_T 0.086 g/dL, CV 0.8 %
Hemoglobin/normal (12.9 g/dL) Within-Run Precision (NCCLS EP5-A):	S_{wr} 0.084 g/dL, CV 0.7 %	S_{wr} 0.102 g/dL, CV 0.8 %
Total Precision (NCCLS EP5-A):	S_T 0.148 g/dL, CV 1.1 %	S_T 0.134 g/dL, CV 1.0 %
Between-Day Imprecision Single observation, 20 days	10.7 g/dL: SD 0.102 g/dL, CV 1.0 % 12.9 g/dL: SD 0.141 g/dL, CV 1.1 % 17.3 g/dL: SD 0.169 g/dL, CV 1.0 %	10.9 g/dL: SD 0.094 g/dL, CV 0.9 % 13.0 g/dL: SD 0.126 g/dL, CV 1.0 % 17.2 g/dL: SD 0.148 g/dL, CV 0.9 %

Correlation Study:

Correlation coefficient HemoPoint® H2 System compared to NCCLS H15-A3 reference method, venous blood: ≥ 0.98

Correlation coefficient HemoPoint® H2 cuvettes on HemoCue Device compared to HemoCue System, venous blood: ≥ 0.97

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS CONT'D

Experimental Data:

HemoPoint® H2 System: (HemoPoint® H2 cuvettes measured in HemoPoint® H2 device):

Regression line and correlation coefficients compared to NCCLS H15-A3 reference method (g/dL), venous blood (Summary from 4 Clinical Study Sites)	- Y= 0.023 + 1.006X - R=0.999 - N=174, duplicate measurements - Range 3.31 g/dL to 24.4 g/dL
Regression line and correlation coefficients compared to HemoCue system (g/dL), venous blood, (Summary from 4 Clinical Study Sites)	- Y= - 0.233 +1.001X - R=0.998 - N=286, duplicate measurements - Range 3.25 g/dL to 23.85 g/dL

HemoPoint® H2 cuvettes measured in HemoCue device[i]:

Regression line and correlation coefficients compared to HemoCue system (g/dL), venous blood, (Summary from 4 Clinical Study Sites)	- Y= 0.139 +986X - R=0.999 - N=286, duplicate measurements - Range 3.25 g/dL to 23.85 g/dL

Comparison to Predicate Device:

Specification	HemoPoint® H2	HemoCue	Comments
Instrument :	No. 1	No. 2	No. 1 ↔ No. 2
Measurement range	0 – 25.6 g/dL	0 – 25.6 g/dL	equivalent
Specified range	0 – 25.6 g/dL	0 – 23.5 g/dL	equivalent
Specified accuracy	± 0.3 g/dL at ≈14 g/dL	± 0.3 g/dL at ≈14 g/dL	equivalent
Sample material	venous, arterial or capillary human blood	venous, arterial or capillary human blood	equivalent
Measuring time	Approximately 30 – 60 sec	Approximately 30 – 60 sec	measuring time depends on the concentration
Measuring units	mol/L, g/dL, g/L	mol/L, g/dL, g/L	equivalent
Calibration	against NCCLS reference method	against ICSH reference method	NCCLS is current version of the method
Method	Azidemethemoglobin method (Vanzetti)	Azidemethemoglobin method (Vanzetti)	equivalent

Conclusion / Substantial Equivalence:

The HemoPoint® H2 Hemoglobin Photometer and HemoPoint® H2 Cuvettes and the predicate devices, HemoCue B-Hemoglobin System with microcuvette are substantially equivalent based on design and function.

Kirk Johnson
QA/Regulatory Affairs Manager
Stanbio Laboratory

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 2 4 2003

Mr. Kirk Johnson
QA/Regulatory Affairs Manager
Stanbio Laboratory
1261 North Main Street
Boerne, Texas 78006

Re: k032482
Trade/Device Name: Stanbio Laboratory HemoPoint® Hemoglobin Measurement System
Regulation Number: 21 CFR § 864.5620
Regulation Name: Automated Hemoglobin System
Regulatory Class: II
Product Code: GKR
Dated: August 5, 2003
Received: August 12, 2003

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032482

Device Name: Stanbio Laboratory HemoPoint® Hemoglobin Measurement System

Indications for use:

The HemoPoint® H2 Hemoglobin Measurement System is indicated for the quantitative determination of hemoglobin in arterial, venous, or capillary blood.

The microcuvettes part number 3010-100 are indicated for use in the HemoPoint® H2 Hemoglobin Measurement System and the Hemocue® measurement system. The microcuvettes are intended to be used only once and must be disposed of after use as potentially infectious waste.

Estimation of hematocrit as a function of Hemoglobin is performed for normal hemoglobin ranges only (120 to 180 g/liter or 12.0 to 18.0 g/deciliter). The estimated hematocrit is not indicative of disease states such as anemia and abnormal values will not be reported.

For In Vitro Diagnostic Use Only

Caution: Federal law restricts this device to sale by or on the order of a physician.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032482

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use ___

(Per 21 CFR801.109)

(Optional Format 1-2-96)

— EXHIBIT H —

JUL 1 8 2008 K081719

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
(As required by 21 CFR 807.92)

Trade Name:	HemoPoint® H2 Hemoglobin Measurement System
Common/Classification Name:	Automated Hemoglobin System
Device Classification:	Class: II CFR: 21 CFR 864.5620 Product Code: GKR
Manufacturer:	Stanbio Laboratory 1261 North Main Street Boerne, Texas 78006

Device Description / Procedure Principle:
The HemoPoint® H2 Hemoglobin Measurement System is comprised of a HemoPoint® H2 Hemoglobin Photometer and HemoPoint® H2 Cuvettes.

The recognized reference method for tHb determination (tHb = total hemoglobin) is the cyanmethemoglobin method, which is also known as the cyanhemoglobin method. The blood sample is diluted 1:251 with a reagent buffering solution. Here the erythrocytes are hemolysed and the bivalent iron in oxy- and desoxyhemoglobin are oxidised by the reagent potassium hexacyanoferrate (III) to trivalent iron and so converted to methemoglobin. Together with cyanide ions, which are also contained in the reagents, the methemoglobin forms a stable, colored complex, namely cyanmethemoglobin. This has a wide absorption maximum at 540 nm. This absorption is proportional to the tHb concentration.

In 1966, Vanzetti suggested to replace KCN by NaN_3 and thus was able to reduce the toxicity of the reagent mixture considerably.

Vanzetti's method is also known as the azide methemogobin method. A modified azide methemoglobin method is used in the HemoPoint® H2 system.

In the *HemoPoint® H2*, however, the use of microcuvettes with short light pathways makes it possible to analyze undiluted blood. The filled cuvette is inserted into the *HemoPoint® H2* photometer, the color produced by the chemical reaction in the cuvette is measured, and the Hb level is calculated and displayed.

In the *HemoPoint® H2* photometer the light transmitted through the cuvette sample is measured.

Principle of photometric transmitted light measurement.

P_0: 100 % - light intensity, P: remaining light intensity, b: distance through the solution

For this purpose, light is directed through the blood sample and the transmission T is measured. From the amount of light absorbed by the sample, the concentration of the hemoglobin in the cuvette can be calculated using Lambert-Beers Law.

Light emitting diodes (LED's) are used as light sources and a photodiode to detect the light. The light emitting diodes utilize the central wavelengths 570 nm (for measurement) and 880 nm (for turbidity compensation).

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS CONT'D

Intended Use:

The HemoPoint H2 Hemoglobin Measurement System is indicated for the quantitative determination of hemoglobin in arterial, venous, or capillary blood.

The microcuvettes part number 3010-100 are indicated for use in the HemoPoint® H2 Hemoglobin Measurement System and compatible measurement systems. The microcuvettes are intended to be used only once and must be disposed of after use as potentially infectious waste.

Estimation of hematocrit as a function of Hemoglobin is performed for normal hemoglobin ranges only (120 to 180 g/L or 12.0 to 18.0 g/dL). The estimated hematocrit is not indicative of disease states such as anemia and abnormal values and will not be reported.

For In Vitro Diagnostic Use Only

Comparison To Predicate Device:

Precision:

Within-run imprecision HemoPoint® H2 System and HemoPoint® H2 Cuvettes on HemoCue Device ≤ 2%

	HemoPoint® H2 cuvette measured in HemoPoint® H2 device	**HemoPoint® H2 measured in HemoCue device**
Hemoglobin/high (15.7 g/dL): Within-Run Precision (NCCLS EP5-A):	S_{wr} 0.087 g/dL, CV 0.5 %	S_{wr} 0.102 g/dL, CV 0.7 %
Total Precision (NCCLS EP5-A):	S_T 0.1747 g/dL, CV 1.1 %	S_T 0.302 g/dL, CV 1.9 %
Hemoglobin/low (11.8 g/dL) Within-Run Precision (NCCLS EP5-A):	S_{wr} 0.070 g/dL, CV 0.6 %	S_{wr} 0.105 g/dL, CV 0.9 %
Total Precision (NCCLS EP5-A):	S_T 0.162 g/dL, CV 1.4 %	S_T 0.198 g/dL, CV 1.6 %
Hemoglobin/normal (8.0 g/dL) Within-Run Precision (NCCLS EP5-A):	S_{wr} 0.058 g/dL, CV 0.7 %	S_{wr} 0.068 g/dL, CV 0.8 %
Total Precision (NCCLS EP5-A):	S_T 0.122 g/dL, CV 1.5 %	S_T 0.158 g/dL, CV 1.9 %
Between-Day Imprecision Single observation, 20 days	15.7 g/dL: SD 0.179 g/dL, CV 1.1 % 11.8 g/dL: SD 0.176 g/dL, CV 1.5 % 8.0 g/dL: SD 0.111 g/dL, CV 1.4 %	15.7 g/dL: SD 0.286 g/dL, CV 1.8 % 11.8 g/dL: SD 0.201 g/dL, CV 1.6 % 8.0 g/dL: SD 0.118 g/dL, CV 1.5 %

Correlation Study:

Correlation coefficient HemoPoint® H2 System compared to NCCLS H15-A3 reference method, venous blood: ≥ 0.998

Correlation coefficient HemoPoint® H2 cuvettes on HemoCue Device compared to HemoCue System, venous blood: ≥ 0.995

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS CONT'D

Experimental Data:

HemoPoint® H2 System: (HemoPoint® H2 cuvettes measured in HemoPoint® H2 device):

Regression line and correlation coefficients compared to NCCLS H15-A3 reference method (g/dL), venous blood (Summary of results)	- Y= 0.2929 + 1.0086X - R=0.999 - N=100, duplicate measurements
Regression line and correlation coefficients compared to HemoCue system (g/dL), venous blood, (Summary of results)	- Y= -5.8261 +1.0462X - R=0.995 - N=100, duplicate measurements

HemoPoint® H2 cuvettes measured in HemoCue device[1]:

Regression line and correlation coefficients compared to HemoCue system (g/dL), venous blood, (Summary of results)	- Y= -0.2181 + 1.0159X - R=0.997 - N=100, duplicate measurements

Comparison to Predicate Device:

Specification	HemoPoint® H2 (current cuvette)	HemoPoint® H2 (modified cuvette)	Comments
[illegible]	[illegible]	[illegible]	[illegible]
Measurement range	0 – 25.6 g/dL	0 – 25.6 g/dL	equivalent
Specified range	0 – 25.6 g/dL	0 – 25.6 g/dL	equivalent
Specified accuracy	± 0.3 g/dL at ≈ 14 g/dL	± 0.3 g/dL at ≈ 14 g/dL	equivalent
Sample material	venous, arterial or capillary human blood	venous, arterial or capillary human blood	equivalent
Measuring time	Approximately 30 – 60 sec	Approximately 30 – 60 sec	equivalent
Measuring units	mol/L, g/dL, g/L	mol/L, g/dL, g/L	equivalent
Calibration	against NCCLS reference method	against NCCLS reference method	equivalent
Method	Azidemethemoglobin method (Vanzetti)	Azidemethemoglobin method (Vanzetti)	equivalent

Conclusion / Substantial Equivalence:

The modified HemoPoint® H2 cuvettes for the HemoPoint® H2 Hemoglobin Photometer and and the predicate devices, Hemo Point® H2 Hemoglobin Measurement System with microcuvette are substantially equivalent based on design and function.

Kirk Johnson
QA/Regulatory Affairs Manager
Stanbio Laboratory

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 18 2008

Stanbio Laboratory
c/o Mr. Kirk Johnson
QA Regulatory Affairs Manager
1261 North Main Street
Boerne, Texas 78006

Re: k081719
Trade/Device Name: Stanbio Laboratory HemoPoint® H2 Hemoglobin Measurement System
Regulation Number: 21 CFR 864.5620
Regulation Name: Automated hemoglobin system
Regulatory Class: Class II
Product Code: GKR
Dated: June 16, 2008
Received: June 18, 2008

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket

notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small ~~Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or~~ (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna Rosue for Maria Chan

Maria M. Chan, Ph.D.
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081719

Device Name: Stanbio Laboratory HemoPoint® Hemoglobin Measurement System

Indications For Use:

The HemoPoint® H2 Hemoglobin Measurement System is indicated for the quantitative determination of hemoglobin in arterial, venous, or capillary blood.

The microcuvettes part number 3010-100 are indicated for use in the HemoPoint® H2 Hemoglobin Measurement System and the Hemocue® measurement system. The microcuvettes are intended to be used only once and must be disposed of after use as potentially infectious waste.

Estimation of hematocrit as a function of Hemoglobin is performed for normal hemoglobin ranges only (120 to 180 g/liter or 12.0 to 18.0 g/deciliter). The estimated hematocrit is not indicative of disease states such as anemia and abnormal values will not be reported.

For In Vitro Diagnostic Use Only

Caution: Federal law restricts this device to sale by or on the order of a physician.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K081719

— EXHIBIT I —

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 2 4 2003

EKF Diagnostic GmbH
c/o Mr. Stephen Gorski
Submission Correspondent
S65 W 35739 Piper Road
Eagle, Wisconsin 53119

Re: k031898
Trade/Device Name: EKF-diagnostic Hemo Control Hemoglobin Measurement System
Regulation Number: 21 CFR § 864.5620
Regulation Name: Automated Hemoglobin System
Regulatory Class: II
Product Code: GKR, KHG
Dated: June 16, 2003
Received: July 1, 2003

Dear Mr. Gorski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: EKF-diagnostic Hemo_Control Hemoglobin Measurement System

Indications for use:

The Hemo_Control Hemoglobin Measurement System is indicated for the quantitative determination of hemoglobin in arterial, venous, or capillary blood.

The microcuvettes part number 3000-3011-050 are indicated for use in the Hemo_Control Hemoglobin Measurement System and compatible measurement systems. The microcuvettes are intended to be used only once and must be disposed of after use as potentially infectious waste.

Estimation of hematocrit as a function of Hemoglobin is performed for normal hemoglobin ranges only (120 to 180 g/liter or 12.0 to 18.0 g/deciliter). The estimated hematocrit is not indicative of disease states such as anemia and abnormal values will not be reported.

For In Vitro Diagnostic Use Only

Caution: Federal law restricts this device to sale by or on the order of a physician.

Josephine Bautista

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031898

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use____

(Per 21 CFR801.109)

(Optional Format 1-2-96)

— EXHIBIT 5 —

U.S. FOOD & DRUG ADMINISTRATION

June 12, 2020

EKF-diagnostic GmbH
Andrew Rutter
Global Head, Quality Assurance & Regulatory Affairs
Ebendorfer Chaussee 3
Barleben, 39179
Germany

Re: K200909
Trade/Device Name: Hemo Control
Regulation Number: 21 CFR 864.5620
Regulation Name: Automated Hemoglobin System
Regulatory Class: Class II
Product Code: GKR
Dated: April 3, 2020
Received: April 6, 2020

Dear Andrew Rutter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Takeesha Taylor-bell -S

Takeesha Taylor-Bell
Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k200909

Device Name
Hemo Control

Indications for Use *(Describe)*
Hemo Control is intended to be used for the quantitative determination of hemoglobin (Hb) concentrations in human blood.

The Hemo Control Hemoglobin Microcuvettes are intended to be used with the Hemo Control photometer for the quantitative determination of hemoglobin (Hb) concentrations in human blood.

For in-vitro diagnostic use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510k Summary

Introduction According to the requirements of 21CFR807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter EKF-diagnostic GmbH
Ebendorfer Chaussee 3
39179 Barleben
Germany

Contact Person: Andrew Rutter
Phone: +44 2920 710570
Fax: +44 2920 705715
Email: andrewrutter@ekfdiagnostics.com

Secondary Contact: Karen Golomb
Phone:
Fax:
Email: karengolomb@ekfdiagnostics.com

Date Prepared: 24th April 2020

Device Name: Proprietary names:
Hemo Control

Common names: As above.

Classification: 21CFR864.5620 (Class II, Automated hemoglobin system)

Product Code: GKR

Device Descriptions: Hemo Control consists of the Hemo Control photometer / analyzer and the Hemo Control Hemoglobin Microcuvettes, its accessories and consumables (i.e. Control Solution Hb-con).
The Hemo Control photometer / analyzer is a semi-automated, spectrophotometric instrument, which provides instant quantitative total hemoglobin results.
Using the reagent filled microcuvette a small amount of arterial, venous or capillary blood is taken up by capillary action. The filled microcuvette is inserted into the Hemo Control photometer. The color produced by chemical reaction in the microcuvette is measured and the Hb value is displayed.
The measurement accuracy of the Hemo Control Hemoglobin Measurement System can be verified by use of Hb-con control solution, a quality control material with pre-determined hemoglobin concentration.

As a second quality control measurement, the control cuvette as a physical standard is used for a comfortable and cheap check of the device.

Predicate Devices: EKF Diagnostic Hemo Control Hemoglobin Measurement System

Predicates 510(k): k031898

Special Conditions for Use: For in vitro diagnostic use.
Rx Only

Special instrument Requirements: None

Intended Use: Hemo Control is intended to be used for the quantitative determination of hemoglobin (Hb) concentrations in human blood.

The Hemo Control Hemoglobin Microcuvettes are intended to be used with the Hemo Control photometer for the quantitative determination of hemoglobin (Hb) concentrations in human blood.

For in-vitro diagnostic use only.

Comparison with predicate:
Similarities and differences compared to the chosen predicate device:-
Hemo Control Hemoglobin System (k031898)

	Predicate Device: Hemo Control	**Candidate Device:** Hemo Control
Model number	3000-0031-6901	3040-0010-0218
Intended Use:	Quantitative determination of hemoglobin	Quantitative determination of hemoglobin
Indications for Use	The Hemo Control Hemoglobin Measurement System is intended to be used for the quantitative determination of hemoglobin (Hb) concentrations in human blood.	Hemo Control is intended to be used for the quantitative determination of hemoglobin (Hb) concentrations in human blood.
Analyte	Hemoglobin	Hemoglobin
Sample requirements	Venous, capillary or arterial blood	Venous, capillary or arterial blood
Methodology	Hem-azide methemoglobin Hct-Estimation from hemoglobin	Hem-azide methemoglobin Hct-Estimation from hemoglobin

Functionality	Data transfer only	Additional data management functionality
Accessory	None	Optional Add Pack Hemo Control DM

Performance Characteristics

Hemo Control

Analytical Performance

a. Precision:

	Within Run (CV)	Total (CV)	Single Observation 20 days (CV)
Hemoglobin/Low (107 g/L)	0.8%	1.0%	0.9%
Hemoglobin/Normal (129 g/L)	0.6%	1.0%	0.8%
Hemoglobin/High (173 g/L)	0.6%	1.1%	1.0%

b. Linearity/assay reportable range:
0 - 25.6 g/dL

c. Traceability (controls, calibrators, or method):
Device calibrated against NCCLS reference method

Comparison studies

a. *Method comparison*
Comparison to NCCLS Reference Method:
y=1.0064x + 0.0234, r=0.0076, n=174

Comparison to HemoCue hemoglobin measurement system
y=1.0005x – 0.2334, r=0.9962, n=286

Comparison of Hemo Control Cuvettes in HemoCue
y=0.9855x + 0.139, r=0.998, n=286

b. *Matrix comparison*
Capillary samples, 4 sites:
y=0.96x + 0.3742, r=0.8256, n=275

Arterial samples, 1 site:
y=0.9868x – 0.0285, r=0.998, n=10

Expected values/Reference range
Based on literature references

Women: 12.0 – 16.0 g/dl
Men: 13.0 – 17.5 g/dl
Children, depending on age: 9.0 -24 g/dl

Proposed Labeling
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

Conclusion

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

Attachment A.II

Record on Appeal

MSDH Response

Dated June 22, 2021

MISSISSIPPI STATE DEPARTMENT OF HEALTH

TRANSMITTED BY E-MAIL AND U.S. MAIL

June 22, 2021

Mark Bellwood
Director of Sales, Specialty Markets
HemoCue America
250 S. Kraemer Blvd.
Brea, CA 928821
mark@hemocue.com

Re: Response to Protest regarding Request for Quotes- Formal (RFQF) Reverse Auction RFx 3140002081 for Hemoglobin Analyzers and Microcuvettes

Dear Mr. Bellwood:

The Mississippi State Department of Health (MSDH) is in receipt of your protest dated April 26, 2021. After consideration thereof as well as the relevant facts and circumstances, MSDH denies your protest and would show the following in support thereof.

STATEMENT OF RELEVANT FACTS

On October 1, 2020, MSDH issued RFx 3140002081 Request for Quotes-Formal (RFQF) Reverse Auction seeking bids for the purchase of Hemoglobin Analyzers and Microcuvettes. MSDH included a list of specifications for the analyzer and microcuvettes. *See MSDH-RFx # 3140002081 Specification Sheet Attached hereto as Exhibit A.* Questions were to be submitted by February 12, 2021, and answers were provided to the offerors on February 24, 2021. After Amendments and weather delays, the bids were submitted by March 19, 2021.

MSDH received bids from two vendors. EKF Diagnostics proposed the Hemo Control Analyzer Model #3040-0010-0218 and HemoCue submitted two hemoglobin analyzers, the HCAM Hb 201+ and Hb 301.

Each submission was reviewed for responsiveness. To ensure that the models submitted met MSDH needs, on March 31, 2021, Kevin Pearson emailed each vendor a copy of the list of specifications and requested that the vendors, "provide a response for each specification as listed on the attached specification sheet and return by email for further review." Each vendor was asked to respond by April 2, 2021. *See emails to EKF Diagnostics and HemoCue attached here to as composite Exhibit B.*

Based on the response provided by EKF, MSDH determined that the analyzer could meet the specifications of B.7 if the test were performed correctly and deemed the analyzer responsive to the request. The vendors were notified that the reverse auction would take place on April 20, 2021, at 9:00 A.M. CST.

On April 19, 2021, on the eve on the reverse auction, an email from Mark Bellwood, was sent to Kevin Pearson asking how to "challenge" the disqualification of the 201. Mr. Pearson was not available on April 19, however, he responded to the request for protest regulations on April 20, 2021, prior to the reverse auction.

MSDH proceeded with the reverse auction as scheduled. HemoCue was informed via email correspondence that it did not win the reverse auction.

HemoCue filed a protest on April 26, 2021, with a random list of EKF products and their functionality arguing that the EKF products did not meet specifications. The protest requests that MSDH vacate its award to EKF because HemoCue alleges that the Hb 301 is the only analyzer that can meet MSDH specifications and that the disqualification of the 201+ was erroneous and prejudicial. HemoCue further requests that MSDH directs the contract award in its favor as the only offeror capable of meeting MSDH specifications.

HemoCue's arguments are incorrect, and it is in the best interest of the State to award to the vendor which proved to be both responsive and the winner of the reverse auction.

DISCUSSION

The decision regarding responsiveness of each product submitted was based on certifications and clarifications provided by each vendor. HemoCue cannot challenge the results of its own statements.

Each vendor completed and submitted a Bid Form signed by the company representative. A statement at the bottom form clearly states that the by signing the form, the company representative certifies that, "the company meets all requirements/specifications and agrees to all provisions of this solicitation and any issued addenda." Mr. Pearson specifically asked each vendor to provide information to clarify their responses regarding the required specifications.

On March 31, 2021, HemoCue provided a written response as requested for the 201+ and the 301 products and EKF provided its response on April 1, 2021.

The responses to each specification objected to by HemoCue in this protest are as follows:

EKF Hemoglobin Analyzer and Microcuvettes

No.	Specification	EKF Response
B.5	Testing sample size must be 10ul or less.	Hemo Control Cuvette sample size is 8uL
B.6	Measuring range must be Hgb: 0-25.6 g/dL.	Hemo Control measuring range is 0-25.6 g/L.
B.7	Measuring time must be 30 seconds or less.	The Hemo Control Analyzer measures hemoglobin and provides a calculated hematocrit. ***The measuring time for one sample can be as quick as 25 seconds, if performed correctly, or up to 60 seconds if performed incorrectly*** or if the hemoglobin concentration is high. (Emphasis added)

HemoCue Hb 301

No.	Specification	HemoCue Response
B.5	Testing sample size must be 10ul or less.	Yes
B.6	Measuring range must be Hgb: 0-25.6 g/dL.	Yes
B.7	Measuring time must be 30 seconds or less.	Yes

HemoCue Hb 201+

No.	Specification	HemoCue Response
B.5	Testing sample size must be 10ul or less.	Yes
B.6	Measuring range must be Hgb: 0-25.6 g/dL.	Yes
B.7	Measuring time must be 30 seconds or less.	*No.* (Emphasis Added)

(See also Email responses from HemoCue and attached hereto as EFX Exhibits C and D.)

Upon further review of the bids and the foregoing responses, MSDH disqualified HemoCue's 201+ as nonresponsive. The 301 was deemed responsive and allowed to proceed to the reverse auction. HemoCue was informed of this decision on April 8, 2021. HemoCue thanked MSDH for the notification and did not protest the disqualification. (See Exhibit E.)

MSDH addressed concerns raised by HemoCue in its protest prior to making a final determination regarding responsiveness. Specifically, MSDH proactively asked for further clarification regarding the specifications. Based on the vendors' responses, MSDH determined that HemoCue's 201+ was the only product that did not meet all specifications as required and the 201+ was disqualified. EKF provided an explanation of its analyzer's function in its response B.7. After consideration of EKF's statement, MSDH determined the EKF product met MSDH specifications. Nothing prohibited HemoCue from providing an explanation of its responses. It chose not to provide any additional information for consideration at that time and is prohibited from doing so now.

MSDH proactively requested additional information from each vendor. Each vendor had an opportunity to respond and provide any additional information. MSDH accepts both HemoCue and EKF's responses as accurate and truthful. The 201+ was disqualified based on the vendor's response, and therefore, was neither erroneous nor prejudicial. Further, if HemoCue truly believed that the 301 was the only product that met MSDH specifications, it should have filed its protest upon notification that the 201+ had been disqualified, or at least notified MSDH of its belief that the 301 was a sole source.

Based on the foregoing information, MSDH sustains its findings that all products met specifications except the Hb 201+ and affirms the results of the reverse auction.

DECISION

For these reasons, the protest submitted by HemoCue is DENIED.

In accordance with OPSCR Rule 7-112.04 *Right to Appeal*, you may appeal this decision to the Public Procurement Review Board within seven (7) calendar days of receipt of this Protest Decision. Any appeal of this decision must follow OPSCR Rule 7-112 *Protest of Solicitations and Awards* found at https://www.dfa.ms.gov/media/9413/pprb-opscr-rules-and-regulations-efficetive-01182020.pdf.

Sincerely,

Thomas Dobbs, MD, MPH
State Health Office
Mississippi State Department of Health

cc: Pat Breheny, EKF Diagnostics, PatBreheny@ekfdiagnostics.com
Brittney Thompson, Director, OPSCR

MSDH-RFx # 3140002081 SPECIFICATION SHEET

Hemoglobin Analyzer and Microcuvettes

A.
A.1 Prospective device must be CLIA Waived.

B. General Specifications-Analyzer
B.1 All devices purchased must be new and model currently in production. Refurbished or demonstrator units are not acceptable. Instrument name and model must be listed.
B.2 The vendor must guarantee manufacturer replacement units for defective units for first 5 years.
B.3 All units must include a physical set of operating manual and brochures.
B.4 All units must include training and education program to all sites as well as refresher trainings at no cost.
B. 5 Testing sample size must be 10µl or less.
B. 6 Measuring range must be Hgb: 0-25.6 g/dL.
B.7 Measuring time must be 30 seconds or less.
B. 8 Unit must provide memory for no less than 100 test results.
B. 9 Unit must include AC adapters and DC battery options.
B. 10 Unit must have internal self check no less than each time unit is powered on.
B. 11 Units will be delivered to WIC Central Office, Ridgeland, MS with no shipping cost.

C. General Specifications-Microcuvettes
C.1 Expiration date at time of shipment must be greater than 18 months.
C.2 Expiration date after opening must be greater than or equal to 90 days.
C. 3 Guaranteed pricing of microcuvette supplies for 5 years.

The specifications listed are the minimum required for this RFQ-F Reverse Auction. They are not intended to limit competition nor specify any particular bidder/respondent, but to ensure that the MSDH receives a quality product meeting the needs of the agency.

Pearson, Kevin

From:	Pearson, Kevin
Sent:	Tuesday, March 30, 2021 8:06 AM
To:	patbreheny@ekfdiagnostics.com
Cc:	Nelson, Johnny
Subject:	Question
Attachments:	RFx 3140002081 Specification Sheet.docx

Thank you for your submitted Response/Quote to MSDH's RFx 3140002081 for Hemoglobin items.

In reviewing your response, and all info submitted with the response, we have been unable to assure compliance with al specifications as listed in the RFx packet.

Please provide a response for each specification as listed on the attached specification sheet, and return by email for further review. Please return the requested information by Friday, April 2, 2021.

Thank you,

Kevin Pearson

ATTACHMENT B
MSDH

Pearson, Kevin

From: Pearson, Kevin
Sent: Tuesday, March 30, 2021 8:10 AM
To: customerservice@hemocue.com
Cc: Nelson, Johnny
Subject: Questions
Attachments: RFx 3140002081 Specification Sheet.docx

Thank you for your submitted Response/Quote to MSDH's RFx 3140002081 for Hemoglobin items.

In reviewing your response, and all info submitted with the response, we have been unable to assure compliance with all specifications as listed in the RFx packet.

Please provide a response for each specification, as listed on the attached specification sheet, and return by email for further review. Please return the requested information by Friday, April 2, 2021.

Thank You

Kevin Pearson

Pearson, Kevin

From:	Spetz, Mary L <Mary.L.Spetz@hemocue.com>
Sent:	Wednesday, March 31, 2021 1:08 PM
To:	Pearson, Kevin; Nelson, Johnny
Cc:	Bellwood, Mark C; Dayton, Sara X
Subject:	RFx 3140002081
Attachments:	RFx 3140002081 Specification Sheet (Hb301).docx; RFx 3140002081 Specification Sheet (Hb201+).docx

Hi Kevin-

In response to your request of yesterday, please find a specification sheet for each unit submitted in MSDH-Rfx#314000208. Please let us know if this meets your expectations, as all supporting documentation was submitted previously. If this response is not in line with what you are looking for, please make us aware and we will submit anything additional that you are in need of by Friday April 2.

Please Note: Please reply to my email address, rather than the customerservice@hemocue.com , as that is a generic email which is not monitored as closely.

Warm Regards,

Mary Spetz
Key Account Representative
585-353-3648
Mary.l.spetz@hemocue.com

ATTACHMENT C
MSDH

MSDH-RFx # 3140002081 SPECIFICATION SHEET

Hemoglobin Analyzer and Microcuvettes

Hb 301

A.
A.1 Prospective device must be CLIA Waived. Yes

B. General Specifications-Analyzer
B.1 All devices purchased must be new and model currently in production. Refurbished or demonstrator units are not acceptable. Instrument name and model must be listed. Yes
B.2 The vendor must guarantee manufacturer replacement units for defective units for first 5 years. Yes
B.3 All units must include a physical set of operating manual and brochures. Yes
B.4 All units must include training and education program to all sites as well as refresher trainings at no cost. Yes
B. 5 Testing sample size must be 10µl or less. Yes
B. 6 Measuring range must be Hgb: 0-25.6 g/dL. Yes
B.7 Measuring time must be 30 seconds or less. Yes
B. 8 Unit must provide memory for no less than 100 test results. Yes, with included Basic Connect package.
B. 9 Unit must include AC adapters and DC battery options. Yes
B. 10 Unit must have internal self check no less than each time unit is powered on. Yes
B. 11 Units will be delivered to WIC Central Office, Ridgeland, MS with no shipping cost. Yes

C. General Specifications-Microcuvettes
C.1 Expiration date at time of shipment must be greater than 18 months. Yes
C.2 Expiration date after opening must be greater than or equal to 90 days. Yes
C. 3 Guaranteed pricing of microcuvette supplies for 5 years. Yes

The specifications listed are the minimum required for this RFQ-F Reverse Auction. They are not intended to limit competition nor specify any particular bidder/respondent, but to ensure that the MSDH receives a quality product meeting the needs of the agency.

MSDH-RFx # 3140002081 SPECIFICATION SHEET

Hemoglobin Analyzer and Microcuvettes

Hb 201+

A.
A.1 Prospective device must be CLIA Waived. Yes

B. General Specifications-Analyzer
B.1 All devices purchased must be new and model currently in production. Refurbished or demonstrator units are not acceptable. Instrument name and model must be listed. Yes
B.2 The vendor must guarantee manufacturer replacement units for defective units for first 5 years. Yes
B.3 All units must include a physical set of operating manual and brochures. Yes
B.4 All units must include training and education program to all sites as well as refresher trainings at no cost. Yes
B. 5 Testing sample size must be 10µl or less. Yes
B. 6 Measuring range must be Hgb: 0-25.6 g/dL. Yes
B.7 Measuring time must be 30 seconds or less. No
B. 8 Unit must provide memory for no less than 100 test results. Yes, with included Basic Connect package.
B. 9 Unit must include AC adapters and DC battery options. Yes
B. 10 Unit must have internal self check no less than each time unit is powered on. Yes
B. 11 Units will be delivered to WIC Central Office, Ridgeland, MS with no shipping cost. Yes

C. General Specifications-Microcuvettes
C.1 Expiration date at time of shipment must be greater than 18 months. Yes
C.2 Expiration date after opening must be greater than or equal to 90 days. Yes
C. 3 Guaranteed pricing of microcuvette supplies for 5 years. Yes

The specifications listed are the minimum required for this RFQ-F Reverse Auction. They are not intended to limit competition nor specify any particular bidder/respondent, but to ensure that the MSDH receives a quality product meeting the needs of the agency.

Pearson, Kevin

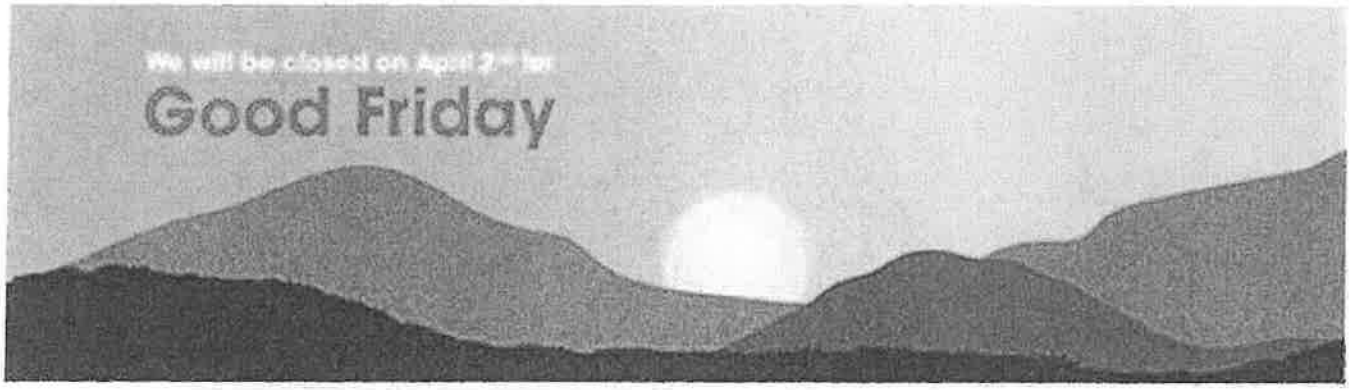
From: Pat Breheny <PatBreheny@ekfdiagnostics.com>
Sent: Thursday, April 1, 2021 5:03 PM
To: Pearson, Kevin
Subject: RE: Question
Attachments: MS RFx 3140002081 Specification Sheet Answered questions 3.31.21.docx

Kevin,
Please see our response to the documented attached for MSDH's RFx 3140002081 for Hemoglobin items.
Please let me know if you have any further questions.

Thank you,
Pat Breheny

Pat Breheny
Public Health Sales Specialist

Cell: 210-601-5252
Email: patbreheny@ekfdiagnostics.com



EKF DIAGNOSTICS STANBIO® STI

1261 North Main Street • Boerne, TX, USA 78006
Tel: 830.249.0772 • Fax: 830.249.0851 • www.stanbio.com

From: Pearson, Kevin [mailto:Kevin.Pearson@msdh.ms.gov]
Sent: Tuesday, March 30, 2021 8:06 AM
To: Pat Breheny
Cc: Nelson, Johnny
Subject: Question

ATTACHMENT D
MSDH

Thank you for your submitted Response/Quote to MSDH's RFx 3140002081 for Hemoglobin items.

In reviewing your response, and all info submitted with the response, we have been unable to assure compliance with al specifications as listed in the RFx packet.

Please provide a response for each specification as listed on the attached specification sheet, and return by email for further review. Please return the requested information by Friday, April 2, 2021.

Thank you,

Kevin Pearson

MSDH-RFx # 3140002081 SPECIFICATION SHEET

Hemoglobin Analyzer and Microcuvettes

A.
A.1 Prospective device must be CLIA Waived
The Hemo Control Analyzer is CLIA Waived.

B. General Specifications-Analyzer
B.1 All devices purchased must be new and model currently in production. Refurbished or demonstrator units are not acceptable. Instrument name and model must be listed.
The Hemo Control Analyzer/s to be provided will be new and of current model year. Hemo Control Analyzer - Model #3040-0010-0218
B.2 The vendor must guarantee manufacturer replacement units for defective units for first 5 years. Hemo Control Analyzer will be under warranty for 5 years for replacement from award of Bid.
B.3 All units must include a physical set of operating manual and brochures. Each Hemo Control Analyzer will include a hard copy of user manual and support literature.
B.4 All units must include training and education program to all sites as well as refresher trainings at no cost. Hemo Control training, education and refreshers to be provided at no cost.
B. 5 Testing sample size must be 10µl or less. Hemo Control Cuvette sample size is 8µL.
B. 6 Measuring range must be Hgb: 0-25.6 g/dL. Hemo Control measuring range is 0-25.6 g/dL.
B.7 Measuring time must be 30 seconds or less. The Hemo Control Analyzer measures hemoglobin and provides a calculated hematocrit. The measuring time for one sample can be as quick as 25 seconds, if performed correctly, or up to 60 seconds if performed incorrectly or if the hemoglobin concentration is high.
B. 8 Unit must provide memory for no less than 100 test results. Hemo Control Analyzer stores 4000 test results in memory.
B. 9 Unit must include AC adapters and DC battery options. Each Hemo Control Analyzer includes an AC adapter as well as a built in rechargeable battery good for up to 100 hours of operation when new and fully charged.
B. 10 Unit must have internal self-check no less than each time unit is powered on. Hemo Control Analyzer performs a self-test automatically at regular intervals while the unit is powered on.
B. 11 Units will be delivered to WIC Central Office, Ridgeland, MS with no shipping cost. Hemo Control Analyzers will be delivered to the WIC Central Office in Ridgeland, MS with no charge freight.
C. General Specifications-Microcuvettes
C.1 Expiration date at time of shipment must be greater than 18 months. The Hemo Control Microcuvettes will have 18 months or better dating at time of shipment.
C.2 Expiration date after opening must be greater than or equal to 90 days. Hemo Control Analyzer Microcuvettes expire 90 days after opening canister when following proper storage and handling procedure.

C. 3 Guaranteed pricing of microcuvette supplies for 5 years. The pricing submitted for the Hemo Control Microcuvette supplies will be guaranteed for 5 years or term of the Bid, including extensions.

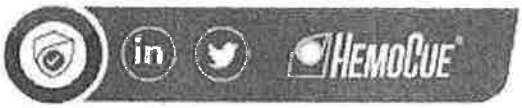
The specifications listed are the minimum required for this RFQ-F Reverse Auction. They are not intended to limit competition nor specify any particular bidder/respondent, but to ensure that the MSDH receives a quality product meeting the needs of the agency.

Pearson, Kevin

From: Bellwood, Mark C <Mark.C.Bellwood@hemocue.com>
Sent: Monday, April 19, 2021 4:41 PM
To: Pearson, Kevin; Brasher, Cynthia; Nelson, Johnny
Cc: Spetz, Mary L; Dayton, Sara X
Subject: RE: Reverse Auction

Hello,
We look forward to participating in the reverse auction tomorrow with our Hb301.
Since the Hb201+ was denied participation, what is the process to challenge the denial.
We have looked but cannot understand a clear process for protest in Mississippi.
Thank you,
M

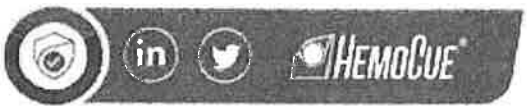
Mark Bellwood
HemoCue America | Director, Specialty Markets | 250 S. Kraemer Blvd. - Mailstop: B1.SW.11 | Brea California 92821 | phone +1 714 646 2273 | fax +1 714 441 8160 | mobile +1 214 412 8900 | Mark.C.Bellwood@hemocue.com
www.hemocue.us



From: Bellwood, Mark C
Sent: Thursday, April 8, 2021 11:49 AM
To: Pearson, Kevin <Kevin.Pearson@msdh.ms.gov>
Cc: Spetz, Mary L <Mary.L.Spetz@hemocue.com>
Subject: RE: Reverse Auction

Hi Kevin,
Thanks for this notification on the Hb 301 being accepted. We will block 4/20 for participation and await the time once it is set.
Can you tell me which analyzers from other vendors were accepted to participate in the reverse auction?
Thanks,
M

Mark Bellwood
HemoCue America | Director, Specialty Markets | 250 S. Kraemer Blvd. - Mailstop: B1.SW.11 | Brea California 92821 | phone +1 714 646 2273 | fax +1 714 441 8160 | mobile +1 214 412 8900 | Mark.C.Bellwood@hemocue.com
www.hemocue.us



ATTACHMENT E
MSDH

From:
Sent: Thursday, April 8, 2021 12:31 PM
To: Spetz, Mary L
Subject: RE: Reverse Auction

You will get something from Cynthia but 4/20 is the date not sure of time yet.

From: Spetz, Mary L <Mary.L.Spetz@hemocue.com>
Sent: Thursday, April 8, 2021 11:30 AM
To: Pearson, Kevin <Kevin.Pearson@msdh.ms.gov>
Cc: Brasher, Cynthia <Cynthia.Brasher@msdh.ms.gov>; Bellwood, Mark C <Mark.C.Bellwood@hemocue.com>; Dayton, Sara X <sara.x.dayton@hemocue.com>
Subject: RE: Reverse Auction

Thank You Kevin!

When is the reverse auction going to take place?

Warm Regards,

Mary Spetz
Key Account Representative
585-353-3648
Mary.L.spetz@hemocue.com

From: Pearson, Kevin <Kevin.Pearson@msdh.ms.gov>
Sent: Thursday, April 8, 2021 11:58 AM
To: Spetz, Mary L <Mary.L.Spetz@hemocue.com>
Cc: Brasher, Cynthia <Cynthia.Brasher@msdh.ms.gov>
Subject: Reverse Auction

Your submission of 3140002081 for the HB 201 was not accepted for the reverse auction. The unit did not meet the specifications.

Your 301 will be included.

Attachment A.III

Record on Appeal

HemoCue's Appeal to PPRB
Dated July 1, 2021

BUTLER | SNOW

July 1, 2021

Via Hand Delivery

Mississippi Public Procurement Review Board
Mississippi Department of Finance and Administration
E.T. Woolfolk State Office Building
501 North West Street, Room 1302
Jackson, MS 39216

Appeal of the Mississippi State Department of Health's Decision Denying HemoCue America's Protest of RFx #3140002081

To the Members of the Public Procurement Review Board:

Pursuant to Mississippi Procurement Manual § 6.204(3)[1], HemoCue America ("HCAM") submits this appeal of a final decision by the Mississippi State Department of Health ("MSDH"), which denied HCAM's protest of a contract for hemoglobin analyzers and microcuvettes awarded to EKF Diagnostics Inc., dba Stanbio Laboratory, ("EKF") under Request for Quotes-Formal Reverse Auction, RFx# 3140002081 ("solicitation" or "RFQF").[2] This appeal is submitted on behalf of HemoCue America – a division of Radiometer America Inc., 250 S. Kraemer Blvd., Brea, CA 92821. The undersigned serves as counsel for HemoCue America.

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1 MSDH cited this provision when setting forth HCAM's appeal rights in an email on June 28, 2021.

2 Although the final decision is dated June 22, 2021, MSDH did not actually transmit that decision to HCAM until June 24. *See* 6/24/21 Email from MSDH to Mark Bellwood of HCAM (attached as Exhibit A). This protest is timely filed within 7 days of that date. *See* Mississippi Procurement Manual § 6.204 ("[T]he aggrieved person shall file an appeal within seven days of receipt of a decision . . . .")

CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION WHICH MAY NOT BE RELEASED WITHOUT THE PRIOR WRITTEN PERMISSION OF HEMOCUE AMERICA PURSUANT TO MISS. CODE ANN. § 25-61-9

Post Office Box 6010
Ridgeland, MS 39158-6010

Mark W. Garriga
601.985.4586
Mark.Garriga@butlersnow.com

Suite 1400
1020 Highland Colony Park
Ridgeland, Mississippi 39157

T 601.948.5711 • F 601.985.4500 • www.butlersnow.com

BUTLER SNOW LLP

The facts show that EKF's analyzer does not meet the solicitation's minimum requirements and, thus, is not eligible for award. Additionally, MSDH treated the offerors unequally by relaxing the minimum requirements for EKF's analyzer but refusing to relax the requirements for HCAM's analyzer. Because of these errors, MSDH's award decision is contrary to law and should be reversed. HCAM respectfully requests that the Public Procurement Review Board ("Board") sustain this protest and direct MSDH to rescind its award to EKF.

STATEMENT OF FACTS

I. Nature of the Procurement

MSDH seeks to buy hemoglobin analyzers and microcuvettes for state health laboratories using a reverse auction process. Hemoglobin analyzers measure proteins in the blood that are critical for providing oxygen to the body, and microcuvettes hold samples of material for testing. MSDH will use the analyzers to measure hemoglobin concentration in samples drawn from the general public, who will have varying levels of hemoglobin in their blood. Some of those patients will have high concentrations of hemoglobin, while others will have average or low hemoglobin levels.

II. Reverse Auction

MSDH's solicitation stated that the procurement would be a "reverse auction." Exhibit B, Solicitation (hereinafter, "Solicitation") at 8. A reverse auction procurement has two steps. First, the state determines whether a product is responsive, and if so, the product is admitted to the auction. *Id.* at 5 ("The MSDH will accept bidder responses . . . who have qualified meeting RFx specifications. Bidders not meeting specifications will not be allowed to participate in the Auction."). Second, bidders admitted to the auction must submit a price for the agency's

consideration. *Id.* at 6 ("Prices accepted from bidder submissions shall be firm[.]"). The agency then selects the lowest-price bidder. *Id.* at 2.

MSDH reserved the right to reject bids and make no award. *Id.* at 6 ("Suppliers should be advised that no award will automatically result from a reverse auction[.]"). As a result, the reverse auction incentivized a bidder to submit as low a price as possible — not simply to underbid any other potential bidders, but also to lessen the risk of the agency making no award.

III. MSDH Required Analyzers to Take Measurements in 30 Seconds or Less

MSDH's solicitation included a list of "specifications" that represented the agency's "minimum required" performance features. Solicitation at 14. These minimum requirements were intended "to ensure that the MSDH receives a quality product meeting the needs of the agency." *Id.* As relevant here, specification B.7 required the hemoglobin analyzer to measure all samples in "***30 seconds or less***." *Id.* (emphasis added). There was no exception to that requirement for samples with high concentrations of hemoglobin.

The solicitation stated that if a bid "does not comply with the minimum provisions of the specification[,]" it would be deemed "non-responsive" and would "not be considered." *Id.* at 5 (underline in original).

IV. Quotes, Evaluation, and Award Decision

Consistent with the RFQF, HCAM submitted two unique quotes. One offered HCAM's Hb 201+ analyzer model, while the other offered HCAM's Hb 301 model. The Hb 201+ had a relatively lower cost than the Hb 301, while the Hb 301 had certain additional features that the Hb 201+ did not.

On March 31, 2021, MSDH contacted HCAM about both quotes, explaining that it had "been unable to assure compliance with all specifications as listed in the [solicitation] packet."

Ex. C, MSDH Protest Decision (hereinafter, "Protest Decision") at 7. MSDH asked HCAM to "provide a response for each specification[.]" *Id.*

HCAM clearly and unequivocally informed MSDH that its Hb 301 hemoglobin analyzer measured results in 30 seconds or less in all instances. *Id.* at 9 (showing HCAM's response of "Yes").

With respect to its other quote, HCAM stated that the Hb 201+ analyzer met all of the RFQF's specifications except for Specification B.7.

On April 8, 2021, MSDH notified HCAM that the Hb 301 analyzer was accepted to participate in the reverse auction, but the Hb 201+ was not accepted because it "did not meet the specifications." Protest Decision at 16. That same day, HCAM asked MSDH, "[c]an you tell me which analyzers from other vendors were accepted to participate in the reverse auction?" MSDH responded that it was "not allowed to give that info." Ex. D, Email of MSDH. In other words, MSDH would neither confirm nor deny that any product other than HCAM's Hb 301 analyzer had been admitted to the reverse auction.

Separately, MSDH informed HCAM on April 8, 2021 that the reverse auction would be held on April 20, 2021. The day before the auction, on April 19, 2021, HCAM emailed MSDH to ask whether there was a process for protesting the exclusion of its lHb 201+ analyzer from the reverse auction. As far as HCAM knew, it was the only bidder in the reverse auction. Having both the Hb 201+ and Hb 301 in the competition would increase the odds of the agency making an award to HCAM rather than electing not to make any award at all. HCAM ultimately decided against protesting the exclusion of the Hb 201+ because that analyzer could not, in fact, meet the B.7 specification.

On April 20, 2021, MSDH notified HCAM by email that it had lost the reverse auction. However, MSDH declined to provide any information about the awardee or the winning analyzer.

V. Protest

On April 27, 2021, HCAM protested the agency's decision based on the minimal information that MSDH had provided. HCAM's protest noted that only two other companies made invasive hemoglobin analyzers, and explained that the publicly available information indicated that neither had a product that could meet the solicitation's requirements. Ex. E, HCAM Protest.

On June 24, 2021, MSDH emailed HCAM its final decision denying HCAM's protest. MSDH's Protest Decision revealed key facts, not previously known by HCAM. MSDH disclosed the identity of the winner: EKF, which proposed its Hemo Control Analyzer Model #3040-0010-0218. The agency also disclosed that it had received bids only from HCAM and EKF. Protest Decision" at 1.

The agency also revealed that it had concerns about the ability of EKF's analyzer to meet the required specifications. It asked EKF on March 31 to "provide a response for each specification" confirming whether they complied. *Id.*

With respect to Specification B.7, EKF did not state that its analyzer would measure samples in 30 seconds or less as required. Rather, EKF stated "[t]he measuring time for one sample ***can be*** as quick as 25 seconds, if performed correctly, or up to ***60 seconds*** if performed incorrectly ***or if the hemoglobin concentration is high***." *Id.* at 13 (emphasis added).

In other words, EKF stated that its analyzer will take as long as one minute — *i.e.*, 100% longer than the solicitation allows — to measure samples with high hemoglobin levels. And

EKF did not state that the measurement time "will be" 30 seconds or less for samples with average or low hemoglobin levels. It stated only that the measurement time "***can be*** . . . as quick as 25 seconds" — indicating that it can also take longer to measure such samples in some instances.

Further, EKF placed a qualifier on its measurement times, saying that even the possibility of meeting the 30-seconds or less requirement depends on the measurement being "performed correctly." EKF did not define "correct performance" or explain how the measurement could be performed "incorrect[ly]" yet still yield an accurate result — or any result at all.

MSDH's protest decision asserted that "[a]fter consideration of EKF's [April 1] statement," MSDH "determined that the analyzer could meet the specifications of B.7 if the test were performed correctly and deemed the analyzer responsive to the request." *See* Protest Decision at 2, 3. MSDH also opined that "if HemoCue truly believed that the 301 was the only product that met MSDH specifications, it should have filed its protest upon notification that the 201 + had been disqualified, or at least notified MSDH of its belief that the 301 was a sole source." *Id.* at 4.

HCAM now appeals MSDH's decision.

LEGAL STANDARDS

It is a fundamental rule of government procurement that a bid must comply with the requirements of the solicitation, or else be rejected as ineligible for award. *W.G. Yates & Sons Constr. Co. v. City of Waveland*, 168 So. 3d 963, 972-73 (Ct. App. Miss. 2012) (reversing contract award, when winning bidder's proposal failed to comply with the solicitation); *see also Alfa Laval Separation, Inc. v. United States*, 175 F.3d 1365, 1367-68 (Fed. Cir. 1999) (sustaining bid protest when the awardee's "proposal was technically noncompliant").

Further, the state's contracting decisions may not be "arbitrary and capricious . . . . If an administrative agency's decision is not based on substantial evidence, it necessarily follows that the decision is arbitrary and capricious." *AT&T Corp. v. Miss. Dep't of Info. Tech. Servs.*, 298 So. 3d 938, 946 (Miss. 2020). "Substantial evidence . . . affords a substantial basis of fact from which the fact in issue can be reasonably inferred." *Id.* (citing *Miss. Div. of Medicaid v. All Health Ctr.*, 174 So. 3d 254, 261 (Miss. 2015)).

DISCUSSION

I. MSDH Violated the Terms of the Solicitation by Selecting EKF's Non-Compliant Analyzer for Award

Specification B.7 of the solicitation required bidders to provide a hemoglobin analyzer that measures samples in "30 seconds or less." Solicitation at 14, Specification B.7. This was a minimum eligibility requirement, and the solicitation stated that non-responsive offers would be unacceptable. *Id.* at 5. By EKF's own admission, its analyzer could not process all samples in 30 seconds or less. Thus, MSDH should have disqualified EKF's product from the competition.

When MSDH asked EKF if its analyzer could measure samples in 30 seconds or less, EKF responded as follows:

> The measuring time for one sample ***can be as quick as 25 seconds,*** if performed correctly, ***or up to 60 seconds*** if performed incorrectly ***or if the hemoglobin concentration is high.***

Protest Decision at 13 (emphasis added). Thus, EKF admitted its analyzer ***will not*** be able to measure samples with high concentrations of hemoglobin in 30 seconds or less as the solicitation requires. It will take up to twice as long to measure the hemoglobin in those samples. *See* Solicitation at 14. EKF's analyzer was, therefore, non-compliant and should have been disqualified. *See* Solicitation at 5.

And EKF's non-compliance problem was not confined to high-hemoglobin samples. Far from committing to meet the Specification B.7 requirement when samples contain low or normal hemoglobin levels, EKF said only that processing time for those samples "***can*** be ***as quick as*** 25 seconds" — as opposed to "will be 25 seconds" or "is 25 seconds." Protest Decision at 13 (emphasis added). In other words, measuring time for those samples also "can be" ***longer*** than 25 seconds. EKF did not explain what percentage of those low or normal hemoglobin level samples will take longer than 25 seconds to measure or how much longer they will take. In fact, EKF conspicuously avoided stating that measuring time will be 30 seconds or less for ***any*** kind of sample.

The Protest Decision states that based on the above statement from EKF, MSDH "determined that the analyzer could meet the specifications of B.7 if the test were performed correctly[.]" Protest Decision at 2. That is not a reasonable interpretation of EKF's statement. EKF plainly stated that the measuring time "can be . . . up to 60 seconds if performed incorrectly ***or*** if the hemoglobin concentration is high." (Emphasis added). By using "or," EKF made clear that there were at least two separate scenarios in which it would take as long as a minute to measure results: (1) if measurements were performed incorrectly; "or" (2) if hemoglobin concentration in the sample is high. EKF's analyzer will have to analyze samples from individuals with varying hemoglobin concentrations — including high hemoglobin concentrations. And by EKF's own admission, its analyzer will not be able to analyze those samples in 30 seconds or less even "if performed correctly."[3] Furthermore, as shown above,

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[3] EKF's "if performed correctly" qualification makes no sense. EKF does not explain what "correct" performance is, or how a measurement that is "incorrectly" performed could still generate an accurate result in any amount of time, much less 60

EKF did not even commit to meet the 30-seconds-or-less requirement when measuring samples with low or normal hemoglobin levels.

Thus, MSDH's conclusion that "the EKF product met MSDH specifications[]" is not supported by substantial evidence. *Id.* at 3. It is contradicted by EKF's own statements. This protest should be sustained on this basis, and MSDH's award decision should be reversed. *See W.G. Yates*, 168 So. 3d at 972-73 (holding it was unlawful to award a contract to a non-compliant bid).

MSDH's contention that HCAM should have "filed its protest upon notification that the 201+ had been disqualified" or "notified MSDH of its belief that the 301 was a sole source[]" is meritless. Protest Decision at 4. HCAM reasonably expected the agency to comply with the terms of the solicitation and enforce the specification requirements. Indeed, MSDH's disqualification of the Hb 201+ and acceptance of the Hb 301 into the reverse auction indicated that MSDH was doing just that. As far as HCAM knew, the Hb 301 was the only analyzer in the reverse auction — MSDH refused to say whether there were other competitors in the auction or identify any other products proposed. Ex. C, Email of MSDH.

MSDH's argument that HCAM should have demanded a sole source award ignores the solicitation's express terms, which make clear that no award was guaranteed in this procurement. MSDH expressly reserved the right to reject all bids for any reason. Even if the Hb 301 were the only analyzer that could meet all of the specifications, HCAM would not automatically receive

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seconds as EKF claims. The language about "correct" vs. "incorrect" performance seems to have been an effort to distract MSDH from the fact that its analyzer ***cannot*** meet the Specification B.7 requirement.

an award. It would have to propose a sufficiently low price to convince the agency to make an award rather than rejecting the bid.[4]

HCAM was plainly prejudiced by MSDH's erroneous evaluation of EKF's analyzer. As the protest decision acknowledges, HCAM's Hb 301 analyzer was fully compliant with all specifications, including Specification B.7. The Hb 301 was admitted to the reverse auction but lost to EKF's non-compliant analyzer. Had MSDH disqualified EKF's product as it should have, MSDH would have won the award as the only other offeror.

II. MSDH Treated HCAM Unequally as Compared to EKF

Mississippi law requires procuring agencies to hold a fair and equal contract competition, so that each bid is evaluated "with all other bids upon the same basis[.]" *Hemphill Constr. Co., Inc. v. City of Laurel*, 760 So. 2d 720, 724 (Miss. 2000). Equal treatment of bids is a key underpinning of competition for government contracts — "a contracting agency must treat all offerors equally, evaluating proposals evenhandedly against common requirements and evaluation criteria." *CliniComp Int'l, Inc. v. United States*, 117 Fed. Cl. 722, 741 (2014) (quotation omitted). MSDH's award decision fails to meet those standards.

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[4] MSDH appears to misunderstand the rules for conducting a sole-source procurement. The Mississippi Procurement Manual states that an agency must conduct a public competition, so long as there is more than one "***potential*** bidder or offeror for that item." Mississippi Procurement Manual § 3.109.02 (emphasis added). Even if an agency determines there is only one potential bidder, the Board can require the agency to use competition if there is "any reasonable doubt" as to whether there is more than one eligible source. *Id.* Thus, Mississippi law strongly favors the use of public competitions, even if there is good reason to believe that only one bidder will be eligible. Under those standards, HCAM could not have protested that the procurement should be a sole-source, and instead needed to participate in the competition.

MSDH found HCAM's Hb 201+ analyzer non-compliant because it does not meet the solicitation's requirement to measure hemoglobin levels in 30 seconds or less without exception. But, EKF's analyzer does not meet that requirement either, as demonstrated above.

The agency cannot relax solicitation requirements for one non-compliant bid, but then strictly apply them to another. *See, e.g., Hunt Building Co., Ltd. v. United States*, 61 Fed. Cl. 243, 274 (2004) (agency violated solicitation terms and treated offerors unequally by relaxing requirements for the awardee, but not for the protester). But the agency's protest decision has revealed that that is exactly what MSDH did here when it waived the B.7 requirement for EKF but failed to do the same for HCAM's Hb 201+ analyzer. That is a textbook example of unfair and unequal treatment. *See, e.g., L-3 Comm. EOTech, Inc. v. United States*, 83 Fed. Cl. 643, 653 (2008) ("Waiver of a mandatory requirement of the solicitation for the benefit of only one offeror invalidates a procurement decision.").

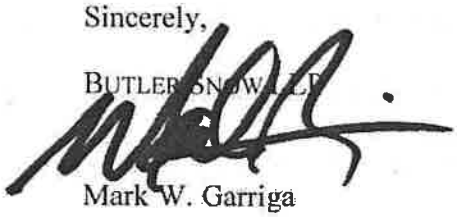
HCAM was prejudiced by the unequal treatment. HCAM is able to offer the Hb 201+ at a substantially lower price than the Hb 301. Had MSDH qualified the HB 201+ for the reverse auction as it should have, there is a substantial chance that HCAM would have underbid EKF and won the award. This protest should be sustained.

CONCLUSION

For these reasons, MSDH's award decision is arbitrary and contrary to the solicitation. We respectfully request that the Board sustain this protest and direct MSDH to rescind its award decision and either re-award to HCAM or solicit new quotes.

Sincerely,

BUTLER SNOW LLP



Mark W. Garriga

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EXHIBIT A

From: Funches, Teselyn <Teselyn.Funches1@msdh.ms.gov>
Sent: Thursday, June 24, 2021 4:59 PM
To: Bellwood, Mark C <Mark.C.Bellwood@hemocue.com>; Pat Breheny <PatBreheny@ekfdiagnostics.com>
Cc: Torri Martin <torri.martin@ago.ms.gov>; Martin, LaTeshya <LaTeshya.Martin@msdh.ms.gov>; Dotson, Jennifer <Jennifer.Dotson@msdh.ms.gov>
Subject: MSDH Decision regarding HemoCue Protest RFx 314002081

All,

Please see the attached MSDH Decision regarding HemoCue's protest of award.

Tess

Teselyn Melton Funches, JD
Procurement Coordinator
Mississippi State Department of Health
570 East Woodrow Wilson Blvd
P.O. Box 1700
Jackson, MS 39215-1700
601-576-7503

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EXHIBIT B

MSDH Request for Quotes-Formal (RFQF) Reverse Auction
RFx #3140002081

GENERAL CONDITIONS- REVERSE AUCTIONS

ALL BIDS SUBMITTED SHALL BE IN COMPLIANCE WITH ALL CONDITIONS SET FORTH HEREIN. THE BID PROCEDURES FOLLOWED BY THIS OFFICE WILL BE IN ACCORDANCE WITH THESE CONDITIONS. THEREFORE, ALL BIDDERS ARE URGED TO READ AND UNDERSTAND THESE CONDITIONS PRIOR TO SUBMITTING A BID.

1. DEFINITIONS

The use of the word "agency" in any Bid Invitation solicitation or specification shall be intended to mean state agencies only. The words "governing authority" when used shall be intended as meaning city, county or other local entities.

2. PREPARATION OF BIDS

2.1 Responding suppliers must provide a Quote with the initial response. Quotes are utilized by the Purchasing Agent to determine market pricing and set the auction parameters (e.g., start price). Bids and/or Quotes may be submitted through the State of Mississippi's e-procurement system (MAGIC), or in person to the Mississippi State Department of Health, Office of Purchasing ("MSDH" or "the State"). Paper bids are allowed. All prices and notations must be printed in ink or typewritten. No erasures permitted. Errors may be crossed out and corrections printed in ink or typewritten adjacent and must be initialed, in ink, by the person signing bid.

2.2 To submit bids electronically, bidders must ensure they are registered in the MAGIC system and have received a login, password, and supplier number and that all technical requirements have been met.

2.3 If a bidder is unwilling or unable to participate through MAGIC, an MSDH representative can enter the Vendor's bid(s) manually (i.e. Surrogate bidding).

2.4 Bidders participating in person by surrogate bidding must so indicate in their response to the initial Request for Quote-Formal (RFQF).

2.5 Failure to examine any drawings, specifications, and instructions will be at bidder's risk.

2.6 Price each item separately. Unit prices shall be shown. Bid prices must be net.

2.7 It is understood that reference to available specifications shall be sufficient to make the terms of such specifications binding on the bidder.

2.8 Bidders must furnish all information requested in the bid specifications. Further, when required, each bidder must submit for bid evaluation cuts, sketches, descriptive literature and technical specifications covering the product offered. Reference to literature submitted with a previous bid or on file with MSDH will not satisfy this provision.

2.9 Samples of items, when requested, must be furnished free of expense, and if not destroyed in testing will, upon request, be returned at the bidder's expense. Request for the return of samples must be made within ten (10) days following opening bids. Each individual sample must be labeled with bidder's name, manufacturer's brand name and number, State of Mississippi commodity number, bid number and item reference.

2.10 Time of performance. The number of calendar days in which delivery will be made after receipt of order shall be indicated in the bid specifications.

3. BID SUBMISSION

3.1 When submitting a bid electronically, the authorized signature may be typed or be an electronic signature.

3.2 Bids and modifications or corrections received after the closing time specified will not be considered.

3.3 When submitting the response to the RFQF in MAGIC, bidder must ensure all questions have been answered within the RFQF and all proposed items in bid have a response.

3.4 Bidders submitting paper responses should submit responses to the MSDH by the response deadline.

4. ACCEPTANCE OF BIDS

MSDH reserves the right to reject any and all bids, to waive any informality in bids and unless otherwise specified by the bidders, to accept any items on the bid. The State reserves the right to modify or cancel in whole or in part its Invitation for Bids.

If a bidder fails to state the time within which a submitted response will expire, it is understood and agreed that the MSDH shall have 60 days to accept.

5. ERROR IN BID

If a vendor is participating in a Live Auction, the vendor can notify MSDH in the event of an erroneous bid via the chat message feature. Erroneous bids, where the mistake is apparent to MSDH, may be deleted during the live auction.

6. SPECIAL DISCOUNT PERIOD

Time in connection with a special discount offered will be computed from date of delivery at destination or from the date correct invoices are received, if the latter date is later than the date of delivery. Cash discounts will not be considered in the award process.

7. AWARD

7.1 Contracts and purchases will be made or entered into with the lowest responsible bidder meeting specifications, except as otherwise specified in the bid specifications. Where more than one item is specified in the specifications, the State reserves the right to determine the low bidder either on the basis of the individual item(s) or on the basis of all items included in its Invitation for Bids, or as expressly provided in the State's Invitation for Bids.

7.2 Unless the bidder specified otherwise in the bid, the State may accept any item or group of items of any kind.

7.3 A written purchase order or contract award furnished to the successful bidder within the time of acceptance specified in the Invitation for Bid results in a binding contract without further action by either party. The contract shall consist solely of these General Conditions, the Instructions and Special Conditions, the successful bidder's bid, and the written purchase order or contract award. The contract shall not be assignable in whole or in part without the written consent of the State.

8. INSPECTION

Final inspection and acceptance or rejection may be made at delivery destination, but all materials and workmanship shall be subject to inspection and test at all times and places, and when practicable. During manufacture, the right is reserved to reject articles which contain defective material and workmanship. Rejected material shall be removed by and at the expense of the contractor promptly after notification or rejection. Final inspection and acceptance or rejection of the materials or supplies shall be made as promptly as practicable, but failure to inspect and accept or reject materials or supplies shall not impose liability on the State or any subdivision thereof for such materials or supplies as are not in accordance with the specification. In the event necessity requires the use of materials or supplies not conforming to the specification, payment therefore may be made at a proper reduction in price.

9. TAXES

The State is exempt from federal excise taxes and state and local sales or use taxes and bidders must quote prices which do not include such taxes. Exemption certificates will be furnished upon request. Contractors making improvements to, additions to or repair work on real property on behalf of the State are liable for any applicable sales or use tax on purchase of tangible personal property for use in connection with the contracts. Contractors are likewise liable for any applicable use tax on tangible personal property furnished to them by the State for use in connection with their contracts.

10. GIFTS, REBATE, GRATUITIES

10.1 Acceptance of gifts from bidders is prohibited. No officer or employee of the MSDH, nor any head of any state department, institution or agency, nor any employee of any state department, institution or agency charged with responsibility of initiating requisitions, shall accept or receive, directly or indirectly, from any person, firm or corporation to whom any contract for the purchase of materials, supplies, or equipment for the State of Mississippi may be awarded, by rebate, gifts, or otherwise, any money or anything of value whatsoever, or any promise, obligation or contract for future rewards or compensation.

10.2 Bidding by state employees is prohibited. It is unlawful for any state official or employee to bid on, or sell, or offer for sale, any merchandise equipment or material, or similar commodity to the State during the tenure of his or her office or employment, or for the period prescribed by law thereafter, or to have any interest in the selling of the same to the State.

11. BID INFORMATION

Bid information and documents may be examined pursuant to the Mississippi Public Records Act of 1983, MS Code 25-61-1 et seq.

12. PRECEDENCE

Bids shall be made and the contract shall be entered into in accordance with the General Conditions as hereinafter amended and modified. Should a conflict exist between the General Conditions and the Instructions and Special Conditions, the Instructions and Special Conditions shall take precedence.

13. COMPETITION

There are no federal or state laws that prohibit bidders from submitting a bid lower than a price or bid given to the U.S. Government. Bidders may bid lower than U.S. Government contract price without any liability as

the State is exempt from the provisions of the Robinson-Patman Act and other related laws. In addition, the U.S. Government has no provisions in any of its purchasing arrangements with bidders whereby a lower price to the State must automatically be given to the U.S. Government.

14. WAIVER

MSDH reserves the right to waive any General Condition, Special Condition, or minor specification deviation when considered to be in the best interest of the State.

15. CANCELLATION

Any contract or item award may be canceled with or without cause by the State with the giving of 30 days written notice of intent to cancel. Cause for the State to cancel may include, but is not limited to, cost exceeding current market prices for comparable purchases; request for increase in prices during the period of the contract; or failure to perform to contract conditions. The Contractor will be required to honor all purchase orders that were prepared and dated prior to the date of expiration or cancellation if received by the Contractor within a period of 30 days following the date of expiration or cancellation. Cancellation by the State does not relieve the Contractor of any liability arising out of a default or nonperformance. If a contract is canceled by the State due to a Contractor's request for increase in prices or failure to perform, that Contractor will be disqualified from bidding for a period of 24 months. The Contractor may cancel a contract for cause with the giving of 30 days written notice of intent to cancel. Cause for the Contractor to cancel may include, but is not limited to the item(s) being discontinued and/or unavailable from the manufacturer.

16. SUBSTITUTIONS DURING CONTRACT

During the term of a contract, if adequate documentation is provided that supports the claim that the contract item(s) are not available, items which meet the minimum specifications may be substituted if approved by MSDH and the substitutions are deemed to be in the best interest of the State.

17. APPLICATION

It is understood and agreed by the bidder that any contract entered into as a result of this Invitation for Bids is established for use by MSDH and all purchases made by MSDH for products included under the provisions of the contract shall be purchased from the bidder receiving the award unless exempt by special authorization from the state Office of Purchasing, Travel and Fleet Management.

Under the provisions of Section 31-7-7 Mississippi Code of 1972, Annotated, the prices offered herein shall be extended to the governing authorities. However, the governing authorities, by provisions of Section 31-7-12 Mississippi Code, may purchase products covered by state contracts from any source offering an identical product at a price that does not exceed the state contract price.

18. ADDENDA

Addenda modifying plans and/or specifications may be issued if time permits. No addendum will be issued within a period of two (2) working days prior to the time and date set for the bid opening. Should it become necessary to issue an addendum within the two (2) day period prior to the bid opening, the bid date will be reset to a date not less than five (5) working days after the date of the addendum, giving bidders ample time

to comply with the addendum. When replying to a bid request on which an addendum has been issued, and the specifications require acknowledgement, the bid shall indicate that provisions of the addendum have been noted and that the bid is being offered in compliance therewith. Failure to make this statement may result in the bid being rejected as not being in accordance with the revised specifications or plans.

19. NONRESPONSIVE BIDS

Nonresponsive bids will not be considered. A non-responsive bid is considered to be a bid that does not comply with the minimum provisions of the specification. Any bidder found to repeatedly offer alternated products that are not compliant with specifications in an attempt to obtain a contract on the basis of pricing only will be disqualified from bidding for a period of 24 months.

20. SPECIFICATION CLARIFICATION

It shall be incumbent upon all bidders to understand the provisions of the specifications and to obtain clarification prior to the time and date set for the live auction or bid opening. Such clarification will be answered only in response to a written request submitted in the specified amount of time set by the MSDH. TheMSDH reserves the right to specify a time frame in which clarification request shall be made.

21. Omitted

22. PRE-QUALIFICATION PROCESS

22.1 The purpose of the RFQF is to advertise the competitive procurement for solicitation of formal quotes from potential bidders to participate in the Reverse Auction. The MSDH will be responsible for defining product categories, adding bidders, and publishing all bid related documents to the procurement portal. Once the responses have been received and the Opening Date has been reached, the MSDH will review the submissions to qualify bidders and determine a starting price for reverse auction items.

22.2 The Invitation for Bids/RFQF shall be advertised in accordance with Section 3.106.05.4 of the Mississippi Procurement Manual. Minimum due date for responses to the RFQF will be on the 8th working day after the last day of advertisement.

22.3 Responses to the RFQF will be reviewed by the MSDH for responsiveness to specifications. Price quotes received will be evaluated in conjunction with other market research to determine the starting price for the Auction.

22.4 The MSDH will accept bidder responses in MAGIC who have qualified meeting RFx specifications. Bidders not meeting specifications will not be allowed to participate in the Auction.

22.5 Once qualified, the MSDH will notify the vendor of Qualification and the date of the Live Auction via email. After receiving the confirmation email, bidders should review/ensure technical requirements for MAGIC have been met or confirm participation in person.

22.6 It is requested that bids be submitted on the basis of statewide distribution. Contractors must maintain adequate distribution capabilities and adequate stock of all items to insure prompt delivery.

23. **FIRM BID PRICE**

Prices accepted from bidder submissions shall be firm for the term of the contract except that the State shall receive the benefit of any price decrease in excess of five (5) percent. The contractor must provide written price reduction information within ten (10) days of its effective date.

24. CONTRACT EXTENSION

24.1 Automatic contract renewals or extensions are not allowed. Contracts must be extended or renewed with the proper documents signed or approved by the MSDH.

24.2 The MSDH reserves the right to extend the term of a contract, when necessary, to continue a source of supply whenever new or replacement contracts are not completed prior to the expiration date. Such extensions are dependent upon the agreement of the Contractor and shall not exceed three (3) months.

25. SUSPENSION AND DEBARMENT

By submitting a bid, the bidder is certifying that neither the bidder nor any potential subcontractors are debarred or suspended or are otherwise excluded from or ineligible for participation in federal assistance programs.

26. ASSIGNMENT

The Contractor shall not assign or subcontract in whole or in part, its right or obligations under this agreement without prior written consent of the MSDH.

27. INDEMINIFICATION

Contractor shall indemnify, defend, save and hold harmless, protect, and exonerate the State of Mississippi, its Commissioners, Board Members, officers, employees, agents, and representatives from and against all claims, demands, liabilities, suits, actions, damages, losses, and costs of every kind and nature whatsoever, including, without limitation, court costs, investigative fees and expenses, and attorneys' fees, arising out of or caused by Contractor's and/or its partners, principals, agents, employees, and/or subcontractors in the performance of or failure to perform this Agreement. In the State's sole discretion, Contractor may be allowed to control the defense of any such claim, suit, etc. In the event Contractor defends said claim, suit, etc., Contractor shall use legal counsel acceptable to the State; Contractor shall be solely liable for all reasonable costs and/or expenses associated with such defense and the State shall be entitled to participate in said defense. Contractor shall not settle any claim, suit, etc., without the State's concurrence, which the State shall not unreasonably withhold.

28. LIVE AUCTION

28.1 Notification of Auction Start date and time will be sent via email to qualifying bidders. If a bidder is unwilling or unable to participate through MAGIC, a representative from the MSDH can enter the Vendor's bid(s) manually (i.e. Surrogate Bidding). If a bidder elects to participate via Surrogate Bidding, the bidder must be physically present at the public bidding location, with the means to submit written bids for each offer made and signed by an authorized agent of the Vendor. A Bid Form will be provided to the Vendor at the start of the auction. This form will not be returned to the bidder but will become a part of the Bid Documentation for Evaluation by the MSDH.

28.2 The Auction time may be extended at the discretion of the MSDH. Examples of reasons to extend an auction include, but are not limited to, technical difficulties experienced by the MSDH or bidder, the need to pause the Auction, or bids placed within the last few moments of bidding.

28.3 Communication with bidders participating electronically during the Auction may be done via the Live Chat Feature. The MSDH has the ability to send messages to particular bidders or broadcast to all bidders. Bidders can ONLY communicate with the MSDH, not other bidders.

28.4 Bidders may be removed from a Live Auction for improper conduct, including but not limited to profanity, threats, consistently entering erroneous or extremely low bids, or other disruptive behavior.

28.5 Bidders/Suppliers should be advised that no award will automatically result from a reverse auction, and that the MSDH will review the results of the auction and make a determination in a timely manner.

29. **FORCE MAJEURE**

If the MSDH is closed for any reason, including but not limited to: acts of God, strikes, lockouts, riots, acts of war, epidemics, governmental regulations superimposed after the fact, fire, earthquakes, floods, or other natural disasters (the "Force Majeure Events"), which closure prevents the opening of bids at the advertised date and time, all bids received shall be publicly opened and read aloud on the next business day that the agency shall be open and at the previously advertised time. The new date and time of the bid opening, as determined in accordance with this paragraph, shall not be advertised, and all bidders, upon submission of a bid proposal, shall be deemed to have knowledge of and shall have agreed to the provisions of this paragraph. Bids shall be received by the agency until the new date and time of the bid opening as set forth herein. The MSDH shall not be held responsible for the receipt of any bids for which the delivery was attempted and failed due to the closure of the MSDH as a result of a Force Majeure Event. Each bidder shall be required to ensure the delivery and receipt of its bid by the MSDH prior to the new date and time of the live auction or bid opening.

MSDH Request for Quotes-Formal (RFQF) Reverse Auction

RFx# 3140002081

INSTRUCTIONS AND SPECIAL CONDITIONS

The Mississippi State Department of Health plans to purchase the following and invites your quote/participation:

Hemoglobin Analyzers and Microcuvettes for use in clinics/locations Statewide

The Purpose of this RFQF is to advertise this competitive procurement for solicitation of formal quotes from potential bidders to participate in a Reverse Auction.

The initial response to the RFQF shall include a proposed product, including specifications and/or sample, for the MSDH to evaluate and determine responsiveness to requirements/specifications. Once a supplier's/bidder's product is determined to be responsive, the supplier/bidder may participate in the reverse auction.

Responding suppliers/bidders must provide a quote with the initial response. Quotes are utilized by the purchasing agent to determine market pricing and set the auction parameters (e.g., Start Price).

Valid quotes will be accepted until 3:00 PM, CST, February 19, 2021

Qualified bidders will be notified approx. 7 working days prior to the auction via email if selected to participate. Once notification has been received, bidders should logon to MAGIC to validate technical requirements prior to the Live Auction.

The anticipated time for this reverse auction, for this procurement, is scheduled to be held on Wednesday, March 10, 2021, beginning at 2:00 PM CST and end at 2:30 PM CST. All bids must be entered into the eProcurement system during the allotted timeframe to be considered however, the MSDH reserves the right to extend the auction date if necessary to complete prequalifications. In addition, no vendor/supplier may be prohibited from participating in the reverse auction in person by paper through surrogate bidding.

Suppliers should be advised that no award will automatically result from a reverse auction, and that the MSDH will review the results of the auction and make a determination in a timely manner.

Vendors/bidders must be registered in MAGIC in order to receive a User ID and Password to log in. Vendors who are new to MAGIC may visit the Vendor information page on State of MS, Department of Finance and Administration's web site, or register online, Vendor Registration.

To Log into MAGIC, open the following URL: https://portal.magic.ms.gov/irj/portal. Enter User ID and Password. The password is case sensitive.

Vendors/bidders are responsible for ensuring Technical Requirements are met for participating in the reverse auction, etc. Technical Requirements are listed below:

Technical Requirements

Bidders are responsible for ensuring technical requirements are met.

Acceptable Internet Browser(s)

- Microsoft Internet Explorer (IE) version 11
- Microsoft Edge
- Google Chrome versions 49 and above

Unsupported Internet Browser(s)

- Microsoft Internet Explorer (IE) version 10 or below
- Safari
- Firefox

Note: Pop-up blocker must be turned off.

MISSISSIPPI STATE DEPARTMENT OF HEALTH

REQUEST FOR QUOTES-FORMAL (RFQF)
REVERSE AUCTION
RFx # 3140002081

The Mississippi State Department of Health (MSDH) will purchase Hemoglobin Analyzers and Microcuvettes for use in clinics/locations Statewide and invites your participation in accordance with the terms and conditions of this RFQF Reverse Auction. Once award of the bid has been made, the terms and conditions as set forth in this RFQF Reverse Auction shall become a contract binding on the successful bidder. Any documents submitted to satisfy a requirement of this request and any assurances made by the successful bidder in satisfaction of this request shall become a part of the agreement between the Mississippi State Department of Health and the successful bidder. The Mississippi State Department of Health shall have the right to rely upon the documents and assurances submitted by the successful bidder.

This RFQF Reverse Auction is for an estimated initial quantity/purchase of (230 Each) Hemoglobin Analyzers and related supplies (Microcuvettes). Estimated quantity of Microcuvettes, for a five year period, is 4500 Boxes of 200. Orders for Microcuvettes will be placed approx. (3) times per year for approx. 300 Boxes.

Pricing for Microcuvettes shall be guaranteed for a five-year period.

Pricing is also requested, and shall be guaranteed for a five-year period, for any New/Additional Analyzers purchased after the initial order.

This RFQF Reverse Auction/Award will be for a five-year period.

Pricing to include all shipping charges.

E-Verify Compliance - Contractor/Seller represent and warrants that it will ensure its compliance with the Mississippi Employment Protection Act (Senate Bill 2988 from the 2008 Regular Legislative Session) and will register and participate in the status verification system for all newly hired employees. The term "employee" as used herein means any person that is hired to perform work within the State of Mississippi. As used herein "status verification system" means the Illegal Immigration Reform and Immigration Responsibility Act of 1996 that is operated by the United States Department of Homeland Security, also known as the E-Verify Program, or any other successor electronic verification system replacing the E-Verify Program. Contractor/Seller agrees to maintain records of such compliance and , upon request of the State, to provide a copy of each such verification to the State. Contractor/Seller further represents and warrants that any person assigned to perform services hereunder meets the employment eligibility requirements of all immigration laws of the State of Mississippi. Contractor/Seller understands and agrees that any breach of these warranties may subject Contract/Seller to the following: (a) termination of this Agreement and Ineligibility for any state or public contract in Mississippi for up to three (3) years, with notice of such (b) the loss of any license, permit, certification or other document granted to Contractor/Seller by an agency, department or governmental entity for the right to do business in Mississippi for up to one (1) year, or (c) both. In the event of such termination/cancellation, Contractor/Seller would also be liable for any additional costs incurred by the State due to contract cancellation or loss of license or permit.

E-Payments – Payments by the Mississippi State Department of Health shall be made and remittance information provided electronically as directed by the State of Mississippi. These payments shall be deposited into the bank account of the Contractor's choice. The state may, at its sole discretion, require the Contractor to submit invoices and supporting documentation electronically at any time during the terms of this agreement. Contractor understands and agrees that the State is exempt from the payment of taxes. All payments shall be in United States currency.

Applicable Law – This purchase(s) shall be governed by and construed in accordance with the laws of the State of Mississippi, excluding its conflicts of law provisions, and any litigation with respect thereto shall be brought in the courts of the State of Mississippi. The vendor shall comply with applicable federal, state and local laws and regulations.

Payment Terms – MS Code Section 31-7-305(3) allows a state entity to pay invoices within 45 days without penalty.

Bid terms are welcome, however, they will not be used as criteria for awarding the bid.

Items will be purchased from the RFQF Reverse Auction by the Mississippi State Department of Health in accordance with the terms and conditions set out in this request and the attachments hereto.

State and Federal law requires that the Mississippi State Department of Health not be liable should federal or state funds not be available to make the purchases. Should federal or state funds be reduced or eliminated, the State of Mississippi, the Mississippi State Department of Health, its agents, servants and employees would have no obligation to purchase any quantity of

goods or services covered by this request for bid. The bidder agrees to hold the above enumerated entities and individuals harmless in that event.

The bidder/prospective vendor must further give assurances in writing that it can provide and deliver the items as ordered on a schedule agreeable to the Mississippi State Department of Health. The contractor shall not assign, sell or subcontract in whole or in part, its rights or obligations under this agreement without prior written consent of the MSDH. Any attempt assignment or sale of the contract without said consent shall be void and of no-effect.

The MSDH reserves the right to refuse any items not meeting the specifications of this bid.

Prospective bidders are to contact Cynthia Brasher, Purchasing Director in writing if there are any questions regarding this RFQF Reverse Auction, either by email cynthia.brasher@msdh.ms.gov or by writing to P. O. Box 1700, Jackson, MS 39215-1700. Questions are to be received no later than the close of business on February 12, 2021. MSDH answers/responses will be posted on the State of MS Transparency website and on the MSDH website within 1-2 days.

Sealed quotes/responses will be accepted/received until 3:00 PM, CST, Friday, February 12, 2021, either hand delivered or by mail to **Mississippi State Department of Health, Purchasing Department, Room 137A, The Underwood Building, 570 E. Woodrow Wilson, Jackson, Mississippi 39216 or Post Office Box 1700, Jackson, MS 39215-1700**. The quotes/responses must be received before and be dated and time stamped by the submission deadline. All bids must be properly stamped. No quotes/responses will be accepted after the established submission deadline.

Currently, due to the continuing Covid-19 pandemic, the Mississippi State Department of Health remains closed to the public.

Prior to the quote/response due date and time, quotes/responses may be Hand Delivered to the agency between the hours of 8:00 a.m. and 5:00 p.m., CST. Entry may be obtained at the Visitor's entrance to the Mississippi State Department of Health, Osborne Building, 570 E Woodrow Wilson, Jackson, MS 39216. A receptionist will be on duty to receive the bid responses and forward to the addressee on the envelope/package.

No facsimile (FAX) quotes/responses will be accepted.

Quote/response BID FORM must be signed by a person with authority to bind the bidder, and must accompany your submission. Failure to comply with this provision, any other provision of this RFQF Reverse Auction, or any provision of state or federal law or regulation regarding the submission of bids may cause the bid to be rejected.

In addition, it is requested that bidders also submit a quote/response on-line in the State of Mississippi electronic procurement system, MAGIC, however, it is not mandatory. In order to submit quotes/responses bidders must be registered as a vendor in MAGIC system and have an I.D. number and password assigned at the time of registration. Technical assistance may be found at http://www.dfa.ms.gov/dfa-offices/mmrs/mississippi-suppliers-vendors/. If a bidder submits both a paper quote/response and an on-line quote/response, the paper quote/response will take precedence if there is a discrepancy between the two.

The Mississippi State Department of Health reserves the right to waive minor informalities, which are matters of form rather than substance, or insignificant mistakes or to allow the bidder to correct them if other bidders are not prejudiced.

The bid will be awarded to the lowest and best responder/participant of this RFQF Reverse Auction as determined by the agency. The awardee will perform the terms and conditions of the bid and any contract awarded hereunder. No assignment of subcontracting of the award or any contract awarded there under shall be allowed without prior written approval of the State Health Officer.

PLEASE MARK YOUR ENVELOPES EXTERNALLY:

RFx #3140002081 Submission Deadline: 3:00 PM, CST, February 19, 2021

MSDH-RFx # 3140002081 SPECIFICATION SHEET

Hemoglobin Analyzer and Microcuvettes

A.
A.1 Prospective device must be CLIA Waived

B. General Specifications-Analyzer
B.1 All devices purchased must be new and model currently in production. Refurbished or demonstrator units are not acceptable. Instrument name and model must be listed.
B.2 The vendor must guarantee manufacturer replacement units for defective units for first 5 years.
B.3 All units must include a physical set of operating manual and brochures.
B.4 All units must include training and education program to all sites as well as refresher trainings at no cost.
B. 5 Testing sample size must be 10µl or less
B. 6 Measuring range must be Hgb: 0-25.6 g/dL
B.7 Measuring time must be 30 seconds or less
B. 8 Unit must provide memory for no less than 100 test results.
B. 9 Unit must include AC adapters and DC battery options
B. 10 Unit must have internal self check no less than each time unit is powered on.

C. General Specifications-Microcuvettes
C.1 Expiration date at time of shipment must be greater than 18 months.
C.2 Expiration date after opening must be greater than or equal to 90 days.
C. 3 Guaranteed pricing of microcuvette supplies for 5 years.

The specifications listed are the minimum required for this RFQ-F Reverse Auction. They are not intended to limit competition nor specify any particular bidder/respondent, but to ensure that the MSDH receives a quality product meeting the needs of the agency.

Response/Quote

BID FORM

RFx 3140002081

Hemoglobin Analyzer - Name and Model # _____

Estimated Quantity – Initial Purchase: 230 Each $_____/EA

Guaranteed Pricing for any NEW/Additional units purchased during a five year period: $_____/EA

Microcuvettes - Name and Product # _____

Estimated Quantity – Five Year Period: 4500 Boxes/200 PER Box $_____/BOX

(Orders to be placed approx. (3) times per year for approx. 300 Boxes)

Name of Company_____

Quoted By_____

Signature_____

Email_____

Telephone_____

By signing this Bid Form, the company representative certifies that he/she has authority to bind the company and has thoroughly read and understands this RFQF Reverse Auction and the attachments herein and that the company meets all requirements/specifications and agrees to all provisions of this solicitation and any issued addenda.

MSDH Anticipated Initial Shipping List for Analyzers: RFx 3140002081

	Nutritionist	Quantity	Address				
Northern Region 1	"	25	Yalobusha County Health Dept.	645 S. Main Street	Water Valley	MS	38965
	"	22	Northern Region I Office	532 S. Church Street	Tupelo	MS	38802
	"	21	Northern Region I Annex	2600 Browning Rd.	Greenwood	MS	38930
Central Region 2	"	20	Starkville Food Center	1203 Louisville St	Starkville	MS	39759
	"	19	Lauderdale County Health Dept.	5224 Valley Street	Meridian	MS	39304
	"	22	Central Region 2 Office	4800 McWillie Circle	Jackson	MS	39206
Southern Region 3	"	23	Adams County Health Dept.	415 Hwy 61 N	Natchez	MS	39120
	"	14	Southern Region - Hattiesburg	208 W. Pine Street, Suite 100	Hattiesburg	MS	39401
	"	14	Southern Region 3 Office	1141 Bayview Ave., Suite 102	Biloxi	MS	39530
WIC Shipping & Receiving	Percy Catchings	50	WIC Central Warehouse	249 West Mitchell Street	Jackson	MS	39213
Total		230					

EXHIBIT C

MISSISSIPPI STATE DEPARTMENT OF HEALTH

TRANSMITTED BY E-MAIL AND U.S. MAIL

June 22, 2021

Mark Bellwood
Director of Sales, Specialty Markets
HemoCue America
250 S. Kraemer Blvd.
Brea, CA 928821
mark@hemocue.com

Re: Response to Protest regarding Request for Quotes- Formal (RFQF) Reverse Auction RFx 3140002081 for Hemoglobin Analyzers and Microcuvettes

Dear Mr. Bellwood:

The Mississippi State Department of Health (MSDH) is in receipt of your protest dated April 26, 2021. After consideration thereof as well as the relevant facts and circumstances, MSDH denies your protest and would show the following in support thereof.

STATEMENT OF RELEVANT FACTS

On October 1, 2020, MSDH issued RFx 3140002081 Request for Quotes-Formal (RFQF) Reverse Auction seeking bids for the purchase of Hemoglobin Analyzers and Microcuvettes. MSDH included a list of specifications for the analyzer and microcuvettes. *See MSDH-RFx # 3140002081 Specification Sheet Attached hereto as Exhibit A.* Questions were to be submitted by February 12, 2021, and answers were provided to the offerors on February 24, 2021. After Amendments and weather delays, the bids were submitted by March 19, 2021.

MSDH received bids from two vendors. EKF Diagnostics proposed the Hemo Control Analyzer Model #3040-0010-0218 and HemoCue submitted two hemoglobin analyzers, the HCAM Hb 201+ and Hb 301.

Each submission was reviewed for responsiveness. To ensure that the models submitted met MSDH needs, on March 31, 2021, Kevin Pearson emailed each vendor a copy of the list of specifications and requested that the vendors, "provide a response for each specification as listed on the attached specification sheet and return by email for further review." Each vendor was asked to respond by April 2, 2021. *See emails to EKF Diagnostics and HemoCue attached here to as composite Exhibit B.*

Based on the response provided by EKF, MSDH determined that the analyzer could meet the specifications of B.7 if the test were performed correctly and deemed the analyzer responsive to the request. The vendors were notified that the reverse auction would take place on April 20, 2021, at 9:00 A.M. CST.

On April 19, 2021, on the eve on the reverse auction, an email from Mark Bellwood, was sent to Kevin Pearson asking how to "challenge" the disqualification of the 201. Mr. Pearson was not available on April 19, however, he responded to the request for protest regulations on April 20, 2021, prior to the reverse auction.

MSDH proceeded with the reverse auction as scheduled. HemoCue was informed via email correspondence that it did not win the reverse auction.

HemoCue filed a protest on April 26, 2021, with a random list of EKF products and their functionality arguing that the EKF products did not meet specifications. The protest requests that MSDH vacate its award to EKF because HemoCue alleges that the Hb 301 is the only analyzer that can meet MSDH specifications and that the disqualification of the 201+ was erroneous and prejudicial. HemoCue further requests that MSDH directs the contract award in its favor as the only offeror capable of meeting MSDH specifications.

HemoCue's arguments are incorrect, and it is in the best interest of the State to award to the vendor which proved to be both responsive and the winner of the reverse auction.

DISCUSSION

The decision regarding responsiveness of each product submitted was based on certifications and clarifications provided by each vendor. HemoCue cannot challenge the results of its own statements.

Each vendor completed and submitted a Bid Form signed by the company representative. A statement at the bottom form clearly states that the by signing the form, the company representative certifies that, "the company meets all requirements/specifications and agrees to all provisions of this solicitation and any issued addenda." Mr. Pearson specifically asked each vendor to provide information to clarify their responses regarding the required specifications.

On March 31, 2021, HemoCue provided a written response as requested for the 201+ and the 301 products and EKF provided its response on April 1, 2021.

The responses to each specification objected to by HemoCue in this protest are as follows:

EKF Hemoglobin Analyzer and Microcuvettes

No.	Specification	EKF Response
B.5	Testing sample size must be 10ul or less.	Hemo Control Cuvette sample size is 8uL
B.6	Measuring range must be Hgb: 0-25.6 g/dL.	Hemo Control measuring range is 0-25.6 g/L.
B.7	Measuring time must be 30 seconds or less.	The Hemo Control Analyzer measures hemoglobin and provides a calculated hematocrit. ***The measuring time for one sample can be as quick as 25 seconds, if performed correctly, or up to 60 seconds if performed incorrectly*** or if the hemoglobin concentration is high. (Emphasis added)

HemoCue Hb 301

No.	Specification	HemoCue Response
B.5	Testing sample size must be 10ul or less.	Yes
B.6	Measuring range must be Hgb: 0-25.6 g/dL.	Yes
B.7	Measuring time must be 30 seconds or less.	Yes

HemoCue Hb 201+

No.	Specification	HemoCue Response
B.5	Testing sample size must be 10ul or less.	Yes
B.6	Measuring range must be Hgb: 0-25.6 g/dL.	Yes
B.7	Measuring time must be 30 seconds or less.	***No.*** (Emphasis Added)

(See also Email responses from HemoCue and attached hereto as EFX Exhibits C and D.)

Upon further review of the bids and the foregoing responses, MSDH disqualified HemoCue's 201+ as nonresponsive. The 301 was deemed responsive and allowed to proceed to the reverse auction. HemoCue was informed of this decision on April 8, 2021. HemoCue thanked MSDH for the notification and did not protest the disqualification. (See Exhibit E.)

MSDH addressed concerns raised by HemoCue in its protest prior to making a final determination regarding responsiveness. Specifically, MSDH proactively asked for further clarification regarding the specifications. Based on the vendors' responses, MSDH determined that HemoCue's 201+ was the only product that did not meet all specifications as required and the 201+ was disqualified. EKF provided an explanation of its analyzer's function in its response B.7. After consideration of EKF's statement, MSDH determined the EKF product met MSDH specifications. Nothing prohibited HemoCue from providing an explanation of its responses. It chose not to provide any additional information for consideration at that time and is prohibited from doing so now.

MSDH proactively requested additional information from each vendor. Each vendor had an opportunity to respond and provide any additional information. MSDH accepts both HemoCue and EKF's responses as accurate and truthful. The 201+ was disqualified based on the vendor's response, and therefore, was neither erroneous nor prejudicial. Further, if HemoCue truly believed that the 301 was the only product that met MSDH specifications, it should have filed its protest upon notification that the 201+ had been disqualified, or at least notified MSDH of its belief that the 301 was a sole source.

Based on the foregoing information, MSDH sustains its findings that all products met specifications except the Hb 201+ and affirms the results of the reverse auction.

DECISION

For these reasons, the protest submitted by HemoCue is DENIED.

In accordance with OPSCR Rule 7-112.04 *Right to Appeal*, you may appeal this decision to the Public Procurement Review Board within seven (7) calendar days of receipt of this Protest Decision. Any appeal of this decision must follow OPSCR Rule 7-112 *Protest of Solicitations and Awards* found at https://www.dfa.ms.gov/media/9413/pprb-opscr-rules-and-regulations-efficetive-01182020.pdf.

Sincerely,

Thomas Dobbs, MD, MPH
State Health Office
Mississippi State Department of Health

cc: Pat Breheny, EKF Diagnostics, PatBreheny@ekfdiagnostics.com
Brittney Thompson, Director, OPSCR

MSDH-RFx # 3140002081 SPECIFICATION SHEET

Hemoglobin Analyzer and Microcuvettes

A.

A.1 Prospective device must be CLIA Waived.

B. General Specifications-Analyzer

B.1 All devices purchased must be new and model currently in production. Refurbished or demonstrator units are not acceptable. Instrument name and model must be listed.
B.2 The vendor must guarantee manufacturer replacement units for defective units for first 5 years.
B.3 All units must include a physical set of operating manual and brochures.
B.4 All units must include training and education program to all sites as well as refresher trainings at no cost.
B. 5 Testing sample size must be 10µl or less.
B. 6 Measuring range must be Hgb: 0-25.6 g/dL.
B.7 Measuring time must be 30 seconds or less.
B. 8 Unit must provide memory for no less than 100 test results.
B. 9 Unit must include AC adapters and DC battery options.
B. 10 Unit must have internal self check no less than each time unit is powered on.
B. 11 Units will be delivered to WIC Central Office, Ridgeland, MS with no shipping cost.

C. General Specifications-Microcuvettes

C.1 Expiration date at time of shipment must be greater than 18 months.
C.2 Expiration date after opening must be greater than or equal to 90 days.
C. 3 Guaranteed pricing of microcuvette supplies for 5 years.

The specifications listed are the minimum required for this RFQ-F Reverse Auction. They are not intended to limit competition nor specify any particular bidder/respondent, but to ensure that the MSDH receives a quality product meeting the needs of the agency.

Pearson, Kevin

From: Pearson, Kevin
Sent: Tuesday, March 30, 2021 8:06 AM
To: patbreheny@ekfdiagnostics.com
Cc: Nelson, Johnny
Subject: Question
Attachments: RFx 3140002081 Specification Sheet.docx

Thank you for your submitted Response/Quote to MSDH's RFx 3140002081 for Hemoglobin items.

In reviewing your response, and all info submitted with the response, we have been unable to assure compliance with al specifications as listed in the RFx packet.

Please provide a response for each specification as listed on the attached specification sheet, and return by email for further review. Please return the requested information by Friday, April 2, 2021.

Thank you,

Kevin Pearson

ATTACHMENT B
MSDH

Pearson, Kevin

From: Pearson, Kevin
Sent: Tuesday, March 30, 2021 8:10 AM
To: customerservice@hemocue.com
Cc: Nelson, Johnny
Subject: Questions
Attachments: RFx 3140002081 Specification Sheet.docx

Thank you for your submitted Response/Quote to MSDH's RFx 3140002081 for Hemoglobin items.

In reviewing your response, and all info submitted with the response, we have been unable to assure compliance with all specifications as listed in the RFx packet.

Please provide a response for each specification, as listed on the attached specification sheet, and return by email for further review. Please return the requested information by Friday, April 2, 2021.

Thank You

Kevin Pearson

Pearson, Kevin

From:	Spetz, Mary L <Mary.L.Spetz@hemocue.com>
Sent:	Wednesday, March 31, 2021 1:08 PM
To:	Pearson, Kevin; Nelson, Johnny
Cc:	Bellwood, Mark C; Dayton, Sara X
Subject:	RFx 3140002081
Attachments:	RFx 3140002081 Specification Sheet (Hb301).docx; RFx 3140002081 Specification Sheet (Hb201+).docx

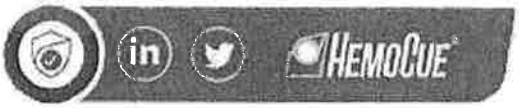
Hi Kevin-

In response to your request of yesterday, please find a specification sheet for each unit submitted in MSDH-Rfx#314000208. Please let us know if this meets your expectations, as all supporting documentation was submitted previously. If this response is not in line with what you are looking for, please make us aware and we will submit anything additional that you are in need of by Friday April 2.

Please Note: Please reply to my email address, rather than the customerservice@hemocue.com , as that is a generic email which is not monitored as closely.

Warm Regards,

Mary Spetz
Key Account Representative
585-353-3648
Mary.l.spetz@hemocue.com



ATTACHMENT C
MSDH

MSDH-RFx # 3140002081 SPECIFICATION SHEET

Hemoglobin Analyzer and Microcuvettes

Hb 301

A.
A.1 Prospective device must be CLIA Waived. Yes

B. General Specifications-Analyzer
B.1 All devices purchased must be new and model currently in production. Refurbished or demonstrator units are not acceptable. Instrument name and model must be listed. Yes
B.2 The vendor must guarantee manufacturer replacement units for defective units for first 5 years. Yes
B.3 All units must include a physical set of operating manual and brochures. Yes
B.4 All units must include training and education program to all sites as well as refresher trainings at no cost. Yes
B. 5 Testing sample size must be 10µl or less. Yes
B. 6 Measuring range must be Hgb: 0-25.6 g/dL. Yes
B.7 Measuring time must be 30 seconds or less. Yes
B. 8 Unit must provide memory for no less than 100 test results. Yes, with included Basic Connect package.
B. 9 Unit must include AC adapters and DC battery options. Yes
B. 10 Unit must have internal self check no less than each time unit is powered on. Yes
B. 11 Units will be delivered to WIC Central Office, Ridgeland, MS with no shipping cost. Yes

C. General Specifications-Microcuvettes
C.1 Expiration date at time of shipment must be greater than 18 months. Yes
C.2 Expiration date after opening must be greater than or equal to 90 days. Yes
C. 3 Guaranteed pricing of microcuvette supplies for 5 years. Yes

The specifications listed are the minimum required for this RFQ-F Reverse Auction. They are not intended to limit competition nor specify any particular bidder/respondent, but to ensure that the MSDH receives a quality product meeting the needs of the agency.

MSDH-RFx # 3140002081 SPECIFICATION SHEET

Hemoglobin Analyzer and Microcuvettes

Hb 201+

A.
A.1 Prospective device must be CLIA Waived. Yes

B. General Specifications-Analyzer
B.1 All devices purchased must be new and model currently in production. Refurbished or demonstrator units are not acceptable. Instrument name and model must be listed. Yes
B.2 The vendor must guarantee manufacturer replacement units for defective units for first 5 years. Yes
B.3 All units must include a physical set of operating manual and brochures. Yes
B.4 All units must include training and education program to all sites as well as refresher trainings at no cost. Yes
B. 5 Testing sample size must be 10µl or less. Yes
B. 6 Measuring range must be Hgb: 0-25.6 g/dL. Yes
B.7 Measuring time must be 30 seconds or less. No
B. 8 Unit must provide memory for no less than 100 test results. Yes, with included Basic Connect package.
B. 9 Unit must include AC adapters and DC battery options. Yes
B. 10 Unit must have internal self check no less than each time unit is powered on. Yes
B. 11 Units will be delivered to WIC Central Office, Ridgeland, MS with no shipping cost. Yes

C. General Specifications-Microcuvettes
C.1 Expiration date at time of shipment must be greater than 18 months. Yes
C.2 Expiration date after opening must be greater than or equal to 90 days. Yes
C. 3 Guaranteed pricing of microcuvette supplies for 5 years. Yes

The specifications listed are the minimum required for this RFQ-F Reverse Auction. They are not intended to limit competition nor specify any particular bidder/respondent, but to ensure that the MSDH receives a quality product meeting the needs of the agency.

Pearson, Kevin

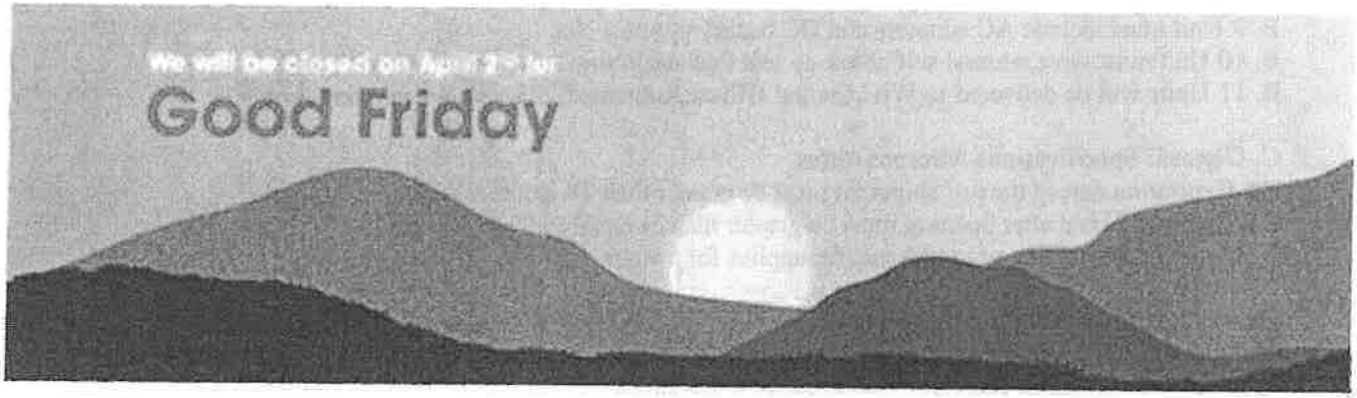
From:	Pat Breheny <PatBreheny@ekfdiagnostics.com>
Sent:	Thursday, April 1, 2021 5:03 PM
To:	Pearson, Kevin
Subject:	RE: Question
Attachments:	MS RFx 3140002081 Specification Sheet Answered questions 3.31.21.docx

Kevin,
Please see our response to the documented attached for MSDH's RFx 3140002081 for Hemoglobin items.
Please let me know if you have any further questions.

Thank you,
Pat Breheny

Pat Breheny
Public Health Sales Specialist

Cell: 210-601-5252
Email: patbreheny@ekfdiagnostics.com



EKF DIAGNOSTICS STANBIO® STI

1261 North Main Street • Boerne, TX, USA 78006
Tel: 830.249.0772 • Fax: 830.249.0851 • www.stanbio.com

From: Pearson, Kevin [mailto:Kevin.Pearson@msdh.ms.gov]
Sent: Tuesday, March 30, 2021 8:06 AM
To: Pat Breheny
Cc: Nelson, Johnny
Subject: Question

ATTACHMENT D
MSDH

Thank you for your submitted Response/Quote to MSDH's RFx 3140002081 for Hemoglobin items.

In reviewing your response, and all info submitted with the response, we have been unable to assure compliance with al specifications as listed in the RFx packet.

Please provide a response for each specification as listed on the attached specification sheet, and return by email for further review. Please return the requested information by Friday, April 2, 2021.

Thank you,

Kevin Pearson

MSDH-RFx # 3140002081 SPECIFICATION SHEET

Hemoglobin Analyzer and Microcuvettes

A.
A.1 Prospective device must be CLIA Waived
The Hemo Control Analyzer is CLIA Waived.

B. General Specifications-Analyzer
B.1 All devices purchased must be new and model currently in production. Refurbished or demonstrator units are not acceptable. Instrument name and model must be listed.
The Hemo Control Analyzer/s to be provided will be new and of current model year. Hemo Control Analyzer - Model #3040-0010-0218
B.2 The vendor must guarantee manufacturer replacement units for defective units for first 5 years. Hemo Control Analyzer will be under warranty for 5 years for replacement from award of Bid.
B.3 All units must include a physical set of operating manual and brochures. Each Hemo Control Analyzer will include a hard copy of user manual and support literature.
B.4 All units must include training and education program to all sites as well as refresher trainings at no cost. Hemo Control training, education and refreshers to be provided at no cost.
B. 5 Testing sample size must be 10µl or less. Hemo Control Cuvette sample size is 8µL.
B. 6 Measuring range must be Hgb: 0-25.6 g/dL. Hemo Control measuring range is 0-25.6 g/dL.
B.7 Measuring time must be 30 seconds or less. The Hemo Control Analyzer measures hemoglobin and provides a calculated hematocrit. The measuring time for one sample can be as quick as 25 seconds, if performed correctly, or up to 60 seconds if performed incorrectly or if the hemoglobin concentration is high.
B. 8 Unit must provide memory for no less than 100 test results. Hemo Control Analyzer stores 4000 test results in memory.
B. 9 Unit must include AC adapters and DC battery options. Each Hemo Control Analyzer includes an AC adapter as well as a built in rechargeable battery good for up to 100 hours of operation when new and fully charged.
B. 10 Unit must have internal self-check no less than each time unit is powered on. Hemo Control Analyzer performs a self-test automatically at regular intervals while the unit is powered on.
B. 11 Units will be delivered to WIC Central Office, Ridgeland, MS with no shipping cost. Hemo Control Analyzers will be delivered to the WIC Central Office in Ridgeland, MS with no charge freight.
C. General Specifications-Microcuvettes
C.1 Expiration date at time of shipment must be greater than 18 months. The Hemo Control Microcuvettes will have 18 months or better dating at time of shipment.
C.2 Expiration date after opening must be greater than or equal to 90 days. Hemo Control Analyzer Microcuvettes expire 90 days after opening canister when following proper storage and handling procedure.

C. 3 Guaranteed pricing of microcuvette supplies for 5 years. The pricing submitted for the Hemo Control Microcuvette supplies will be guaranteed for 5 years or term of the Bid, including extensions.

The specifications listed are the minimum required for this RFQ-F Reverse Auction. They are not intended to limit competition nor specify any particular bidder/respondent, but to ensure that the MSDH receives a quality product meeting the needs of the agency.

Pearson, Kevin

From: Bellwood, Mark C <Mark.C.Bellwood@hemocue.com>
Sent: Monday, April 19, 2021 4:41 PM
To: Pearson, Kevin; Brasher, Cynthia; Nelson, Johnny
Cc: Spetz, Mary L; Dayton, Sara X
Subject: RE: Reverse Auction

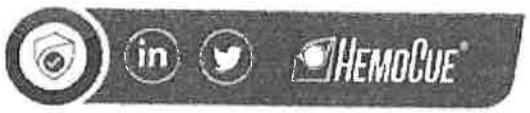
Hello,
We look forward to participating in the reverse auction tomorrow with our Hb301.
Since the Hb201+ was denied participation, what is the process to challenge the denial.
We have looked but cannot understand a clear process for protest in Mississippi.
Thank you,
M

Mark Bellwood
HemoCue America | Director, Specialty Markets | 250 S. Kraemer Blvd. - Mailstop: B1.SW.11 | Brea California 92821 | phone +1 714 646 2273 | fax +1 714 441 8160 | mobile +1 214 412 8900 | Mark.C.Bellwood@hemocue.com
www.hemocue.us

From: Bellwood, Mark C
Sent: Thursday, April 8, 2021 11:49 AM
To: Pearson, Kevin <Kevin.Pearson@msdh.ms.gov>
Cc: Spetz, Mary L <Mary.L.Spetz@hemocue.com>
Subject: RE: Reverse Auction

Hi Kevin,
Thanks for this notification on the Hb 301 being accepted. We will block 4/20 for participation and await the time once it is set.
Can you tell me which analyzers from other vendors were accepted to participate in the reverse auction?
Thanks,
M

Mark Bellwood
HemoCue America | Director, Specialty Markets | 250 S. Kraemer Blvd. - Mailstop: B1.SW.11 | Brea California 92821 | phone +1 714 646 2273 | fax +1 714 441 8160 | mobile +1 214 412 8900 | Mark.C.Bellwood@hemocue.com
www.hemocue.us



ATTACHMENT E
MSDH

From:
Sent: Thursday, April 8, 2021 12:31 PM
To: Spetz, Mary L
Subject: RE: Reverse Auction

You will get something from Cynthia but 4/20 is the date not sure of time yet.

From: Spetz, Mary L <Mary.L.Spetz@hemocue.com>
Sent: Thursday, April 8, 2021 11:30 AM
To: Pearson, Kevin <Kevin.Pearson@msdh.ms.gov>
Cc: Brasher, Cynthia <Cynthia.Brasher@msdh.ms.gov>; Bellwood, Mark C <Mark.C.Bellwood@hemocue.com>; Dayton, Sara X <sara.x.dayton@hemocue.com>
Subject: RE: Reverse Auction

Thank You Kevin!

When is the reverse auction going to take place?

Warm Regards,

Mary Spetz
Key Account Representative
585-353-3648
Mary.L.spetz@hemocue.com

From: Pearson, Kevin <Kevin.Pearson@msdh.ms.gov>
Sent: Thursday, April 8, 2021 11:58 AM
To: Spetz, Mary L <Mary.L.Spetz@hemocue.com>
Cc: Brasher, Cynthia <Cynthia.Brasher@msdh.ms.gov>
Subject: Reverse Auction

Your submission of 3140002081 for the HB 201 was not accepted for the reverse auction. The unit did not meet the specifications.

Your 301 will be included.

EXHIBIT D

From: Brasher, Cynthia <Cynthia.Brasher@msdh.ms.gov>
Sent: Thursday, April 8, 2021 4:29:56 PM
To: Spetz, Mary L <Mary.L.Spetz@hemocue.com>
Subject: RE:

No, I'm not allowed to give that info.

Cynthia

From: Spetz, Mary L <Mary.L.Spetz@hemocue.com>
Sent: Thursday, April 8, 2021 3:02 PM
To: Brasher, Cynthia <Cynthia.Brasher@msdh.ms.gov>
Subject:

Hi Cynthia-

Thank You for all the information. Can you tell me what other vendor/instrument we are up against?

Sent from Mail for Windows 10

Please be advised that this email may contain confidential information. If you are not the intended recipient, please notify us by email by replying to the sender and delete this message. The sender disclaims that the content of this email constitutes an offer to enter into, or the acceptance of, any agreement; provided that the foregoing does not invalidate the binding effect of any digital or other electronic reproduction of a manual signature that is included in any attachment.

EXHIBIT E

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CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION WHICH MAY NOT BE RELEASED WITHOUT THE PRIOR WRITTEN PERMISSION OF HEMOCUE AMERICA

26 April, 2021

Dr. Thomas Dobbs, State Health Officer
&
Chief Procurement Officer
Mississippi State Department of Health
Purchasing Department
Room 137A
The Underwood Building
570 E. Woodrow Wilson
Jackson, MS 39216

Ref: **REQUEST FOR QUOTES-FORMAL (RFQF) REVERSE AUCTION**
RFx #3140002081 for Hemoglobin Analyzers and Microcuvettes

Dear Dr. Dobbs and Chief Procurement Officer,

This letter serves as HemoCue America, a division of Radiometer America Inc's ("HCAM") formal protest of the award made by the Mississippi State Department of Health ("MSDH") under for RFQF RFx#**3140002081** ("RFQF"). As the posting of the award notice was on April 20, 2021, this protest is timely filed and meets the requirements of the Mississippi Procurement Manual Chapter 6 Legal and Contractual Remedies, which we were instructed by the agency to follow.

Based on publicly available information, and given that the specifications established in the RFQF clearly do not include non-invasive technologies, HCAM is the only company that offers a product that meets the agency's needs. Indeed, only two other companies make invasive analyzers — EKF Diagnostics Inc., dba Stanbio Laboratory ("EKF") and Immunostics, Inc. ("Immunostics") — but neither has a product that can meet the solicitation's requirements. The agency's decision not to make award to HCAM was thus unreasonable and contrary to the solicitation's terms.

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I. The Agency's Award Decision Is Improper, Because HCAM's Hb 301 Analyzer Was the Only Product that Could Meet the Agency's Minimum Requirements

MSDH's solicitation sought a hemoglobin analyzer that had several key features. In particular, the solicitation's Specification Sheet required the following:

- Section B.5: "Testing sample size must be 10µl or less."
- Section B.6: "Measuring range must be Hgb: 0-25.6 g/dL."
- Section B.7: "Measuring time must be 30 seconds or less."

Exhibit A. In its question-and-answer session, MSDH explained that compliance with these standards was "mandatory," because they were "the minimum required" features to meet "the needs of the agency." *See* Exhibit B. The solicitation reiterated this point, stating that "[n]on-responsive bids will not be considered. A non-responsive bid is . . . a bid that does not comply with the minimum provisions of the specification." Exhibit. C, § 19.

Measured against that standard, it is clear that none of EKF's or Immunostic's products can comply. Indeed, only HCAM's Hb 301 product meets these standards.

Immunostic's hemochroma PLUS System Does Not Comply with the Solicitation

In the 510K Substantial Equivalence Determination Decision Summary for the hemochroma PLUS System (#K182298 Attached) (Exhibit D), the hemochroma PLUS System has a stated measuring range of 5.0-25.6 g/dL and a stated sample volume of 15 microliters. Immunostic's hemochroma PLUS System, therefore, cannot meet the requirements established in #B.5 nor #B.6.

Differences		
Item	Device hemochroma PLUS System K182298	Predicate HemoCue Hb 301 System K061047
Test Principle	Dual wavelengths for Hgb measurement and reference absorption.	Dual wavelengths for Hgb measurement and turbidity compensation.
Wavelength	Dual wavelengths 530 and 850 nm	Dual wavelengths 506 and 880 nm
Measuring Range	5.0–25.6 g/dL	0–25.6 g/dL
Sample Type	Capillary and venous whole blood	Capillary, venous, and arterial whole blood
Sample Volume	15µL	10µL
Test time	3 seconds	10 seconds
Parameter(s)	Estimation of hematocrit (HCT)	No estimation of HCT

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EKF's DiaSpect Tm System Does Not Comply with the Solicitation

In 2018, EKF was awarded 510K approval for their DiaSpect Tm System (#K172173 Attached) (Exhibit E) and CBER clearance of this product was established in 2020 (#BK200520 Attached) (Exhibit F). This device utilizes a reagentless cuvette and has a stated measuring range of 1.2 – 25.5 g/dL. Therefore, it does not meet the Mandatory Specification established in #B.6.

Performance	Predicate Device HemoPoint H2 Measurement System (K081719)	Candidate Device DiaSpect Tm system (K172173)
Method of detection (Test methodology)	Azide methemoglobin	Optical absorbance
Sample type	Capillary, arterial or venous	Capillary or venous
Sample volume	8 µL	< 10µL
Cuvette reagent components	Azide methemoglobin reagent	None
Cuvette storage	15 – 30°C	0 – 50°C
Cuvette components	2 canisters of 50 or 4 canisters of 50	5 packs of 100
Control Kit components	Two concentration levels of controls (3 vials of each)	Three concentration levels of controls (1 vial of each)
Quality Control	Requires two buffer based controls to validate the calibration	Requires three buffer based controls to validate the calibration
Measurement Range	0.0 – 25.6 g/dL	1.2 – 25.5 g/dL
Measuring Time	30-60 seconds	1 second

EKF's HemoPoint H2/HemoControl System Does Not Comply with the Solicitation

In the FDA 510K approval letter for the HemoPoint H2 product (#K032482 attached) (Exhibit G), EKF used the HemoCue B-Hemoglobin testing system (an old discontinued system) as a predicate device and its measuring time is the same as that discontinued HCAM system "approximately 30-60 seconds" (highlighted below). It is also noted that "measuring time depends on the concentration." The system is based on an Azide methemoglobin method. Reagent in the microcuvette interacts with the sample and absorption is measured. This absorption is proportional to the tHb (total hemoglobin) concentration. Therefore, the measuring

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time is always to be expressed as a range and can never meet the mandatory specification as written in #B.7 — "Measuring time must be 30 seconds or less."

Comparison to Predicate Device:

Specification	HemoPoint® H2	HemoCue	Comments
Instrument :	No. 1	No. 2	No.1 ~~&~~ No. 2
Measurement range	0 – 25.6 g/dL	0 – 25.6 g/dL	equivalent
Specified range	0 – 25.6 g/dL	0 – 23.5 g/dL	equivalent
Specified accuracy	± 0.3 g/dL at ≈14 g/dL	± 0.3 g/dL at ≈14 g/dL	equivalent
Sample material	venous, arterial or capillary human blood	venous, arterial or capillary human blood	equivalent
Measuring time	Approximately 30 – 60 sec	Approximately 30 – 60 sec	measuring time depends on the concentration
Measuring units	mol/L, g/dL, g/L	mol/L, g/dL, g/L	equivalent
Calibration	against NCCLS reference method	against ICSH reference method	NCCLS is current version of the method
Method	Azidemethemoglobin method (Vanzetti)	Azidemethemoglobin method (Vanzetti)	equivalent

Conclusion / Substantial Equivalence:
The HemoPoint® H2 Hemoglobin Photometer and HemoPoint® H2 Cuvettes and the predicate devices, HemoCue B-Hemoglobin System with microcuvette are substantially equivalent based on design and function.

OCT 2 4 2003

K032482

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
(As required by 21 CFR 807.92)

Trade Name: HemoPoint® H2 Hemoglobin Measurement System

Common/Classification Name: Automated Hemoglobin System

Device Classification: Class: II
CFR: 21 CFR 864.5620
Product Code: GKR

Manufacturer: Stanbio Laboratory
1261 North Main Street
Boerne, Texas 78006

Device Description / Procedure Principle:
The HemoPoint® H2 Hemoglobin Measurement System is comprised of a HemoPoint® H2 Hemoglobin Photometer and HemoPoint® H2 Cuvettes.

The recognized reference method for tHb determination (tHb = total hemoglobin) is the cyanmethemoglobin method, which is also known as the cyanhemoglobin method. The blood sample is diluted 1:251 with a reagent buffering solution. Here the erythrocytes are hemolysed and the bivalent iron in oxy- and desoxyhemoglobin are oxidised by the reagent potassium hexacyanoferrate (III) to trivalent iron and so converted to methemoglobin. Together with cyanide ions, which are also contained in the reagents, the methemoglobin forms a stable, colored complex, namely cyanmethemoglobin. This has a wide absorption maximum at 540 nm. This absorption is proportional to the tHb concentration.

In 1966, Vanzetti suggested to replace KCN by NaN_3 and thus was able to reduce the toxicity of the reagent mixture considerably.

Vanzetti's method is also known as the azide methemogobin method. A modified azide methemoglobin method is used in the HemoPoint® H2 system.

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Additionally, when the EKF cuvettes were updated in 2008 and a new 510K approval was received (#K081719 attached) (Exhibit H), this measuring time was reaffirmed and reapproved as "Approximately 30-60 sec". While the predicate device is now noted as the previous version of the H2 cuvette, the measuring time and Azide methemoglobin methodology do not change.

Comparison to Predicate Device:

Specification	HemoPoint® H2 (current cuvette)	HemoPoint® H2 (modified cuvette)	Comments
Instrument:	No. 1	No. 2	No.1 ⟷ No. 2
Measurement range	0 – 25.6 g/dL	0 – 25.6 g/dL	equivalent
Specified range	0 – 25.6 g/dL	0 – 25.6 g/dL	equivalent
Specified accuracy	± 0.3 g/dL at ≈ 14 g/dL	± 0.3 g/dL at ≈ 14 g/dL	equivalent
Sample material	venous, arterial or capillary human blood	venous, arterial or capillary human blood	equivalent
Measuring time	Approximately 30 – 60 sec	Approximately 30 – 60 sec	equivalent
Measuring units	mol/L, g/dL, g/L	mol/L, g/dL, g/L	equivalent
Calibration	against NCCLS reference method	against NCCLS reference method	equivalent
Method	Azidemethemoglobin method (Vanzetti)	Azidemethemoglobin method (Vanzetti)	equivalent

Finally, in 2003 and updated in 2020, EKF submitted and was granted FDA approval — (#K031898) (Exhibit I Attached) and (#K200909 Attached) (Exhibit J) — for their HemoControl device. While these approvals were data based, the measuring time is not changed and the methodology remains reagent based on Azide methemoglobin.

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Around the time of the release of the RFQF, EKF Diagnostics started making changes to the "measuring time definition" publicly attainable on their https://www.ekfusa.com/ website. The screenshot below was taken on 2/1/21, after the publication of the RFQF but before the State reached a final decision on which analyzers to include in the Reverse Auction.

EKF's website makes clear that it can take up to 60 seconds to take a measurement, even though it may be able to perform in "just 30 seconds" or "from 25 seconds." At best, EKF offers a range of time from "25-60" seconds, which does not meet the solicitation's mandatory standard.

Thus, HCAM's Hb 301 Analyzer is the only analyzer that could meet the agency's requirements. MSDH should have disqualified the other analyzers and made award to HCAM.

II. MSDH Engaged in Unequal Treatment by Disqualifying HCAM's Hb 201 Analyzer

On April 8, 2021, MSDH disqualified HCAM's Hb 201 analyzer from the competition, because it cannot measure hemoglobin in 30 seconds or less. Despite that, and for the reasons discussed in Section I, it is clear that the agency selected a hemoglobin analyzer that also cannot comply with the solicitation's minimum requirements. Thus, the agency engaged in unequal and irrational treatment — MSDH relaxed the solicitation standards for the awardee's product, but then applied a strict standard to disqualify HCAM's Hb 201 analyzer. But for that error, there is a substantial chance that the agency would have selected the Hb 201 analyzer, because of its combined competitive price and technical merits. That is a classic example of unequal treatment, and this protest should be sustained.

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III. Conclusion

For the above reasons, MSDH's award decision was contrary to the solicitation's standards and prejudiced HCAM. As the only eligible offeror, there is a substantial chance that HCAM would have been selected for award, but-for the agency's evaluation error. To remedy this error, the agency should direct an award to HCAM, as the only offeror whose product meets solicitation requirements. Thank you for your time and consideration.

Respectfully,

Mark Bellwood

Mark Bellwood
Director of Sales, Specialty Markets
HemoCue America
(214) 412-8900
mark@hemocue.com

BUTLER | SNOW

Post Office Box 6010 • Ridgeland, MS 39158-6010

BUTLER SNOW LLP

PROTEST

Mississippi Public Procurement Review Board
Mississippi Department of Finance and Administration
c/o Ross Campbell, Director, Office of Purchasing, Travel, and
Fleet Management
E.T. Woolfolk State Office Building
501 North West Street, Ste. 701
Jackson, MS 39216

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Post Office Box 6010 • Ridgeland, MS 39158-6010

BUTLER SNOW LLP

PROTEST

Mississippi Public Procurement Review Board
Catoria Martin, Esq., Special Assistant Attorney General
E.T. Woolfolk State Office Building
501 North West Street, Ste. 1404
Jackson, MS 39216

Attachment A.IV

Record on Appeal

EKF's Response to HemoCue's Appeal
Dated July 30, 2021

BURR FORMAN LLP
results matter

John M. Lassiter
jlassite@burr.com
Direct Dial: (601) 709-3432
Direct Fax: (866) 443-1583

The Pinnacle at Jackson Place
190 East Capitol Street
Suite M-100
Jackson, MS 39201

Office (601) 355-3434
Fax (601) 355-5150
Toll-free (866) 355-3439

BURR.COM

July 30, 2021

VIA EMAIL [torri.martin@ago.ms.gov]
ORIGINAL TO FOLLOW VIA U.S. MAIL

Mississippi Public Procurement Review Board
Mississippi Department of Finance and Administration
E.T. Woolfolk State Office Building
501 North West Street, Room 1302
Jackson, MS 39216
Attention: Torri Martin, Special Assistant Attorney General

Re: Response to HemoCue America's ("HemoCue") Appeal of the Mississippi State Department of Health's Denial of HemoCue's Protest (MSDH RFx #3140002081)

Dear Members of the Public Procurement Review Board:

Please accept this letter as EKF Diagnostics, Inc.'s ("EKF") response to HemoCue's July 1, 2021 appeal letter to this Public Procurement Review Board (the "Board") regarding the Mississippi State Department of Health's (the "Department") Request for Quotes-Formal (RFQF) Reverse Auction RFx #3140002081 for Hemoglobin Analyzers and Microcuvettes. For the reasons stated herein, the Board should affirm the Department's denial of HemoCue's bid protest and uphold the contract award to EKF.

I. INTRODUCTION

This appeal stems from the Department's decision to award EKF—the lowest and best bidder at public reverse auction—a contract for the supply of hemoglobin analyzers to be provided for its Women's Infant and Children ("WIC") Central Office in Ridgeland.

HemoCue, an EKF competitor, has now protested the award. It asks this Board to, in effect: (1) assume the role of the Department, (2) interpret the Department's performance specifications (and the Department's need in relation to the performance specifications), and (3) overturn an award so that the same bid process can start over again, all (4) so the Department can determine a product responsive when HemoCue already represented to the Department that the product was not responsive.

This is a tall order. Any petitioner seeking to overturn an award through this Board must establish that "the solicitation or award was not in accordance with the Constitution, statutes, regulations, and the terms and conditions of the solicitation." *See* Mississippi Procurement Manual (the "Procurement Manual"), § 6.204(3). HemoCue's protest does not begin to show that the award was improper. In reality, EKF's Hemo Control Analyzer measures samples within 30 seconds and meets the Solicitation's performance specifications. The Department, the creator of its own specification, already reviewed the matter closely (at the behest of HemoCue) and confirmed that EKF's Hemo Control Analyzer meets all specifications at issue.

Nor does HemoCue establish that the Department treated it disparately during the bid process. HemoCue represented to the Department, unequivocally, that one of its analyzers did not meet a mandatory specification in the bid request. The Department, as any procuring entity would, relied on HemoCue's own statement in disqualifying the product. Not only was this disqualification not unfair, the alternative would be for the Department to consider a product admitted as non-responsive.

Both of Hemocue's arguments fail. The protest should be denied and the award to EKF upheld.

II. FACTUAL BACKGROUND

A. The Solicitation

1. On October 1, 2020, the Department issued a solicitation seeking public bids for the purchase of Hemoglobin Analyzers and Microcuvettes, more particularly identified as Request for Quotes – Formal (RFQF) Reverse Auction RFx # 3140002081 (the "Solicitation"). In conformity with § 3.106.03.4(1)-(5) of the Procurement Manual, the Solicitation included General Conditions, Special Conditions, Specifications, a Bid Form, and an Anticipated Initial Shipping List. *Id.* A true and correct copy of the Solicitation is attached hereto as **Exh. 1**.

2. The Solicitation provided the "bid will be awarded to the lowest and best responder/participant of this RFQF Reverse Auction as determined by the agency," and that the Department "shall have the right to rely upon the documents and assurances submitted by the successful bidder." *Id.* at pp. 1 and 4.

3. The Department structured the Solicitation as a live reverse auction, which is mandated by Miss. Code Ann. § 13-7-31 as "the primary method for receiving bids" for public purchases over $50,000. Reverse auctions involve a two-step process: (1) an initial prequalification period, during which prospective bidders submit information about their product for the purchasing entity to evaluate and determine whether the product is responsive to the solicitation; and (2) a live auction, where pre-qualified bidders submit successive competing bids in an attempt to be the lowest bidder and secure the contract. *See* Procurement Manual, §1.106.22.

B. Initial Response and Pre-Qualification

4. The Solicitation permitted prospective bidders seeking pre-qualification to submit sealed initial responses/quotes until 3:00 PM, CST, February 12, 2021. *See* Exh. 1, Solicitation, p. 3. The Special Conditions required bidders to identify a product and provide "specifications and/or sample" so the Department could evaluate whether the product was responsive to the Specifications. *See* Exh. 1, Special Conditions, p. 1.

5. The General Conditions provided "[i]t shall be incumbent upon all bidders to understand the provisions of the specifications and to obtain clarification prior to the time and date set for the live auction or bid opening." See Exh. 1, General Conditions, § 20. Relevantly, no bidders submitted any RFI regarding the Departments' intended meaning of Specification B.7 ("Measuring time must be 30 seconds or less").

6. Prior to accepting initial responses, the Department answered three requests for information ("RFI"), which appear to have been submitted by HemoCue:

	QUESTIONS	ANSWERS
1.	Are the specifications listed in the MSDh0RFX #3140002081(in section AA 1; section B.B. 1 – B10 and section C.C1 = C3) mandatory specifications?	Yes
2.	What is the process for protesting after the award for MSDH -RFX 3140002081?	This is reverse auction request. The vendors submit quotes and the program reviews if they meet the requirements. We then do open auction on or around Wednesday, March 10, 2021. The vendor with the lowest bid will win the auction.
3.	Can a responding supplier to MSDH RFX 3140002081 submit two unique bid responses? If so, please explain the process to do so.	This is up to the vendor.

See **Exh. 2**, Solicitation Questions and Answers.

7. The Department received three submissions in response to the Solicitation, one (1) from EKF and two (2) from HemoCue. *See* the Department's decision denying HemoCue's protest ("Decision"), a true and correct copy of which is attached hereto as **Exh. 3**.

C. EKF's Pre-Qualifying Bid.

8. EKF submitted the Hemo Control Analyzer Model #3040-0010-0218 ("EKF Hemo Control Analyzer"), which included a product insert, specification sheet, and warranty information. A true and correct copy of the bid package is attached hereto as **Exh. 4**.

9. EKF's literature for the EKF Hemo Control Analyzer provided that the tester measures results "in as quick as 25 seconds (and up to 60 seconds depending on the concentration)." *Id.*, product sheet, p. 9.

Practical and portable	• Hemoglobin and hematocrit results from one sample available in as quick as 25 seconds (and up to 60 seconds depending on the concentration)

10. On March 30, 2021, the Department emailed EKF requesting written assurance as to whether the EKF Hemo Control Analyzer complied with each Specification. True and correct copies of the Department's emails are attached hereto as **Exh. 5.**

11. EKF responded by confirming that the Hemo Control Analyzer complied with all Specifications. With regard to the Specification related to measuring time, Specification B.7, which HemoCue claims as the basis for overturning the award, EKF responded as follows:

> B.7 Measuring time must be 30 seconds or less. The Hemo Control Analyzer measures hemoglobin and provides a calculated hematocrit. The measuring time for one sample can be as quick as 25 seconds, if performed correctly, or up to 60 seconds if performed incorrectly or if the hemoglobin concentration is high.

See **Exh. 6**, EKF's Confirmation.

12. The Department accepted EKF's response in prequalifying its bid. Because the EKF Hemo Control Analyzer was the lowest bid of the pre-qualifiers, the Department awarded it the contract.

D. HemoCue's Denied Pre-Qualification.

13. HemoCue submitted the Hb 201+ analyzer for prequalification, but the Department determined that it did not comply with the Solicitation's Specifications. This denial is the source of HemoCue's argument that it was treated unfairly.

14. The product brochure for the Hb 201+ states that results "are displayed in g/dL within 15 – 60 seconds depending on the hemoglobin concentration." Similarly, the product insert states that "measuring time is 15 – 60 seconds for Hb values below 20 g/dL." *See* the H201+ Product Brochure, p. 4, and Product Insert, p. 2, collectively attached hereto as **Exh.** 7.

15. On March 30, 2021, the Department emailed HemoCue requesting written assurance as to whether the Hb 201+ complied with each Specification. *See* Exh. 5.

16. HemoCue's HB 201+ would likely have qualified had it not been for Hemocue's Response to the Department's email. *See* **Exh. 8**. HemoCue answered "yes" for all Specifications except for Specification B.7, to which HemoCue answered "no." *Id.* HemoCue did not request any clarification as to the meaning of Specification B.7. Instead, HemoCue answered "no" despite the fact that, according to the Department's response to the RFI, compliance with that specification was mandatory.[1] *See* Exh. 2, Solicitation Questions and Answers.

17. Based on the product information/specifications provided by EKF and HemoCue, as well as their written responses to each Specification, the Department determined that both EKF's Hemo Control Analyzer and HemoCue's Hb 301 complied with the Specifications and were qualified to participate in the reverse auction. *See* Exh. 3, Decision, p. 3.

18. Not surprisingly, the Hb 201+, which HemoCue unequivocally stated did not meet a mandatory specification, was not approved for the reverse auction.

E. HemoCue's Protest and Appeal

19. On April 27, 2021, HemoCue filed a protest to the Department, making many of the same arguments that it raises before this Board.

20. On June 24, 2021, the Department denied the protest, confirming after review that the EKF Hemo Control Analyzer was responsive. *See* Exh. 3, Decision.

21. On July 1, 2021, HemoCue filed the subject appeal contesting the denial of its prior protest to the Board.

III. STANDARD OF REVIEW

The sole question on appeal before the Board is whether the "award was in accordance with the Constitution, statutes, regulations, and the terms and conditions of the solicitation."[2] *See* Procurement Manual, § 6.204(3). In its appeal, HemoCue does not argue that the award to EKF violated any statute, regulation, or provision of the Constitution. Instead, HemoCue's sole

[1] EKF can conceive of only two reasonable explanations for HemoCue's submission of the Hb 201+ and subsequent "admission" that it did not meet the requirements of Specification B.7. Either (1) HemoCue submitted the Hb 201+ with the belief that its 15 – 60 second measuring time satisfied Specification B.7, but later had a change of heart; or (2) HemoCue submitted the Hb 201+ *with the belief that it did not comply with the Specifications* and then informed the Department that it did not comply. In either instance, it is reasonable to assume HemoCue's actions were calculated to render its model Hb 301 as the only responsive analyzer.

[2] Thus, for purposes of an appeal to the Board, the standards relied upon by HemoCue of "substantial evidence" and "arbitrary or capricious" are irrelevant and should not be considered.

argument is that EKF's Hemo Control Analyzer does not meet the Solicitation's performance specifications.

The Department could reject a low bid if "the supply… offered in the bid is unacceptable by reason of its failure to meet the requirements of the specifications… set forth in the Invitation for Bids." *See* Procurement Manual, § 3.112.05.03(1)(c). Although HemoCue does not cite that particular section of the Procurement Manual, HemoCue essentially argues that the Department should have rejected EKF's bid pursuant to § 3.112.05.03(1)(c) because, according to HemoCue's apparent interpretation of the Specifications, the Hemo Control Analyzer does not comply with Specification B.7. Such a narrow interpretation of Specification B.7 is unreasonable and contrary to the spirit of Mississippi's public procurement laws and regulations.

While the appeal proceedings are to be conducted *de novo*, the Board must view the record through the lens of the Procurement Manual and its guidance to the awarding agency. In so doing, the Board should consider that the Manual encourages open competition and discourages overly restrictive interpretations of bid specifications:

- One of the stated purposes of the regulations set forth the in Procurement Manual is to "foster effective broad-based competition with the free enterprise system." *See* Procurement Manual, § 1.101.01(2)(f).
- "It will not be the intent of the Office of Purchasing, Travel and Fleet Management to either write or approve any specifications that are restrictive and preclude competitive bidding." *Id.* at § 4.106.
- "All specifications shall seek to promote overall economy for the purposes intended and encourage competition in satisfying the State's needs, and shall not be unduly restrictive." *Id.* at § 4.107.
- "All specifications shall be written in such a manner as to describe the requirements to be met, without having the effect of exclusively requiring a proprietary commodity or equipment item, or procurement from a sole source, unless no other manner of description will suffice." *Id.* at § 4.107.01.

In light of those rules, the Board should uphold the Department's decision, and find that the award of the purchase contract to EKF was proper and in conformance with Mississippi law as well as the terms of the Solicitation itself.

IV. ARGUMENT

A. The Department's decision to award the contract to EKF was in accordance with the terms of the Solicitation.

The primary question on appeal is whether, given the information and assurances provided by EKF, the Department complied with the conditions of the Solicitation by approving

EKF's Hemo Control Analyzer for participation in the auction. To answer that question, the Board need only compare the language of Specification B.7 to the information and assurances that EKF gave the Department. All other considerations are extraneous.

EKF does not dispute that Specification B.7 is a mandatory specification, as was confirmed by the Department in its responses to RFI. *See* Exh. 2, Solicitation Questions and Answers. The simple fact is, the EKF Hemo Control Analyzer complies with the minimum requirements of Specification B.7. This was the finding of the Department both when it approved the EKF Hemo Control Analyzer for participation in the auction and when it denied HemoCue's bid protest. It should likewise be the finding of the Board on this appeal.

Information Considered by the Department

In determining whether EKF's Hemo Control Analyzer complied with Specification B.7, and for that matter all Specifications, the Department reviewed: (1) the Hemo Control specifications and product literature showing a testing time "between 25-60 seconds" (*See* Exh. 4, p. 9) and (2) EKF's written assurance that "measuring time for one sample can be as quick as 25 seconds, if performed correctly, or up to 60 seconds if performed incorrectly or if the hemoglobin concentration is high." *See* Exh. 6, EKF's Confirmation. According to the Procurement Manual and Solicitation, this information was precisely the sort of information the Department was required to rely upon.

As to the product literature and specifications, the Procurement Manual provides that purchasing entities conducting pre-qualification for reverse auctions should require the "initial response to the Invitation for Bids [to] include a proposed product, *including specifications and/or samples*, for the purchasing entity to evaluate and determine responsiveness to requirements." *See* Procurement Manual, § 3.106.22.2(2) (emphasis added); *see also*, Special Conditions, p. 1 (requiring potential bidders to "include a proposed product, including specifications and/or samples, for the MSDH to evaluate and determine responsiveness to requirements/specifications.")

As to EKF's assurance of compliance, the Solicitation provided that the Department had "the right to rely upon the documents *and assurances* submitted by the successful bidder." *See* Exh. 1, Solicitation, p. 1. Accordingly, the Department was presented with and relied upon sufficient information to determine that the EKF Hemo Control Analyzer complied with Specification B.7.

The Department's Decision

Taking that information into consideration, the Department determined that the EKF Hemo Control Analyzer was responsive to all Specifications and was approved to be included in the auction. With regard to Specification B.7, the Department determined that the analyzer "could meet the specifications of B.7 if the test were performed correctly..." *See* Exh. 3, Decision, p. 2. That determination was reasonable given the terms of the Specifications and the provisions of the Procurement Manual.

The Specification provides only that "Measuring time must be 30 seconds or less." *See* Exh. 1, Specifications, B.7. In essence, HemoCue disagrees with the Department's interpretation of its own Specification. HemoCue would rather B.7 have required that the analyzer "must measure samples in 30 seconds or less *in all instances*." In fact, HemoCue represented to the Board that Specification B.7 "requires the hemoglobin analyzer to measure *all samples* in '30 seconds or less.'" *See* HemoCue's appeal, p. 3 (emphasis added). Unfortunately for HemoCue, the Specification contains no such restrictive language.

The better interpretation of Specification B.7, and the one employed by the Department, is that analyzers "must *be capable of* measuring samples in 30 seconds or less." The Department, as the drafter of Specification B.7, is in the best position to interpret it. *See, e.g., Peters v. Shreveport*, 818 F.2d 1148, n. 4 (5th. Cir. 1987) (holding that the Secretary of Labor, "having participated with the relevant subcommittees in the drafting of the [Equal Pay] Act, was in a position to accurately interpret the Act in accordance with Congress's intentions.").

The Department clearly meant B.7 to include analyzers that have the capability of measuring samples within 30 seconds, as it determined that the Hemo Control Analyzer complied with B.7 because it "*could* meet the specifications of B.7 if the test were performed correctly…" *See* Exh. 3, Decision, p. 2 (emphasis added). HemoCue had the opportunity and obligation[3] to obtain clarification regarding the meaning of B.7, but instead chose to remain willfully ignorant.

First, the very fact that HemoCue submitted the Hb 201+ for prequalification suggests that *even HemoCue believed the Department's interpretation was correct.* In fact, during the pre-qualification process, both bidders seemed to have the same understanding of the Specification's meaning. EKF bid the Hemo Control Analyzer and HemoCue bid the Hb 201+. Both these machines tests in under 30 seconds under normal conditions, but can take longer if hemoglobin concentration is abnormally high. HemoCue cannot argue that the interpretation of the Department is unreasonable when HemoCue submitted a bid believing the Hb 201+ to be responsive.

Second, the Department's interpretation is consistent with the policies in the Procurement Manual that encourage open competition and discourage sole source contracts. *See* Procurement Manual, §§ 1.101.01(2)(f); 4.106; 4.107; and 4.107.01. HemoCue admits that, if its interpretation of Specification B.7 were correct, the Hb 301 would be the sole source in the industry for this solicitation. This was clearly not the intent of the Department, who would not have gone through the bid process for a sole source award.

[3] *See* Exh. 1, General Conditions, § 20 ("[i]t shall be incumbent upon all bidders to understand the provisions of the specifications and to obtain clarification prior to the time and date set for the live auction or bid opening.").

Tellingly, the Department has done nothing to render this bid closer to a sole source scenario. The only reason sole source is being discussed is because HemoCue made the decision to pull the Hb 201+ from consideration in deference to its more expensive product. Because the Procurement Manual favors an interpretation of public bidding over sole source, and the only interpretation offered by HemoCue would lead to a sole source scenario, its position should be denied.

B. The Department did not treat HemoCue unequally.

HemoCue's argument that the Department treated it "unequally" as compared to EKF is completely without merit. HemoCue complains that the Department should have denied the EKF Hemo Control Analyzer because it has a similar measuring time as the Hb 201+. While the analyzers appear to have similar measuring times, HemoCue ignores the fact that the denial of Hb 201+ was caused solely by *HemoCue's own representation of product non-conformity*, not some disparate treatment by the Department.

The parties were treated identically throughout the bid process. The Department gave both HemoCue and EKF an opportunity to provide written assurance that their respective products complied with the Specifications. In response, EKF provided an explanation of how the Hemo Control's measuring time complied with Specification B.7. On the other hand, HemoCue flatly stated that its Hb 201+ did ***not*** comply with the Specification, without any explanation or qualification. Moreover, when informed that the Hb 201+ had not been approved, HemoCue did not attempt to explain its answer, or seek clarification of the Specification's meaning, or appeal the Board's decision, or take any action whatsoever to indicate that it disagreed with the Board's decision.[4]

What other option did the Department have but to deny the Hb 201+, when its manufacturer unequivocally told the Department the analyzer does not comply with a mandatory Specification? The Department did not treat HemoCue unequally. It acted in the only reasonable manner it could, given the assurances of HemoCue, which it had the right to rely on pursuant to the terms of the Solicitation. *See* Exh. 1, Solicitation, p. 1. There is nothing in the record on this point that would support a protest to overturn a bid award.

[4] This lack of action on the part of HemoCue stokes EKF's suspicions as to HemoCue's objectives in self-sabotaging the Hb 201+ submission. For instance, if HemoCue believed that its "admission" of noncompliance would force the Board to deny all devices with a similar measuring time, it could in effect convert the Solicitation into a sole source contract with the Hb 301, its more expensive hemoglobin analyzer, being the only responsive device. Of course, an interpretation of a specification that restricts rather than promotes a competitive bid scenario is precisely what the Procurement Manual seeks to avoid. *Id.* at § 4.107.01.

V. CONCLUSION

For the foregoing reasons, EKF respectfully requests that the Board deny HemoCue's appeal and uphold the contract award to EKF.

Respectfully submitted,

John M. Lassiter
Attorney for EKF Diagnostics, Inc.

JML/srb
Enclosures

cc: EKF Diagnostics, Inc.
Mississippi Department of Health
Teselyn Funches
LaTeshya Martin
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MISSISSIPPI STATE DEPARTMENT OF HEALTH

REQUEST FOR QUOTES-FORMAL (RFQF)
REVERSE AUCTION
RFx # 3140002081

The Mississippi State Department of Health (MSDH) will purchase Hemoglobin Analyzers and Microcuvettes for use in clinics/locations Statewide and invites your participation in accordance with the terms and conditions of this RFQF Reverse Auction. Once award of the bid has been made, the terms and conditions as set forth in this RFQF Reverse Auction shall become a contract binding on the successful bidder. Any documents submitted to satisfy a requirement of this request and any assurances made by the successful bidder in satisfaction of this request shall become a part of the agreement between the Mississippi State Department of Health and the successful bidder. The Mississippi State Department of Health shall have the right to rely upon the documents and assurances submitted by the successful bidder.

This RFQF Reverse Auction is for an estimated initial quantity/purchase of (230 Each) Hemoglobin Analyzers and related supplies (Microcuvettes). Estimated quantity of Microcuvettes, for a five year period, is 4500 Boxes of 200. Orders for Microcuvettes will be placed approx. (3) times per year for approx. 300 Boxes.

Pricing for Microcuvettes shall be guaranteed for a five-year period.

Pricing is also requested, and shall be guaranteed for a five-year period, for any New/Additional Analyzers purchased after the initial order.

This RFQF Reverse Auction/Award will be for a five-year period.

Pricing to include all shipping charges.

E-Verify Compliance - Contractor/Seller represent and warrants that it will ensure its compliance with the Mississippi Employment Protection Act (Senate Bill 2988 from the 2008 Regular Legislative Session) and will register and participate in the status verification system for all newly hired employees. The term "employee" as used herein means any person that is hired to perform work within the State of Mississippi. As used herein "status verification system" means the Illegal Immigration Reform and Immigration Responsibility Act of 1996 that is operated by the United States Department of Homeland Security, also known as the E-Verify Program, or any other successor electronic verification system replacing the E-Verify Program. Contractor/Seller agrees to maintain records of such compliance and , upon request of the State, to provide a copy of each such verification to the State. Contractor/Seller further represents and warrants that any person assigned to perform services hereunder meets the employment eligibility requirements of all immigration laws of the State of Mississippi. Contractor/Seller understands and agrees that any breach of these warranties may subject Contract/Seller to the following: (a) termination of this Agreement and Ineligibility for any state or public contract in Mississippi for up to three (3) years, with notice of such (b) the loss of any license, permit, certification or other document granted to Contractor/Seller by an agency, department or governmental entity for the right to do business in Mississippi for up to one (1) year, or (c) both. In the event of such termination/cancellation, Contractor/Seller would also be liable for any additional costs incurred by the State due to contract cancellation or loss of license or permit.

E-Payments – Payments by the Mississippi State Department of Health shall be made and remittance information provided electronically as directed by the State of Mississippi. These payments shall be deposited into the bank account of the Contractor's choice. The state may, at its sole discretion, require the Contractor to submit invoices and supporting documentation electronically at any time during the terms of this agreement. Contractor understands and agrees that the State is exempt from the payment of taxes. All payments shall be in United States currency.

Applicable Law – This purchase(s) shall be governed by and construed in accordance with the laws of the State of Mississippi, excluding its conflicts of law provisions, and any litigation with respect thereto shall be brought in the courts of the State of Mississippi. The vendor shall comply with applicable federal, state and local laws and regulations.

Payment Terms – MS Code Section 31-7-305(3) allows a state entity to pay invoices within 45 days without penalty.

Bid terms are welcome, however, they will not be used as criteria for awarding the bid.

Items will be purchased from the RFQF Reverse Auction by the Mississippi State Department of Health in accordance with the terms and conditions set out in this request and the attachments hereto.

State and Federal law requires that the Mississippi State Department of Health not be liable should federal or state funds not be available to make the purchases. Should federal or state funds be reduced or eliminated, the State of Mississippi, the Mississippi State Department of Health, its agents, servants and employees would have no obligation to purchase any quantity of

goods or services covered by this request for bid. The bidder agrees to hold the above enumerated entities and individuals harmless in that event.

The bidder/prospective vendor must further give assurances in writing that it can provide and deliver the items as ordered on a schedule agreeable to the Mississippi State Department of Health. The contractor shall not assign, sell or subcontract in whole or in part, its rights or obligations under this agreement without prior written consent of the MSDH. Any attempt assignment or sale of the contract without said consent shall be void and of no-effect.

The MSDH reserves the right to refuse any items not meeting the specifications of this bid.

Prospective bidders are to contact Cynthia Brasher, Purchasing Director in writing if there are any questions regarding this RFQF Reverse Auction, either by email cynthia.brasher@msdh.ms.gov or by writing to P. O. Box 1700, Jackson, MS 39215-1700. Questions are to be received no later than the close of business on February 12, 2021. MSDH answers/responses will be posted on the State of MS Transparency website and on the MSDH website within 1-2 days.

Sealed quotes/responses will be accepted/received until 3:00 PM, CST, Friday, February 12, 2021, either hand delivered or by mail to **Mississippi State Department of Health, Purchasing Department, Room 137A, The Underwood Building, 570 E. Woodrow Wilson, Jackson, Mississippi 39216 or Post Office Box 1700, Jackson, MS 39215-1700.** The quotes/responses must be received before and be dated and time stamped by the submission deadline. All bids must be properly stamped. No quotes/responses will be accepted after the established submission deadline.

Currently, due to the continuing Covid-19 pandemic, the Mississippi State Department of Health remains closed to the public.

Prior to the quote/response due date and time, quotes/responses may be Hand Delivered to the agency between the hours of 8:00 a.m. and 5:00 p.m., CST. Entry may be obtained at the Visitor's entrance to the Mississippi State Department of Health, Osborne Building, 570 E Woodrow Wilson, Jackson, MS 39216. A receptionist will be on duty to receive the bid responses and forward to the addressee on the envelope/package.

No facsimile (FAX) quotes/responses will be accepted.

Quote/response BID FORM must be signed by a person with authority to bind the bidder, and must accompany your submission. Failure to comply with this provision, any other provision of this RFQF Reverse Auction, or any provision of state or federal law or regulation regarding the submission of bids may cause the bid to be rejected.

In addition, it is requested that bidders also submit a quote/response on-line in the State of Mississippi electronic procurement system, MAGIC, however, it is not mandatory. In order to submit quotes/responses bidders must be registered as a vendor in MAGIC system and have an I.D. number and password assigned at the time of registration. Technical assistance may be found at http://www.dfa.ms.gov/dfa-offices/mmrs/mississippi-suppliers-vendors/. If a bidder submits both a paper quote/response and an on-line quote/response, the paper quote/response will take precedence if there is a discrepancy between the two.

The Mississippi State Department of Health reserves the right to waive minor informalities, which are matters of form rather than substance, or insignificant mistakes or to allow the bidder to correct them if other bidders are not prejudiced.

The bid will be awarded to the lowest and best responder/participant of this RFQF Reverse Auction as determined by the agency. The awardee will perform the terms and conditions of the bid and any contract awarded hereunder. No assignment of subcontracting of the award or any contract awarded there under shall be allowed without prior written approval of the State Health Officer.

PLEASE MARK YOUR ENVELOPES EXTERNALLY:

RFx #3140002081 Submission Deadline: 3:00 PM, CST, February 19, 2021

MSDH Request for Quotes-Formal (RFQF) Reverse Auction
RFx #3140002081

GENERAL CONDITIONS- REVERSE AUCTIONS

ALL BIDS SUBMITTED SHALL BE IN COMPLIANCE WITH ALL CONDITIONS SET FORTH HEREIN. THE BID PROCEDURES FOLLOWED BY THIS OFFICE WILL BE IN ACCORDANCE WITH THESE CONDITIONS. THEREFORE, ALL BIDDERS ARE URGED TO READ AND UNDERSTAND THESE CONDITIONS PRIOR TO SUBMITTING A BID.

1. DEFINITIONS

The use of the word "agency" in any Bid Invitation solicitation or specification shall be intended to mean state agencies only. The words "governing authority" when used shall be intended as meaning city, county or other local entities.

2. PREPARATION OF BIDS

2.1 Responding suppliers must provide a Quote with the initial response. Quotes are utilized by the Purchasing Agent to determine market pricing and set the auction parameters (e.g., start price). Bids and/or Quotes may be submitted through the State of Mississippi's e-procurement system (MAGIC), or in person to the Mississippi State Department of Health, Office of Purchasing ("MSDH" or "the State"). Paper bids are allowed. All prices and notations must be printed in ink or typewritten. No erasures permitted. Errors may be crossed out and corrections printed in ink or typewritten adjacent and must be initialed, in ink, by the person signing bid.

2.2 To submit bids electronically, bidders must ensure they are registered in the MAGIC system and have received a login, password, and supplier number and that all technical requirements have been met.

2.3 If a bidder is unwilling or unable to participate through MAGIC, an MSDH representative can enter the Vendor's bid(s) manually (i.e. Surrogate bidding).

2.4 Bidders participating in person by surrogate bidding must so indicate in their response to the initial Request for Quote-Formal (RFQF).

2.5 Failure to examine any drawings, specifications, and instructions will be at bidder's risk.

2.6 Price each item separately. Unit prices shall be shown. Bid prices must be net.

2.7 It is understood that reference to available specifications shall be sufficient to make the terms of such specifications binding on the bidder.

2.8 Bidders must furnish all information requested in the bid specifications. Further, when required, each bidder must submit for bid evaluation cuts, sketches, descriptive literature and technical specifications covering the product offered. Reference to literature submitted with a previous bid or on file with MSDH will not satisfy this provision.

2.9 Samples of items, when requested, must be furnished free of expense, and if not destroyed in testing will, upon request, be returned at the bidder's expense. Request for the return of samples must be made within ten (10) days following opening bids. Each individual sample must be labeled with bidder's name, manufacturer's brand name and number, State of Mississippi commodity number, bid number and item reference.

2.10 Time of performance. The number of calendar days in which delivery will be made after receipt of order shall be indicated in the bid specifications.

3. BID SUBMISSION

3.1 When submitting a bid electronically, the authorized signature may be typed or be an electronic signature.

3.2 Bids and modifications or corrections received after the closing time specified will not be considered.

3.3 When submitting the response to the RFQF in MAGIC, bidder must ensure all questions have been answered within the RFQF and all proposed items in bid have a response.

3.4 Bidders submitting paper responses should submit responses to the MSDH by the response deadline.

4. ACCEPTANCE OF BIDS

MSDH reserves the right to reject any and all bids, to waive any informality in bids and unless otherwise specified by the bidders, to accept any items on the bid. The State reserves the right to modify or cancel in whole or in part its Invitation for Bids.

If a bidder fails to state the time within which a submitted response will expire, it is understood and agreed that the MSDH shall have 60 days to accept.

5. ERROR IN BID

If a vendor is participating in a Live Auction, the vendor can notify MSDH in the event of an erroneous bid via the chat message feature. Erroneous bids, where the mistake is apparent to MSDH, may be deleted during the live auction.

6. SPECIAL DISCOUNT PERIOD

Time in connection with a special discount offered will be computed from date of delivery at destination or from the date correct invoices are received, if the latter date is later than the date of delivery. Cash discounts will not be considered in the award process.

7. AWARD

7.1 Contracts and purchases will be made or entered into with the lowest responsible bidder meeting specifications, except as otherwise specified in the bid specifications. Where more than one item is specified in the specifications, the State reserves the right to determine the low bidder either on the basis of the individual item(s) or on the basis of all items included in its Invitation for Bids, or as expressly provided in the State's Invitation for Bids.

7.2 Unless the bidder specified otherwise in the bid, the State may accept any item or group of items of any kind.

7.3 A written purchase order or contract award furnished to the successful bidder within the time of acceptance specified in the Invitation for Bid results in a binding contract without further action by either party. The contract shall consist solely of these General Conditions, the Instructions and Special Conditions, the successful bidder's bid, and the written purchase order or contract award. The contract shall not be assignable in whole or in part without the written consent of the State.

8. INSPECTION

Final inspection and acceptance or rejection may be made at delivery destination, but all materials and workmanship shall be subject to inspection and test at all times and places, and when practicable. During manufacture, the right is reserved to reject articles which contain defective material and workmanship. Rejected material shall be removed by and at the expense of the contractor promptly after notification or rejection. Final inspection and acceptance or rejection of the materials or supplies shall be made as promptly as practicable, but failure to inspect and accept or reject materials or supplies shall not impose liability on the State or any subdivision thereof for such materials or supplies as are not in accordance with the specification. In the event necessity requires the use of materials or supplies not conforming to the specification, payment therefore may be made at a proper reduction in price.

9. TAXES

The State is exempt from federal excise taxes and state and local sales or use taxes and bidders must quote prices which do not include such taxes. Exemption certificates will be furnished upon request. Contractors making improvements to, additions to or repair work on real property on behalf of the State are liable for any applicable sales or use tax on purchase of tangible personal property for use in connection with the contracts. Contractors are likewise liable for any applicable use tax on tangible personal property furnished to them by the State for use in connection with their contracts.

10. GIFTS, REBATE, GRATUITIES

10.1 Acceptance of gifts from bidders is prohibited. No officer or employee of the MSDH, nor any head of any state department, institution or agency, nor any employee of any state department, institution or agency charged with responsibility of initiating requisitions, shall accept or receive, directly or indirectly, from any person, firm or corporation to whom any contract for the purchase of materials, supplies, or equipment for the State of Mississippi may be awarded, by rebate, gifts, or otherwise, any money or anything of value whatsoever, or any promise, obligation or contract for future rewards or compensation.

10.2 Bidding by state employees is prohibited. It is unlawful for any state official or employee to bid on, or sell, or offer for sale, any merchandise equipment or material, or similar commodity to the State during the tenure of his or her office or employment, or for the period prescribed by law thereafter, or to have any interest in the selling of the same to the State.

11. BID INFORMATION

Bid information and documents may be examined pursuant to the Mississippi Public Records Act of 1983, MS Code 25-61-1 et seq.

12. PRECEDENCE

Bids shall be made and the contract shall be entered into in accordance with the General Conditions as hereinafter amended and modified. Should a conflict exist between the General Conditions and the Instructions and Special Conditions, the Instructions and Special Conditions shall take precedence.

13. COMPETITION

There are no federal or state laws that prohibit bidders from submitting a bid lower than a price or bid given to the U.S. Government. Bidders may bid lower than U.S. Government contract price without any liability as

the State is exempt from the provisions of the Robinson-Patman Act and other related laws. In addition, the U.S. Government has no provisions in any of its purchasing arrangements with bidders whereby a lower price to the State must automatically be given to the U.S. Government.

14. WAIVER

MSDH reserves the right to waive any General Condition, Special Condition, or minor specification deviation when considered to be in the best interest of the State.

15. CANCELLATION

Any contract or item award may be canceled with or without cause by the State with the giving of 30 days written notice of intent to cancel. Cause for the State to cancel may include, but is not limited to, cost exceeding current market prices for comparable purchases; request for increase in prices during the period of the contract; or failure to perform to contract conditions. The Contractor will be required to honor all purchase orders that were prepared and dated prior to the date of expiration or cancellation if received by the Contractor within a period of 30 days following the date of expiration or cancellation. Cancellation by the State does not relieve the Contractor of any liability arising out of a default or nonperformance. If a contract is canceled by the State due to a Contractor's request for increase in prices or failure to perform, that Contractor will be disqualified from bidding for a period of 24 months. The Contractor may cancel a contract for cause with the giving of 30 days written notice of intent to cancel. Cause for the Contractor to cancel may include, but is not limited to the item(s) being discontinued and/or unavailable from the manufacturer.

16. SUBSTITUTIONS DURING CONTRACT

During the term of a contract, if adequate documentation is provided that supports the claim that the contract item(s) are not available, items which meet the minimum specifications may be substituted if approved by MSDH and the substitutions are deemed to be in the best interest of the State.

17. APPLICATION

It is understood and agreed by the bidder that any contract entered into as a result of this Invitation for Bids is established for use by MSDH and all purchases made by MSDH for products included under the provisions of the contract shall be purchased from the bidder receiving the award unless exempt by special authorization from the state Office of Purchasing, Travel and Fleet Management.

Under the provisions of Section 31-7-7 Mississippi Code of 1972, Annotated, the prices offered herein shall be extended to the governing authorities. However, the governing authorities, by provisions of Section 31-7-12 Mississippi Code, may purchase products covered by state contracts from any source offering an identical product at a price that does not exceed the state contract price.

18. ADDENDA

Addenda modifying plans and/or specifications may be issued if time permits. No addendum will be issued within a period of two (2) working days prior to the time and date set for the bid opening. Should it become necessary to issue an addendum within the two (2) day period prior to the bid opening, the bid date will be reset to a date not less than five (5) working days after the date of the addendum, giving bidders ample time

to comply with the addendum. When replying to a bid request on which an addendum has been issued, and the specifications require acknowledgement, the bid shall indicate that provisions of the addendum have been noted and that the bid is being offered in compliance therewith. Failure to make this statement may result in the bid being rejected as not being in accordance with the revised specifications or plans.

19. NONRESPONSIVE BIDS

Nonresponsive bids will not be considered. A non-responsive bid is considered to be a bid that does not comply with the minimum provisions of the specification. Any bidder found to repeatedly offer alternated products that are not compliant with specifications in an attempt to obtain a contract on the basis of pricing only will be disqualified from bidding for a period of 24 months.

20. SPECIFICATION CLARIFICATION

It shall be incumbent upon all bidders to understand the provisions of the specifications and to obtain clarification prior to the time and date set for the live auction or bid opening. Such clarification will be answered only in response to a written request submitted in the specified amount of time set by the MSDH. TheMSDH reserves the right to specify a time frame in which clarification request shall be made.

21. Omitted

22. PRE-QUALIFICATION PROCESS

22.1 The purpose of the RFQF is to advertise the competitive procurement for solicitation of formal quotes from potential bidders to participate in the Reverse Auction. The MSDH will be responsible for defining product categories, adding bidders, and publishing all bid related documents to the procurement portal. Once the responses have been received and the Opening Date has been reached, the MSDH will review the submissions to qualify bidders and determine a starting price for reverse auction items.

22.2 The Invitation for Bids/RFQF shall be advertised in accordance with Section 3.106.05.4 of the Mississippi Procurement Manual. Minimum due date for responses to the RFQF will be on the 8th working day after the last day of advertisement.

22.3 Responses to the RFQF will be reviewed by the MSDH for responsiveness to specifications. Price quotes received will be evaluated in conjunction with other market research to determine the starting price for the Auction.

22.4 The MSDH will accept bidder responses in MAGIC who have qualified meeting RFx specifications. Bidders not meeting specifications will not be allowed to participate in the Auction.

22.5 Once qualified, the MSDH will notify the vendor of Qualification and the date of the Live Auction via email. After receiving the confirmation email, bidders should review/ensure technical requirements for MAGIC have been met or confirm participation in person.

22.6 It is requested that bids be submitted on the basis of statewide distribution. Contractors must maintain adequate distribution capabilities and adequate stock of all items to insure prompt delivery.

23. **FIRM BID PRICE**

Prices accepted from bidder submissions shall be firm for the term of the contract except that the State shall receive the benefit of any price decrease in excess of five (5) percent. The contractor must provide written price reduction information within ten (10) days of its effective date.

24. CONTRACT EXTENSION

24.1 Automatic contract renewals or extensions are not allowed. Contracts must be extended or renewed with the proper documents signed or approved by the MSDH.

24.2 The MSDH reserves the right to extend the term of a contract, when necessary, to continue a source of supply whenever new or replacement contracts are not completed prior to the expiration date. Such extensions are dependent upon the agreement of the Contractor and shall not exceed three (3) months.

25. SUSPENSION AND DEBARMENT

By submitting a bid, the bidder is certifying that neither the bidder nor any potential subcontractors are debarred or suspended or are otherwise excluded from or ineligible for participation in federal assistance programs.

26. ASSIGNMENT

The Contractor shall not assign or subcontract in whole or in part, its right or obligations under this agreement without prior written consent of the MSDH.

27. INDEMINIFICATION

Contractor shall indemnify, defend, save and hold harmless, protect, and exonerate the State of Mississippi, its Commissioners, Board Members, officers, employees, agents, and representatives from and against all claims, demands, liabilities, suits, actions, damages, losses, and costs of every kind and nature whatsoever, including, without limitation, court costs, investigative fees and expenses, and attorneys' fees, arising out of or caused by Contractor's and/or its partners, principals, agents, employees, and/or subcontractors in the performance of or failure to perform this Agreement. In the State's sole discretion, Contractor may be allowed to control the defense of any such claim, suit, etc. In the event Contractor defends said claim, suit, etc., Contractor shall use legal counsel acceptable to the State; Contractor shall be solely liable for all reasonable costs and/or expenses associated with such defense and the State shall be entitled to participate in said defense. Contractor shall not settle any claim, suit, etc., without the State's concurrence, which the State shall not unreasonably withhold.

28. LIVE AUCTION

28.1 Notification of Auction Start date and time will be sent via email to qualifying bidders. If a bidder is unwilling or unable to participate through MAGIC, a representative from the MSDH can enter the Vendor's bid(s) manually (i.e. Surrogate Bidding). If a bidder elects to participate via Surrogate Bidding, the bidder must be physically present at the public bidding location, with the means to submit written bids for each offer made and signed by an authorized agent of the Vendor. A Bid Form will be provided to the Vendor at the start of the auction. This form will not be returned to the bidder but will become a part of the Bid Documentation for Evaluation by the MSDH.

28.2 The Auction time may be extended at the discretion of the MSDH. Examples of reasons to extend an auction include, but are not limited to, technical difficulties experienced by the MSDH or bidder, the need to pause the Auction, or bids placed within the last few moments of bidding.

28.3 Communication with bidders participating electronically during the Auction may be done via the Live Chat Feature. The MSDH has the ability to send messages to particular bidders or broadcast to all bidders. Bidders can ONLY communicate with the MSDH, not other bidders.

28.4 Bidders may be removed from a Live Auction for improper conduct, including but not limited to profanity, threats, consistently entering erroneous or extremely low bids, or other disruptive behavior.

28.5 Bidders/Suppliers should be advised that no award will automatically result from a reverse auction, and that the MSDH will review the results of the auction and make a determination in a timely manner.

29. **FORCE MAJEURE**

If the MSDH is closed for any reason, including but not limited to: acts of God, strikes, lockouts, riots, acts of war, epidemics, governmental regulations superimposed after the fact, fire, earthquakes, floods, or other natural disasters (the "Force Majeure Events"), which closure prevents the opening of bids at the advertised date and time, all bids received shall be publicly opened and read aloud on the next business day that the agency shall be open and at the previously advertised time. The new date and time of the bid opening, as determined in accordance with this paragraph, shall not be advertised, and all bidders, upon submission of a bid proposal, shall be deemed to have knowledge of and shall have agreed to the provisions of this paragraph. Bids shall be received by the agency until the new date and time of the bid opening as set forth herein. The MSDH shall not be held responsible for the receipt of any bids for which the delivery was attempted and failed due to the closure of the MSDH as a result of a Force Majeure Event. Each bidder shall be required to ensure the delivery and receipt of its bid by the MSDH prior to the new date and time of the live auction or bid opening.

MSDH Request for Quotes-Formal (RFQF) Reverse Auction

RFx# 3140002081

INSTRUCTIONS AND SPECIAL CONDITIONS

The Mississippi State Department of Health plans to purchase the following and invites your quote/participation:

Hemoglobin Analyzers and Microcuvettes for use in clinics/locations Statewide

The Purpose of this RFQF is to advertise this competitive procurement for solicitation of formal quotes from potential bidders to participate in a Reverse Auction.

The initial response to the RFQF shall include a proposed product, including specifications and/or sample, for the MSDH to evaluate and determine responsiveness to requirements/specifications. Once a supplier's/bidder's product is determined to be responsive, the supplier/bidder may participate in the reverse auction.

Responding suppliers/bidders must provide a quote with the initial response. Quotes are utilized by the purchasing agent to determine market pricing and set the auction parameters (e.g., Start Price).

Valid quotes will be accepted until 3:00 PM, CST, February 19, 2021

Qualified bidders will be notified approx. 7 working days prior to the auction via email if selected to participate. Once notification has been received, bidders should logon to MAGIC to validate technical requirements prior to the Live Auction.

The anticipated time for this reverse auction, for this procurement, is scheduled to be held on Wednesday, March 10, 2021, beginning at 2:00 PM CST and end at 2:30 PM CST. All bids must be entered into the eProcurement system during the allotted timeframe to be considered however, the MSDH reserves the right to extend the auction date if necessary to complete prequalifications. In addition, no vendor/supplier may be prohibited from participating in the reverse auction in person by paper through surrogate bidding.

Suppliers should be advised that no award will automatically result from a reverse auction, and that the MSDH will review the results of the auction and make a determination in a timely manner.

Vendors/bidders must be registered in MAGIC in order to receive a User ID and Password to log in. Vendors who are new to MAGIC may visit the Vendor information page on State of MS, Department of Finance and Administration's web site, or register online, Vendor Registration.

To Log into MAGIC, open the following URL: https://portal.magic.ms.gov/irj/portal. Enter User ID and Password. The password is case sensitive.

Vendors/bidders are responsible for ensuring Technical Requirements are met for participating in the reverse auction, etc. Technical Requirements are listed below:

Technical Requirements

Bidders are responsible for ensuring technical requirements are met.

Acceptable Internet Browser(s)

- Microsoft Internet Explorer (IE) version 11
- Microsoft Edge
- Google Chrome versions 49 and above

Unsupported Internet Browser(s)

- Microsoft Internet Explorer (IE) version 10 or below
- Safari
- Firefox

Note: Pop-up blocker must be turned off.

MSDH-RFx # 3140002081 SPECIFICATION SHEET

Hemoglobin Analyzer and Microcuvettes

A.
A.1 Prospective device must be CLIA Waived.

B. General Specifications-Analyzer
B.1 All devices purchased must be new and model currently in production. Refurbished or demonstrator units are not acceptable. Instrument name and model must be listed.
B.2 The vendor must guarantee manufacturer replacement units for defective units for first 5 years.
B.3 All units must include a physical set of operating manual and brochures.
B.4 All units must include training and education program to all sites as well as refresher trainings at no cost.
B. 5 Testing sample size must be 10µl or less.
B. 6 Measuring range must be Hgb: 0-25.6 g/dL.
B.7 Measuring time must be 30 seconds or less.
B. 8 Unit must provide memory for no less than 100 test results.
B. 9 Unit must include AC adapters and DC battery options.
B. 10 Unit must have internal self check no less than each time unit is powered on.
B. 11 Units will be delivered to WIC Central Office, Ridgeland, MS with no shipping cost.

C. General Specifications-Microcuvettes
C.1 Expiration date at time of shipment must be greater than 18 months.
C.2 Expiration date after opening must be greater than or equal to 90 days.
C. 3 Guaranteed pricing of microcuvette supplies for 5 years.

The specifications listed are the minimum required for this RFQ-F Reverse Auction. They are not intended to limit competition nor specify any particular bidder/respondent, but to ensure that the MSDH receives a quality product meeting the needs of the agency.

Response/Quote

BID FORM

RFx 3140002081

Hemoglobin Analyzer - Name and Model # _____

Estimated Quantity – Initial Purchase: 230 Each $_____/EA

Guaranteed Pricing for any NEW/Additional units purchased during a five year period: $_____/EA

Microcuvettes - Name and Product # _____

Estimated Quantity – Five Year Period: 4500 Boxes/200 PER Box $_____/BOX

(Orders to be placed approx. (3) times per year for approx. 300 Boxes)

Name of Company_____

Quoted By_____

Signature_____

Email_____

Telephone_____

By signing this Bid Form, the company representative certifies that he/she has authority to bind the company and has thoroughly read and understands this RFQF Reverse Auction and the attachments herein and that the company meets all requirements/specifications and agrees to all provisions of this solicitation and any issued addenda.

MSDH Anticipated Initial Shipping List for Analyzers: RFx 3140002081

		Quantity	Address				
Northern Region 1	Nutritionist	25	Yalobusha County Health Dept.	645 S. Main Street	Water Valley	MS	38965
	"	22	Northern Region I Office	532 S. Church Street	Tupelo	MS	38802
	"	21	Northern Region I Annex	2600 Browning Rd.	Greenwood	MS	38930
Central Region 2	"	20	Starkville Food Center	1203 Louisville St	Starkville	MS	39759
	"	19	Lauderdale County Health Dept.	5224 Valley Street	Meridian	MS	39304
	"	22	Central Region 2 Office	4800 McWillie Circle	Jackson	MS	39206
Southern Region 3	"	23	Adams County Health Dept.	415 Hwy 61 N	Natchez	MS	39120
	"	14	Southern Region - Hattiesburg	208 W. Pine Street, Suite 100	Hattiesburg	MS	39401
	"	14	Southern Region 3 Office	1141 Bayview Ave., Suite 102	Biloxi	MS	39530
WIC Shipping & Receiving	Percy Catchings	50	WIC Central Warehouse	249 West Mitchell Street	Jackson	MS	39213
Total		230					

MISSISSIPPI STATE DEPARTMENT OF HEALTH

MISSISSIPPI STATE DEPARTMENT OF HEALTH
MAGIC RFx#3140002081
for
Hemoglobin Analyzers and Microcuvettes

AMENDMENT #3 - ATTACHMENT A
Solicitation Questions and Answers

	QUESTIONS	ANSWERS
1.	Are the specifications listed in the MSDh0RFX #3140002081(in section AA 1; section B.B. 1 – B10 and section C.C1 = C3) mandatory specifications?	Yes
2.	What is the process for protesting after the award for MSDH -RFX 3140002081?	This is reverse auction request. The vendors submit quotes and the program reviews if they meet the requirements. We then do open auction on or around Wednesday, March 10, 2021. The vendor with the lowest bid will win the auction.
3.	Can a responding supplier to MSDH RFX 3140002081 submit two unique bid responses? If so, please explain the process to do so.	This is up to the vendor.

EXHIBIT 2

MISSISSIPPI STATE DEPARTMENT OF HEALTH

TRANSMITTED BY E-MAIL AND U.S. MAIL

June 22, 2021

Mark Bellwood
Director of Sales, Specialty Markets
HemoCue America
250 S. Kraemer Blvd.
Brea, CA 928821
mark@hemocue.com

Re: Response to Protest regarding Request for Quotes- Formal (RFQF) Reverse Auction RFx 3140002081 for Hemoglobin Analyzers and Microcuvettes

Dear Mr. Bellwood:

The Mississippi State Department of Health (MSDH) is in receipt of your protest dated April 26, 2021. After consideration thereof as well as the relevant facts and circumstances, MSDH denies your protest and would show the following in support thereof.

STATEMENT OF RELEVANT FACTS

On October 1, 2020, MSDH issued RFx 3140002081 Request for Quotes-Formal (RFQF) Reverse Auction seeking bids for the purchase of Hemoglobin Analyzers and Microcuvettes. MSDH included a list of specifications for the analyzer and microcuvettes. *See MSDH-RFx # 3140002081 Specification Sheet Attached hereto as Exhibit A*. Questions were to be submitted by February 12, 2021, and answers were provided to the offerors on February 24, 2021. After Amendments and weather delays, the bids were submitted by March 19, 2021.

MSDH received bids from two vendors. EKF Diagnostics proposed the Hemo Control Analyzer Model #3040-0010-0218 and HemoCue submitted two hemoglobin analyzers, the HCAM Hb 201+ and Hb 301.

Each submission was reviewed for responsiveness. To ensure that the models submitted met MSDH needs, on March 31, 2021, Kevin Pearson emailed each vendor a copy of the list of specifications and requested that the vendors, "provide a response for each specification as listed on the attached specification sheet and return by email for further review." Each vendor was asked to respond by April 2, 2021. *See emails to EKF Diagnostics and HemoCue attached here to as composite Exhibit B.*

EXHIBIT 3

Based on the response provided by EKF, MSDH determined that the analyzer could meet the specifications of B.7 if the test were performed correctly and deemed the analyzer responsive to the request. The vendors were notified that the reverse auction would take place on April 20, 2021, at 9:00 A.M. CST.

On April 19, 2021, on the eve on the reverse auction, an email from Mark Bellwood, was sent to Kevin Pearson asking how to "challenge" the disqualification of the 201. Mr. Pearson was not available on April 19, however, he responded to the request for protest regulations on April 20, 2021, prior to the reverse auction.

MSDH proceeded with the reverse auction as scheduled. HemoCue was informed via email correspondence that it did not win the reverse auction.

HemoCue filed a protest on April 26, 2021, with a random list of EKF products and their functionality arguing that the EKF products did not meet specifications. The protest requests that MSDH vacate its award to EKF because HemoCue alleges that the Hb 301 is the only analyzer that can meet MSDH specifications and that the disqualification of the 201+ was erroneous and prejudicial. HemoCue further requests that MSDH directs the contract award in its favor as the only offeror capable of meeting MSDH specifications.

HemoCue's arguments are incorrect, and it is in the best interest of the State to award to the vendor which proved to be both responsive and the winner of the reverse auction.

DISCUSSION

The decision regarding responsiveness of each product submitted was based on certifications and clarifications provided by each vendor. HemoCue cannot challenge the results of its own statements.

Each vendor completed and submitted a Bid Form signed by the company representative. A statement at the bottom form clearly states that the by signing the form, the company representative certifies that, "the company meets all requirements/specifications and agrees to all provisions of this solicitation and any issued addenda." Mr. Pearson specifically asked each vendor to provide information to clarify their responses regarding the required specifications.

On March 31, 2021, HemoCue provided a written response as requested for the 201+ and the 301 products and EKF provided its response on April 1, 2021.

The responses to each specification objected to by HemoCue in this protest are as follows:

EKF Hemoglobin Analyzer and Microcuvettes

No.	Specification	EKF Response
B.5	Testing sample size must be 10ul or less.	Hemo Control Cuvette sample size is 8uL
B.6	Measuring range must be Hgb: 0-25.6 g/dL.	Hemo Control measuring range is 0-25.6 g/L.
B.7	Measuring time must be 30 seconds or less.	The Hemo Control Analyzer measures hemoglobin and provides a calculated hematocrit. ***The measuring time for one sample can be as quick as 25 seconds, if performed correctly, or up to 60 seconds if performed incorrectly*** or if the hemoglobin concentration is high. (Emphasis added)

HemoCue Hb 301

No.	Specification	HemoCue Response
B.5	Testing sample size must be 10ul or less.	Yes
B.6	Measuring range must be Hgb: 0-25.6 g/dL.	Yes
B.7	Measuring time must be 30 seconds or less.	Yes

HemoCue Hb 201+

No.	Specification	HemoCue Response
B.5	Testing sample size must be 10ul or less.	Yes
B.6	Measuring range must be Hgb: 0-25.6 g/dL.	Yes
B.7	Measuring time must be 30 seconds or less.	*No.* (Emphasis Added)

(See also Email responses from HemoCue and attached hereto as EFX Exhibits C and D.)

Upon further review of the bids and the foregoing responses, MSDH disqualified HemoCue's 201+ as nonresponsive. The 301 was deemed responsive and allowed to proceed to the reverse auction. HemoCue was informed of this decision on April 8, 2021. HemoCue thanked MSDH for the notification and did not protest the disqualification. (See Exhibit E.)

MSDH addressed concerns raised by HemoCue in its protest prior to making a final determination regarding responsiveness. Specifically, MSDH proactively asked for further clarification regarding the specifications. Based on the vendors' responses, MSDH determined that HemoCue's 201+ was the only product that did not meet all specifications as required and the 201+ was disqualified. EKF provided an explanation of its analyzer's function in its response B.7. After consideration of EKF's statement, MSDH determined the EKF product met MSDH specifications. Nothing prohibited HemoCue from providing an explanation of its responses. It chose not to provide any additional information for consideration at that time and is prohibited from doing so now.

MSDH proactively requested additional information from each vendor. Each vendor had an opportunity to respond and provide any additional information. MSDH accepts both HemoCue and EKF's responses as accurate and truthful. The 201+ was disqualified based on the vendor's response, and therefore, was neither erroneous nor prejudicial. Further, if HemoCue truly believed that the 301 was the only product that met MSDH specifications, it should have filed its protest upon notification that the 201+ had been disqualified, or at least notified MSDH of its belief that the 301 was a sole source.

Based on the foregoing information, MSDH sustains its findings that all products met specifications except the Hb 201+ and affirms the results of the reverse auction.

DECISION

For these reasons, the protest submitted by HemoCue is DENIED.

In accordance with OPSCR Rule 7-112.04 *Right to Appeal*, you may appeal this decision to the Public Procurement Review Board within seven (7) calendar days of receipt of this Protest Decision. Any appeal of this decision must follow OPSCR Rule 7-112 *Protest of Solicitations and Awards* found at https://www.dfa.ms.gov/media/9413/pprb-opscr-rules-and-regulations-efficetive-01182020.pdf.

Sincerely,

Thomas Dobbs, MD, MPH
State Health Office
Mississippi State Department of Health

cc: Pat Breheny, EKF Diagnostics, PatBreheny@ekfdiagnostics.com
Brittney Thompson, Director, OPSCR

EKF HEMO CONTROL

EXHIBIT 4

EKF
Hemo Control Analyzer

Response/Quote
BID FORM

RFx 3140002081

Hemoglobin Analyzer - Name and Model # Hemo Control Analyzer Model # 3040-0010-0218

Estimated Quantity – Initial Purchase: 230 Each $$400.00 /EA

Guaranteed Pricing for any NEW/Additional units purchased during a five year period: $$400.00 /EA

Microcuvettes - Name and Product # Hemo Control Microcuvetts # 3000-3012-0765

Estimated Quantity – Five Year Period: 4500 Boxes/200 PER Box $ 165.00 /BOX

(Orders to be placed approx. (3) times per year for approx. 300 Boxes)

Name of Company EKF Diagnostics Inc. dba Stanbio Laboratory

Quoted By Pat Breheny

Signature Pat Breheny

Email patbreheny@ekfdiagnostics.com

Telephone 210-601-5252

By signing this Bid Form, the company representative certifies that he/she has authority to bind the company and has thoroughly read and understands this RFQF Reverse Auction and the attachments herein and that the company meets all requirements/specifications and agrees to all provisions of this solicitation and any issued addenda.

MISSISSIPPI STATE DEPARTMENT OF HEALTH

February 4, 2021

MEMORANDUM

TO: Bidders –Hemoglobin Analyzers and Microcuvettes

FROM: Cynthia Brasher, Purchasing Director
Support Services

AMENDMENT #1 TO REQUEST FOR QUOTES-FORMAL (RFQF) REVERSE AUCTION RFx #3140002081

This correspondence is to make corrections/changes to the Mississippi State Department of Health RFQF Reverse Auction mentioned above for Hemoglobin Analyzers and Microcuvettes, due on February 19, 2021.

Corrections/changes have been made to the REQUEST FOR QUOTES-FORMAL (RFQF) REVERSE AUCTION RFx 3140002081 section as follows:
Page 3, Paragraph 4, "Sealed quotes/responses will be accepted/received until 3:00 PM, CST, Friday, February 12, 2021" has been changed to: "Sealed quotes/responses will be accepted/received until 3:00 PM, CST, Friday, February 19, 2021"

Please make the necessary corrections/changes in your bid packet.

Please include a "signed/acknowledged" copy of this amendment with your quote/response submission.

Acknowledgement/Signature Pat Buckley 3-1-21

MISSISSIPPI STATE DEPARTMENT OF HEALTH

February 22, 2021

MEMORANDUM

TO: Bidders – Hemoglobin Analyzers and Microcuvettes

FROM: Cynthia Brasher, Purchasing Director
Support Services

AMENDMENT #2 TO REQUEST FOR QUOTES-FORMAL (RFQF) REVERSE AUCTION RFx 3140002081

This correspondence is to make changes to the Mississippi State Department of Health RFQF Reverse Auction mentioned above for Hemoglobin Analyzers and Microcuvettes, that was due on February 19, 2021.

The due date for the quotes/responses of 3:00 PM, CST, February 19, 2021 has been changed to 3:00 PM, CST, March 5, 2021.

The anticipated time for the reverse auction of Wednesday, March 10, 2021 beginning at 2:00 PM CST and end at 2:30 PM CST, has been changed to Friday, March 19, 2021 beginning at 2:00 PM CST and end at 2:30 PM CST.

MSDH response to Vendor questions, that were received by the stated deadline in the IFB, will be posted 2/23/2021.

Please make the necessary changes in your bid packet.

Please include a "signed/acknowledgement" copy of this amendment with your quote/response submission.

Acknowledgement/Signature Pat Brasher 3-1-21

570 East Woodrow Wilson • Post Office Box 1700 • Jackson, Mississippi 39215-1700
601/576-8090 • 1-866-HLTHY4U (1-866-458-4948) • www.HealthyMS.com

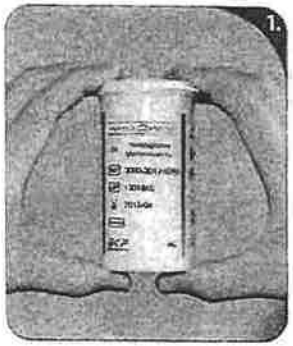
MISSISSIPPI STATE DEPARTMENT OF HEALTH
MAGIC RFx#3140002081
for
Hemoglobin Analyzers and Microcuvettes

AMENDMENT #3 - ATTACHMENT A
Solicitation Questions and Answers

	QUESTIONS	ANSWERS
1.	Are the specifications listed in the MSDh0RFX #3140002081(in section AA 1; section B.B. 1 – B10 and section C.C1 = C3) mandatory specifications?	Yes
2.	What is the process for protesting after the award for MSDH -RFX 3140002081?	This is reverse auction request. The vendors submit quotes and the program reviews if they meet the requirements. We then do open auction on or around Wednesday, March 10, 2021. The vendor with the lowest bid will win the auction.
3.	Can a responding supplier to MSDH RFX 3140002081 submit two unique bid responses? If so, please explain the process to do so.	This is up to the vendor.

Pat Buchy 3-1-21

MSDH EKF
5



DE

⚠ Achtung!
Sicherheitshinweise für die Lagerung und Handhabung von Hemoglobin Microcuvettes

Hemoglobin Microcuvettes sind zur **quantitativen Bestimmung von Hämoglobin im Blut und nur für die Verwendung mit folgenden Geräten bestimmt:**
Hemo Control, Hemo Control Manager, Hemo Vet, Hemo Vet Manager. Die Mikroküvetten dürfen nur durch qualifiertes Fachpersonal verwendet werden.

Für weitere Informationen beachten Sie die Bedienungsanleitung des jeweiligen Gerätes.

Die Küvetten sind ausschließlich in der Originalverpackung bei 15°C bis 30°C zu lagern. Originalverschlossene Dosen sind bis zum aufgedruckten Haltbarkeitsdatum verwendbar. Nach dem Öffnen der Dose sind die Küvetten bei korrekter Handhabung 3 Monate unter den angegebenen Bedingungen stabil.

Nehmen Sie nur eine Küvette auf einmal aus der Dose. Verschließen Sie die Dose sofort nach Entnahme der Küvette wieder sorgfältig **(siehe Abb. 1.)**. Vergewissern Sie sich, dass der Deckel der Küvettendose immer rundherum komplett verschlossen ist **(siehe Abb. 2.)**.
Ist der Deckel nicht komplett verschlossen **(siehe Abb. 3.)**, kann Feuchtigkeit in die Dose eindringen und die Reagenzien in der Küvette zerstören. Die Verwendung solcher Küvetten kann zu fehlerhaften Ergebnissen führen. Verwenden Sie niemals Küvetten aus einer Dose, die nicht korrekt verschlossen war!

IT

⚠ Attenzione!
Indicazioni di sicurezza per la conservazione e la manipolazione delle Hemoglobin Microcuvettes

Le Hemoglobin Microcuvettes servono alla determinazione quantitativa dell'emoglobina nel sangue e devono essere utilizzate esclusivamente con gli strumenti elencati di seguito:
Hemo Control, Hemo Control Manager, Hemo Vet, Hemo Vet Manager. Le microcuvette devono essere utilizzate esclusivamente da personale qualificato.

Per ulteriori informazioni consultare il manuale d'uso dello strumento specifico.

Le cuvette devono essere conservate esclusivamente nella confezione originale ad una temperatura compresa tra 15°C e 30°C. I flaconi originali sigillati possono essere utilizzati fino alla data di scadenza stampata sulla confezione. Dopo l'apertura del flacone, le cuvette sono stabili per 3 mesi se utilizzate correttamente e conservate nelle specifiche condizioni.
Togliere dal flacone una cuvetta alla volta. Richiudere accuratamente il flacone subito dopo aver prelevato la cuvetta **(vedere fig. 1.)**. Accertarsi che il coperchio del flacone delle cuvette sia sempre ben chiuso tutt'intorno **(vedere fig. 2.)**.
Se il coperchio non è completamente chiuso **(vedere fig. 3.)**, l'umidità può penetrare nel flacone e deteriorare i reagenti nella cuvetta. L'impiego di tali cuvette può portare a risultati errati. Non utilizzare cuvette di un flacone che non è stato chiuso correttamente!

FR

⚠ Attention!
Consignes de sécurité relatives au stockage et à la manipulation de Hemoglobin Microcuvettes

Hemoglobin Microcuvettes sont destinées à mesurer le taux d'hémoglobine dans le sang et doivent être utilisées exclusivement avec les appareils suivants:
Hemo Control, Hemo Control Manager, Hemo Vet, Hemo Vet Manager. Les microcuvettes ne doivent être utilisées que par un personnel qualifié.

Consulter le manuel d'utilisation de l'appareil concerné pour de plus amples informations.

Les microcuvettes doivent être stockées uniquement dans leur emballage d'origine et à une température ambiante de 15°C à 30°C. Les boîtes fermées d'origine peuvent être utilisées jusqu'à la date de péremption imprimée sur l'étiquette. Une fois la boîte ouverte, les cuvettes sont stables durant 3 mois à condition qu'elles soient manipulées correctement et aux températures ambiantes indiquées.
Ne retirer qu'une seule cuvette à la fois de la boîte. Une fois la cuvette retirée de la boîte, refermer le couvercle **soigneusement (voir la fig. 1.)**. **S'assurer que le couvercle est refermé de façon complètement hermétique sur toute la circonférence de la boîte (voir la fig. 2.)**.
Si le couvercle n'est pas hermétiquement fermé **(voir la fig. 3.)**, l'humidité risque de pénétrer dans la boîte et endommager les réactifs secs tapissant les cuvettes. L'utilisation de cuvettes ainsi détériorées provoque des résultats erronés. Ne jamais utiliser de cuvettes provenant d'une boîte qui n'a pas été correctement fermée!

PT

⚠ Atenção!
Instruções de segurança para conservação e manuseamento de Hemoglobin Microcuvettes

As Hemoglobin Microcuvettes destinam-se à determinação quantitativa de hemoglobina no sangue e para utilização exclusiva com os dispositivos seguintes:
Hemo Control, Hemo Control Manager, Hemo Vet, Hemo Vet Manager. Apenas pessoal qualificado pode utilizar as microcuvetes.

Para mais informações, consulte o manual do operador do respectivo equipamento.

As cuvetes têm de ser armazenadas exclusivamente na sua embalagem original, entre 15°C a 30°C. As cuvetes fechadas nas latas de origem podem ser utilizadas até à data de validade impressa na lata. Após abertura da lata, as cuvetes ficam estáveis durante 3 meses, desde que correctamente manuseadas e sob as condições indicadas.
Retire apenas uma única cuvete da lata. Feche a lata imediata e cuidadosamente após retirada a cuvete **(veja fig. 1.)**. Verifique se a tampa da lata de cuvetes está sempre hermeticamente fechada, em toda a volta **(veja fig. 2.)**.

Se a tampa não ficar hermeticamente fechada **(veja fig. 3.)**, a humidade pode penetrar na lata, destruindo os reagentes na cuvete. A utilização de tais cuvetes pode provocar resultados errados. Nunca utilize cuvetes provenientes de latas não correctamente fechadas!

ES

⚠ ¡Atención!
Instrucciones de seguridad para la conservación y manipulación de Hemoglobin Microcuvettes

Hemoglobin Microcuvettes están indicadas para la determinación cuantitativa de hemoglobina en la sangre, y sólo deben usarse con los equipos siguientes:
Hemo Control, Hemo Control Manager, Hemo Vet, Hemo Vet Manager. Solamente el personal cualificado debe utilizar las microcubetas.

Para más información, ver las instrucciones de manejo del equipo correspondiente.

Las cubetas deben conservarse exclusivamente en su envase original, de 15°C a 30°C. Los frascos con el cierre original se pueden utilizar hasta la fecha de caducidad impresa. Tras abrir el frasco, y con una manipulación correcta, las cubetas se mantienen estables hasta 3 meses, en las condiciones mencionadas.

Saque cada vez sólo una cubeta del frasco. Cierre el frasco con cuidado inmediatamente tras extraer la cubeta **(ver Fig. 1.)**. **Asegúrese de que la tapa del frasco de cubetas esté siempre completamente cerrada en todo su entorno (ver Fig. 2.)**.
Si la tapa no está completamente cerrada **(ver Fig. 3.)** puede penetrar humedad en el frasco y estropear los reactivos de la cubeta. La utilización de estas cubetas puede llevar a la obtención de resultados erróneos. ¡No utilice nunca cubetas que procedan de un frasco que no estuviera convenientemente cerrado!

NL

⚠ Let op!
Veiligheidsvoorschriften voor de opslag en manipulatie van Hemoglobin Microcuvettes

Hemoglobin Microcuvettes zijn bestemd voor kwantitatieve bloedhemoglobinebepaling met uitsluitend de volgende instrumenten:

Hemo Control, Hemo Control Manager, Hemo Vet, Hemo Vet Manager. De microcuvetten mogen alleen worden gebruikt door deskundig personeel.

Raadpleeg de gebruiksaanwijzing van de betreffende instrumenten voor meer informatie.

Bewaar de cuvetten uitsluitend in de oorspronkelijke verpakking bij 15°C - 30°C. De ongeopende container mag worden gebruikt tot aan de houdbaarheidsdatum op de container. Na opening van de container zijn de microcuvetten nog stabiel gedurende 3 maanden, indien de juiste opslag- en manipulatievoorwaarden in acht worden genomen.
Neem telkens slechts één microcuvet tegelijk uit de container. Sluit de container goed af na het uitnemen van een microcuvet **(zie afb. 1.)**. Zorg ervoor dat de deksel altijd helemaal rondom goed afsluit **(zie afb. 2.)**.

Als de container niet goed is afgesloten **(zie afb. 3.)**, kan vocht uit de lucht het reagens beïnvloeden. Het gebruik van dergelijke cuvetten kan leiden tot foutieve testresultaten. Gebruik nooit microcuvetten uit een container die mogelijk niet goed afgesloten is geweest!

EN

⚠ Attention!
Safety requirements for storage and handling of Hemoglobin Microcuvettes

Hemoglobin Microcuvettes are intended to be used for quantitative determination of hemoglobin in blood and to use only with the following devices:
Hemo Control, Hemo Control Manager, Hemo Vet, Hemo Vet Manager. The microcuvettes must only be used by qualified personnel.

For further information refer to the user manual of the respective device.

Store the cuvettes exclusively in their original packing at 15 °C to 30 °C. The unopened container can be used until the expiry date printed on it. Once the container is opened, the microcuvettes are stable for 3 month under specified conditions and correct handling.

Remove only one microcuvette at a time from the container. Properly close the container immediately after taking out a microcuvette **(see fig. 1.)**. Make sure that the lid is carefully closed all around at any time **(see fig. 2.)**.

If the lid is not properly closed **(see fig. 3.)**, humidity can intrude into the container and the reagent is deteriorated. The use of such cuvettes can lead to erroneous results. Never use microcuvettes from a container which was not properly closed!

SV

⚠ Varning!
Säkerhetsanvisningar för lagring och hantering av Hemoglobin Microcuvettes

Hemoglobin Microcuvettes är avsedda att användas för fastställande av hemoglobin i blod, och för användning endast med följande apparater:
Hemo Control, Hemo Control Manager, Hemo Vet, Hemo Vet Manager. Mikrokuvetterna får endast användas av kvalificerad yrkespersonal.

För ytterligare information var god beakta bruksanvisningen för respektive apparat.

Kuvetterna får endast förvaras i sin originalförpackning vid temperaturer från 15°C till 30°C. Originalförslutna burkar kan användas ända fram till det befintliga hållbarhetsdatumet. Efter att en burk har öppnats förblir kuvetterna stabila under 3 månader under förutsättning att de hanteras **korrekt under här angivna betingelser.**
Tag endast ut en kuvett åt gången ur burken. Återförslut burken noggrant efter uttagande av en kuvett (se ill. 1.). Säkerställ att locket av kuvettburken är fullständigt och tätt förslutet runt om (se ill. 2.).

Ifall locket ej tillsluts fullständigt **(se ill. 3.)** kan fukt tränga in i burken vilket kan leda till att reagenserna i kuvetterna förstörs. **Användning** av sådana kuvetter kanleda till felaktiga resultat. Använd aldrig kuvetter som härstammar ur en burk som ej varit korrekt tillsluten!

NO

⚠ OBS!
Sikkerhetsinstrukser for lagring og håndtering av Hemoglobin Microcuvettes

Hemoglobin Microcuvettes er kun ment brukt til bestemmelse av hemoglobin i blod og må kun brukes i forbindelse med følgende apparater:

Hemo Control, Hemo Control Manager, Hemo Vet, Hemo Vet Manager. Mikrokuvettene får kun benyttes av kvalifisert fagpersonal.

For ytterligere informasjoner ber vi deg se bruksanvisningen til de respektive apparatene.

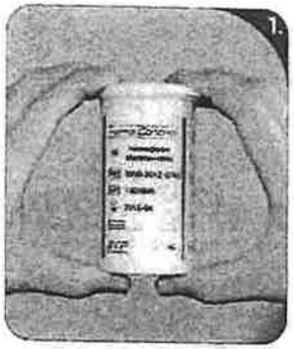
Kuvettene må kun lagres i originalemballasjen ved 15°C til 30°C. Lukkete originalbokser er holdbare til den datoen er påskrevet. Etter at bokser er åpnet er kuvettene stabile i de oppgitte betingelsene i 3 måneder hvis de behandles riktig.

Ta kun en kuvett om gangen ut av boksen. Lukk boksen godt igjen straks etter at kuvetten er tatt ut (se fig. 2.). Forsikre deg om at lokket til kuvettboksen alltid er helt lukket (se fig. 2.).

Hvis lokket ikke er helt lukket (se fig. 3.), kan fuktighet trenge inn og ødelegge reagensene i kuvettene. Bruk av slike kuvetter kan medføre feilaktige resultater. Benytt aldri kuvetter fra en boks som ikke var korrekt lukket!

EKF DIAGNOSTICS

Hemo Control
Hemoglobin Microcuvettes



EL ⚠ Προσοχή!
Υποδείξεις ασφαλείας για την αποθήκευση και το χειρισμό των Hemoglobin Microcuvettes

Οι Hemoglobin Microcuvettes προορίζονται για τον ποσοτικό καθορισμό της αιμοσφαιρίνης στο αίμα και για χρήση μόνο με τις εξής συσκευές:

Hemo Control, Hemo Control Manager, Hemo Vet, Hemo Vet Manager. Οι μικροκυβέτες πρέπει να χρησιμοποιούνται μόνο από εξειδικευμένο προσωπικό.

Για περισσότερες πληροφορίες ανατρέξτε στις οδηγίες χρήσης της εκάστοτε συσκευής.

Οι κυβέτες πρέπει να διατηρούνται αποκλειστικά στην αρχική συσκευασία στους 15°C με 30°C. Ο κατασκευαστής επιτρέπει την χρήση των κυβετών μέχρι την αναγραφόμενη ημερομηνία με την προϋπόθεση πως η συσκευασία δεν μένει ανοικτή. Μετά την αποσφράγιση της συσκευασίας, οι κυβέτες είναι κατάλληλες για χρήση για 3 μήνες εφόσον ο χειρισμός τους έχει γίνει σύμφωνα με τις οδηγίες του κατασκευαστή. Κάθε φορά αφαιρέστε από την συσκευασία μια κυβέτα. Κατόπιν κλείστε προσεκτικά το κουτί **(βλέπε σχήμα 1.)**. Βεβαιωθείτε ότι το καπάκι έχει σφραγίσει πλήρως το κουτί **(βλέπε σχήμα 2.)**.

Αν το καπάκι δεν είναι ερμητικά κλειστό **(βλέπε σχήμα 3.)**, ενδέχεται να διεισδύσει υγρασία και να καταστρέψει το αντιδραστήριο στην κυβέτα. Αν αυτές οι κυβέτες χρησιμοποιηθούν μπορεί να βγουν λάθος αποτελέσματα. Μη χρησιμοποιείτε ποτέ κυβέτες από κουτί που δεν είναι σωστά κλεισμένο!

RU ⚠ Внимание!
Указания по технике безопасности при хранении и работе с Hemoglobin Microcuvettes

Hemoglobin Microcuvettes предназначены для определения количественного содержания гемоглобина в крови и должны использоваться только на следующих анализаторах:
Hemo Control, Hemo Control Manager, Hemo Vet, Hemo Vet Manager. Микрокюветы должны использоваться только квалифицированным персоналом.

Дополнительную информацию см. в инструкции по эксплуатации соответствующего прибора.
Хранить кюветы только в оригинальной упаковке при температуре от 15°C до 30°C. Содержимое упакованных на заводе банок годно к употреблению до указанного на них срока. После вскрытия банки кюветы могут быть использованы в течение 3 месяцев, при условии соблюдения всех условий эксплуатации.
За один раз берите из банки только одну кювету. Сразу после взятия кюветы тщательно закройте банку **(см. рис. 1.)**. Всегда проверяйте, плотно ли закрыта крышка банки с кюветами по всему периметру **(см. рис. 2.)**.

Если крышка закрыта не полностью **(см. рис. 3.)**, в банку может проникнуть влага и разрушить реактивы в кювете. Использование таких кювет может дать неправильные результаты. Ни в коем случае не используйте кюветы из неправильно закрытой банки!

DA ⚠ Bemærk!
Sikkerhedsinformationer til opbevaring og håndtering af Hemoglobin Microcuvettes

Hemoglobin Microcuvettes er beregnet til brug ved kvantitativ bestemmelse af hæmoglobin i blod og kun til brug sammen med de følgende apparater:
Hemo Control, Hemo Control Manager, Hemo Vet, Hemo Vet Manager. Mikrocuvetterne må kun anvendes af kvalificeret personale.

Yderligere oplysninger findes i betjeningsvejledningen til det pågældende apparat.
Cuvetterne skal altid opbevares i original emballage ved 15°C til 30°C. Dåser med original forsegling kan anvendes til den påtrykte holdbarhedsdato. Efter åbning af dåsen er cuvetterne ved korrekt håndtering under de angivne betingelser stabile i 3 måneder.

Tag kun en cuvette ad gangen ud af dåsen. Luk dåsen omhyggeligt igen straks efter at cuvetten er taget ud (se **fig. 1.**). Kontroller at cuvettedåsens låg altid er lukket hele vejen rundt **(se fig. 2.)**.

Er dåsen ikke helt lukket **(se fig. 3.)**, kan der trænge fugt ind i dåsen, hvilket kan ødelægge reagenserne i cuvetten. Brugen af en sådan cuvette kan medføre forkerte resultater. Brug aldrig cuvetter fra en dåse, der ikke har været lukket korrekt.

FI ⚠ Huomio!
Turvallisuusohjeet Hemoglobin Microcuvettes varastointia ja käsittelyä varten

Hemoglobin Microcuvettes on tarkoitettu käytettäväksi hemoglobiinin kvantitatiiviseen määritykseen verestä ja ainoastaan seuraavien laitteiden kanssa:
Hemo Control, Hemo Control Manager, Hemo Vet, Hemo Vet Manager. Mikrokyvettejä saa käyttää vain pätevä henkilöstö.

Katso lisätietoja vastaavan laitteen käyttöohjeesta.

Kyvetit varastoidaan alkuperäispakkauksessa lämpötilassa 15°C – 30°C. Avaamattomat purkit ovat käyttökelpoisia merkittyyn säilyvyyspäivämäärään asti. Purkin avaamisen jälkeen kyvetit säilyvät oikein käsiteltyinä ja oikein määritetyissä olosuhteissa 3 kuukautta.

Ota vain yksi kyvetti purkista kerralla. Sulje purkki jälleen huolellisesti heti kyvetin ottamisen jälkeen **(katso kuva 1.)**. Varmista, että kyvettipurkin kansi on aina täysin suljettu **(katso kuva 2.)**.

Jos kansi ei ole täysin suljettu **(katso kuva 3.)**, kosteus voi päästä purkkiin ja heikentää kyvetissä olevien reagenssien suorituskykyä. Tällaisten kyvettien käyttö voi johtaa vääriin tuloksiin. Älä käytä kyvettejä purkista, joka ei ole ollut oikein suljettu!

HR ⚠ Pozor!
Sigurnosne napomene za skladištenje i rukovanje mikrokivetama Hemoglobin Microcuvettes

Mikrokivete Hemoglobin Microcuvettes namijenjene su kvantitativnom određivanju hemoglobina u krvi te za uporabu samo sa sljedećim uređajima:
Hemo Control, Hemo Control Manager, Hemo Vet, Hemo Vet Manager. Mikrokivete smije upotrebljavati samo osposobljeno osoblje.

Za daljnje informacije obratiti pozornost na upute za uporabu konkretnog uređaja.

Kivete skladištiti isključivo u originalnoj ambalaži na temperaturi od 15°C do 30°C. Originalno neotvorene doze smiju se koristiti do otisnutog datuma roka trajanja. Nakon otvaranja doze kivete su stabilne 3 mjeseca pod navedenim uvjetima, ako se njima korektno rukuje.

Iz doze uvijek uzimati samo po jednu kivetu odjednom. Nakon uzimanja kivete dozu odmah brižljivo zatvoriti **(vidi sliku 1.)**. Uvijek provjeriti da je poklopac doze s kivetama kompletno zatvoren sa svih strana **(vidi sliku 2.)**.
Ako poklopac nije kompletno zatvoren **(vidi sliku 3.)**, u dozu može prodrijeti vlaga i razoriti reagense u kiveti. Korištenje takvih kiveta može dovesti do pogrešnih rezultata. Nikada ne koristiti kivete iz doze koja nije bila korektno zatvorena!

TR ⚠ Dikkat!
Hemoglobin Microcuvettes'in saklama ve kullanımına dair güvenlik talimatları

Hemoglobin Microcuvettes kandaki hemoglobin miktarının tespit edilmesi amacıyla kullanıma endikedir ve sadece aşağıdaki cihazlarla kullanılabilir:
Hemo Control, Hemo Control Manager, Hemo Vet, Hemo Vet Manager. Mikro küvetler sadece nitelikli personel tarafından kullanılmalıdır.

Diğer bilgiler için ilgili cihazın kullanım talimatları dikkate alınmalıdır.

Küvetler sadece orijinal ambalajında 15°C - 30°C arası sıcaklıkta muhafaza edilmelidir. Orijinal kapalı kutular, üzerinde yazılı bulunan son kullanım tarihine kadar kullanılabilir. Kutu açıldığında küvetler uygun kullanım şartlarında, belirtilen koşullarda 3 aya kadar özelliğini korur.

Kutudan sadece tek bir küvet bir defada çıkarılmalıdır. Küvet çıkarıldıktan hemen sonra kutu itinalı bir şekilde kapatılmalıdır **(bkz. şekil 1.)**. Her seferinde, kapağın etrafının tamamen kapalı olmasını kontrol edin **(bkz. şekil 2.)**.
Kapağın tamamen kapalı olmaması halinde **(bkz. şekil 3.)** kutuya nem sızıp küvetteki reaktife zarar verebilir. Bu tür küvetlerin kullanımı hatalı sonuçlara neden olabilir. Doğru şekilde kapatılmamış bir kutudan asla küvet kullanmayın!

PL ⚠ Uwaga!
Warunki bezpieczeństwa przechowywania i magazynowania Hemoglobin Microcuvettes

Hemoglobin Microcuvettes są przeznaczone do ilościowego oznaczania stężenia hemoglobiny w krwi ludzkiej i mogą być używane tylko do następujących urządzeń:
Hemo Control, Hemo Control Manager, Hemo Vet, Hemo Vet Manager. Mikrokuwety są przeznaczone do użycia tylko przez wykwalifikowany personel.

Więcej informacji znajduje się w instrukcji użytkownika poszczególnych urządzeń.

Mikrokuwety należy przechowywać wyłącznie w oryginalnych opakowaniach w temperaturze od 15°C do 30°C. Nie otworzone opakowanie może być użyte do daty ważności wydrukowanej na nim. Mikrokuwety z raz otwartego opakowania są trwałe przez 3 miesiące przy zachowaniu podanych warunków i właściwym przechowywaniu.

Za każdym razem należy wyciągnąć tylko jedną mikrokuwetę z opakowania. Natychmiast po wyciągnięciu mikrokuwety należy dokładnie zamknąć opakowanie **(patrz rys.1)**. Upewnić się, że pokrywa jest ściśle dociśnięta dookoła **(patrz rys.2)**.
Jeżeli pokrywa opakowania nie zostanie całkowicie dociśnięta **(patrz rys.3)** wówczas wilgoć może się dostać do wnętrza opakowania i pogorszyć jakość odczynników. Nigdy nie należy używać do badań mikrokuwet z opakowania, które nie zostało właściwie zamknięte pokrywą!

LT ⚠ Dėmesio!
Mikrokiuvečių „Hemoglobin Microcuvettes" laikymo ir naudojimo saugos reikalavimai

Mikrokiuvečių „Hemoglobin Microcuvettes" paskirtis – kiekybinis hemoglobino koncentracijos nustatymas žmogaus kraujyje, o jos turi būti naudojamos tik su šiais prietaisais:
Hemo Control, Hemo Control Manager, Hemo Vet, Hemo Vet Manager. Mikrokiuvetes turi naudoti tik kvalifikuotas personalas.

Daugiau informacijos žr. konkretaus prietaiso operatoriaus vadove.

Mikrokiuvetes laikykite išimtinai tik originalioje pakuotėje 15–30 °C temperatūroje. Neatidarytoje dėžutėje esančias mikrokiuvetes galima naudoti iki ant dėžutės išspausdintos galiojimo pabaigos datos. Atidarius dėžutę mikrokiuvetės lieka stabilios 3 mėnesius esant nurodytoms sąlygoms ir jas tinkamai naudojant.

Vienu metu iš dėžutės išimkite tik vieną mikrokiuvetę. Išėmę mikrokiuvetę iškart tinkamai uždarykite dėžutę **(žr. 1 pav.)**. Užtikrinkite, kad dangtelis visada būtų sandariai uždarytas **(žr. 2 pav.)**.
Jei dangtelis nebus tinkamai uždaromas **(žr. 3 pav.)**, į dėžutę gali patekti drėgmės ir gali pablogėti reagento savybės. Naudojant tokias mikrokiuvetes galima gauti klaidingus rezultatus. Niekada nenaudokite mikrokiuvečių iš dėžutės, kuri nebuvo tinkamai uždaryta!

Hemo Control hemoglobin and hematocrit analyzer

Hematology

Maternal and Women's Health

NEW
Bi-directional interface

Enhanced data management functions

Hemo Control

Accurate hemoglobin and hematocrit* results with one simple test

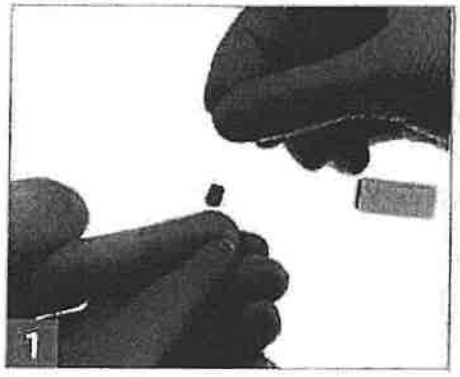
- 2 results in 1 test
- Easy to use
- Small 8 µL sample volume
- No routine maintenance required

CLIA WAIVED

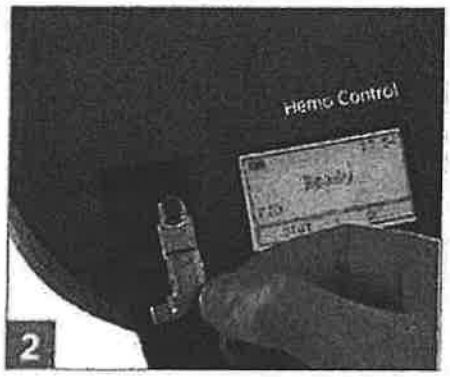
EKF Diagnostics for life

Accurate near patient testing for hemoglobin and hematocrit* meets advanced connectivity and reporting requirements

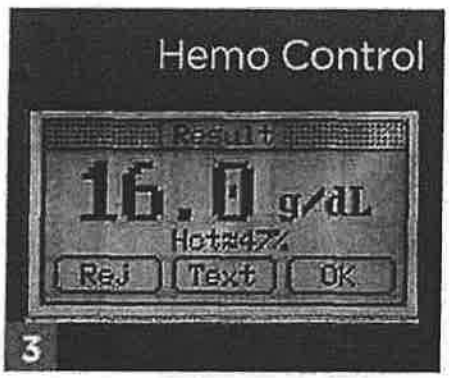
Easy to use	• User friendly features minimises training time • Step by step instructions on screen • Backlit touch screen • User selectable language menu • Soft-load cuvette holder minimizes risk of contamination
Practical and portable	• Hemoglobin and hematocrit results from one sample available in as quick as 25 seconds (and up to 60 seconds depending on the concentration) • Venous, arterial or capillary blood • Sample volume only 8 µl • Microcuvette design minimizes risk of air bubbles • Compact in size and weighing just 1.5 lbs • No maintenance required. Auto self-test • Integrated rechargeable battery (100 hours)
Accurate and reliable	• Operating ambient temperature 15°C–40°C • Photometric azide methemoglobin method • Measuring range: 0–25.6 g/dL; 0–15.9 mmol/L • Precision: CV <1.5% • Linearity: 0–20 g/dL: ±0.3 g/dL; >20 g/dL: ±0.7 g/dL • Factory-calibrated with no need for further calibration • Control cuvette included • Hematocrit range 36 – 54 % (calculated)
Data management functions	• Bidirectional interface using a standard communication protocol • Stores 4,000 patient results • Connect to PC via USB connector cable • Basic device upgradeable with data management (DM) functions: Barcode identification of patients, operators, cuvette LOT and control materials, quality control lockout function, additionally stores 500QC results • Connectible with EKF Data Management software for easy configuration and reporting



Collect blood sample.



Put microcuvette into analyser.



Result appears in 25–60 seconds.

Local Representation
EKF Diagnostics, Inc.
1261 North Main Street
Boerne, TX 78006
USA
1-800-531-5535
techsupport@ekfdiagnostics.com
www.ekfusa.com

CLIA WAIVED

Manufacturer
EKF-diagnostic GmbH
Ebendorfer Chaussee 3
39179 Barleben, Germany
+49 (0) 39203 511 0

www.ekfdiagnostics.com

EKF Diagnostics for life

*Hct result is calculated when the Hgb result is from 12 - 18 g/dL

EKF Diagnostics Inc.
1261 North Main Street
Boerne, Texas 78006
USA

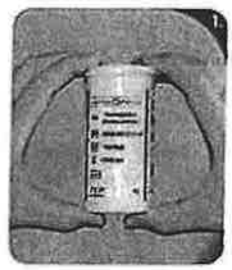
Phone: 1.830.249.0772
Email: stanbiolab@ekfdiagnostics.com
Web: www.ekfusa.com

Hemo Control Analyzer Warranty

Your Hemo Control Analyzer product is warranted against defects in material and workmanship for 5 years from the date of delivery. Stanbio Laboratory or their authorized representative will supply, free of charge, the labor and material required to repair any defects during the warranty period at a EKF/Stanbio authorized repair facility except as excluded below.

- **Warranty excludes repair of failures resulting from mishandling or abuse.**
- **Warranty excludes consumable items.**
- **Warranty does not apply to damage sustained in transit.**
- **We reserve the right to replace or repair any part which is found to be defective.**
- **Warranty service may only be performed by Stanbio Laboratory or authorized representatives.**
- **Warranty does not include shipping, freight, transportation or insurance charges to or from the Stanbio authorized repair facility.**
- **Warranty is not transferable.**

The warranties and remedies set forth above are exclusive and are in lieu of all other warranties and remedies, whether statutory, expressed or implied (including warranties of merchantability and fitness for a particular purpose and warranties arising from the course of dealing or usage of trade).



EN ⚠ Attention!

Safety requirements for storage and handling of Hemoglobin Microcuvettes.

Hemoglobin Microcuvettes are intended to be used for quantitative determination of hemoglobin in blood and to use only with the following devices:
Hemo Control, Hemo Control Manager, Hemo Vet, Hemo Vet Manager. The microcuvettes must only be used by qualified personnel.

For further information refer to the user manual of the respective device.

Store the cuvettes exclusively in their original packing at 15 °C to 30 °C. The unopened container can be used until the expiry date printed on it. Once the container is opened, the microcuvettes are stable for 3 month under specified conditions and correct handling.

Remove only one microcuvette at a time from the container. Properly close the container immediately after taking out a microcuvette (see fig. 1.). Make sure that the lid is carefully closed all around at any time (see fig. 2.).

If the lid is not properly closed (see fig. 3.), humidity can intrude into the container and the reagent is deteriorated. The use of such cuvettes can lead to erroneous results. Never use microcuvettes from a container which was not properly closed!

Hemo Control

Hemoglobin Microcuvettes

ekfdiagnostics.com

EL

RU

DA

FI

HR

TR

PL

LT

MSDH EKF
12

Hemo Control hemoglobin and hematocrit analyzer

Hematology

Maternal and Women's Health

NEW
Bi-directional interface

Enhanced data management functions

Hemo Control

Accurate hemoglobin and hematocrit* results with one simple test

- 2 results in 1 test
- Easy to use
- Small 8 µL sample volume
- No routine maintenance required

CLIA WAIVED

Diagnostics for life

Accurate near patient testing for hemoglobin and hematocrit* meets advanced connectivity and reporting requirements

Easy to use

- User friendly features minimises training time
- Step by step instructions on screen
- Backlit touch screen
- User selectable language menu
- Soft-load cuvette holder minimizes risk of contamination

Practical and portable

- Hemoglobin and hematocrit results from one sample available in as quick as 25 seconds (and up to 60 seconds depending on the concentration)
- Venous, arterial or capillary blood
- Sample volume only 8 µl
- Microcuvette design minimizes risk of air bubbles
- Compact in size and weighing just 1.5 lbs
- No maintenance required. Auto self-test
- Integrated rechargeable battery (100 hours)

Accurate and reliable

- Operating ambient temperature 15°C–40°C
- Photometric azide methemoglobin method
- Measuring range: 0–25.6 g/dL; 0–15.9 mmol/L
- Precision: CV <1.5%
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Data management functions

- Bidirectional interface using a standard communication protocol
- Stores 4,000 patient results
- Connect to PC via USB connector cable
- Basic device upgradeable with data management (DM) functions: Barcode identification of patients, operators, cuvette LOT and control materials, quality control lockout function, additionally stores 500QC results
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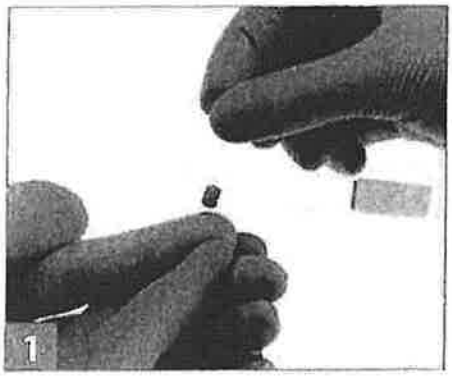
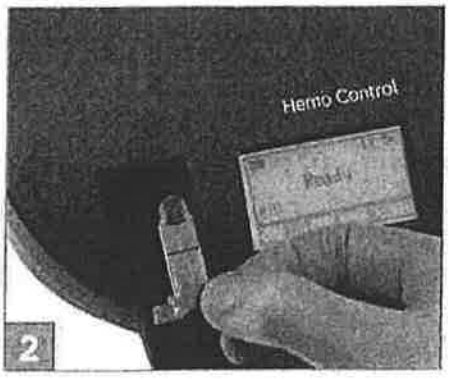


Collect blood sample.



Put microcuvette into analyser.

Result appears in 25–60 seconds.

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EKF Diagnostics for life

MSDH EKF 14

*Hct result is calculated when the Hgb result is from 12 - 18 g/dL

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Hemo Control Analyzer Warranty

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- **Warranty excludes consumable items.**
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MSDH-RFx # 3140002081 SPECIFICATION SHEET

Hemoglobin Analyzer and Microcuvettes

A.
A.1 Prospective device must be CLIA Waived
The Hemo Control Analyzer is CLIA Waived.

B. General Specifications-Analyzer
B.1 All devices purchased must be new and model currently in production. Refurbished or demonstrator units are not acceptable. Instrument name and model must be listed.
The Hemo Control Analyzer/s to be provided will be new and of current model year. Hemo Control Analyzer - Model #3040-0010-0218
B.2 The vendor must guarantee manufacturer replacement units for defective units for first 5 years. Hemo Control Analyzer will be under warranty for 5 years for replacement from award of Bid.
B.3 All units must include a physical set of operating manual and brochures. Each Hemo Control Analyzer will include a hard copy of user manual and support literature.
B.4 All units must include training and education program to all sites as well as refresher trainings at no cost. Hemo Control training, education and refreshers to be provided at no cost.
B. 5 Testing sample size must be 10µl or less. Hemo Control Cuvette sample size is 8µL.
B. 6 Measuring range must be Hgb: 0-25.6 g/dL. Hemo Control measuring range is 0-25.6 g/dL.
B.7 Measuring time must be 30 seconds or less. The Hemo Control Analyzer measures hemoglobin and provides a calculated hematocrit. The measuring time for one sample can be as quick as 25 seconds, if performed correctly, or up to 60 seconds if performed incorrectly or if the hemoglobin concentration is high.
B. 8 Unit must provide memory for no less than 100 test results. Hemo Control Analyzer stores 4000 test results in memory.
B. 9 Unit must include AC adapters and DC battery options. Each Hemo Control Analyzer includes an AC adapter as well as a built in rechargeable battery good for up to 100 hours of operation when new and fully charged.
B. 10 Unit must have internal self-check no less than each time unit is powered on. Hemo Control Analyzer performs a self-test automatically at regular intervals while the unit is powered on.
B. 11 Units will be delivered to WIC Central Office, Ridgeland, MS with no shipping cost. Hemo Control Analyzers will be delivered to the WIC Central Office in Ridgeland, MS with no charge freight.
C. General Specifications-Microcuvettes
C.1 Expiration date at time of shipment must be greater than 18 months. The Hemo Control Microcuvettes will have 18 months or better dating at time of shipment.
C.2 Expiration date after opening must be greater than or equal to 90 days. Hemo Control Analyzer Microcuvettes expire 90 days after opening canister when following proper storage and handling procedure.

C. 3 Guaranteed pricing of microcuvette supplies for 5 years. The pricing submitted for the Hemo Control Microcuvette supplies will be guaranteed for 5 years or term of the Bid, including extensions.

The specifications listed are the minimum required for this RFQ-F Reverse Auction. They are not intended to limit competition nor specify any particular bidder/respondent, but to ensure that the MSDH receives a quality product meeting the needs of the agency.

Pearson, Kevin

From: Pearson, Kevin
Sent: Tuesday, March 30, 2021 8:06 AM
To: patbreheny@ekfdiagnostics.com
Cc: Nelson, Johnny
Subject: Question
Attachments: RFx 3140002081 Specification Sheet.docx

Thank you for your submitted Response/Quote to MSDH's RFx 3140002081 for Hemoglobin items.

In reviewing your response, and all info submitted with the response, we have been unable to assure compliance with al specifications as listed in the RFx packet.

Please provide a response for each specification as listed on the attached specification sheet, and return by email for further review. Please return the requested information by Friday, April 2, 2021.

Thank you,

Kevin Pearson

Pearson, Kevin

From:	Pearson, Kevin
Sent:	Tuesday, March 30, 2021 8:10 AM
To:	customerservice@hemocue.com
Cc:	Nelson, Johnny
Subject:	Questions
Attachments:	RFx 3140002081 Specification Sheet.docx

Thank you for your submitted Response/Quote to MSDH's RFx 3140002081 for Hemoglobin items.

In reviewing your response, and all info submitted with the response, we have been unable to assure compliance with all specifications as listed in the RFx packet.

Please provide a response for each specification, as listed on the attached specification sheet, and return by email for further review. Please return the requested information by Friday, April 2, 2021.

Thank You

Kevin Pearson

Pearson, Kevin

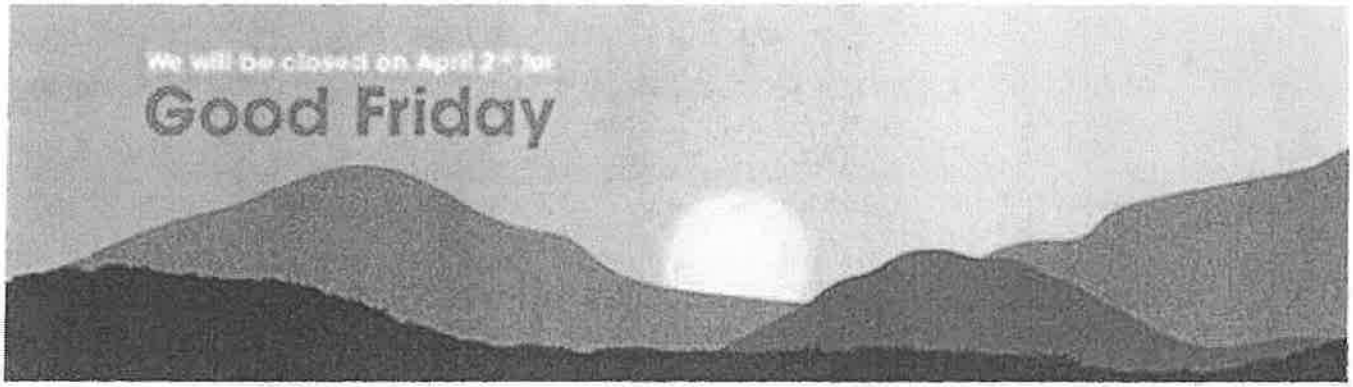
From: Pat Breheny <PatBreheny@ekfdiagnostics.com>
Sent: Thursday, April 1, 2021 5:03 PM
To: Pearson, Kevin
Subject: RE: Question
Attachments: MS RFx 3140002081 Specification Sheet Answered questions 3.31.21.docx

Kevin,
Please see our response to the documented attached for MSDH's RFx 3140002081 for Hemoglobin items.
Please let me know if you have any further questions.

Thank you,
Pat Breheny

Pat Breheny
Public Health Sales Specialist

Cell: 210-601-5252
Email: patbreheny@ekfdiagnostics.com



EKF DIAGNOSTICS STANBIO® STI

1261 North Main Street • Boerne, TX, USA 78006
Tel: 830.249.0772 • Fax: 830.249.0851 • www.stanbio.com

From: Pearson, Kevin [mailto:Kevin.Pearson@msdh.ms.gov]
Sent: Tuesday, March 30, 2021 8:06 AM
To: Pat Breheny
Cc: Nelson, Johnny
Subject: Question

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EXHIBIT 6

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Kevin Pearson

MSDH-RFx # 3140002081 SPECIFICATION SHEET

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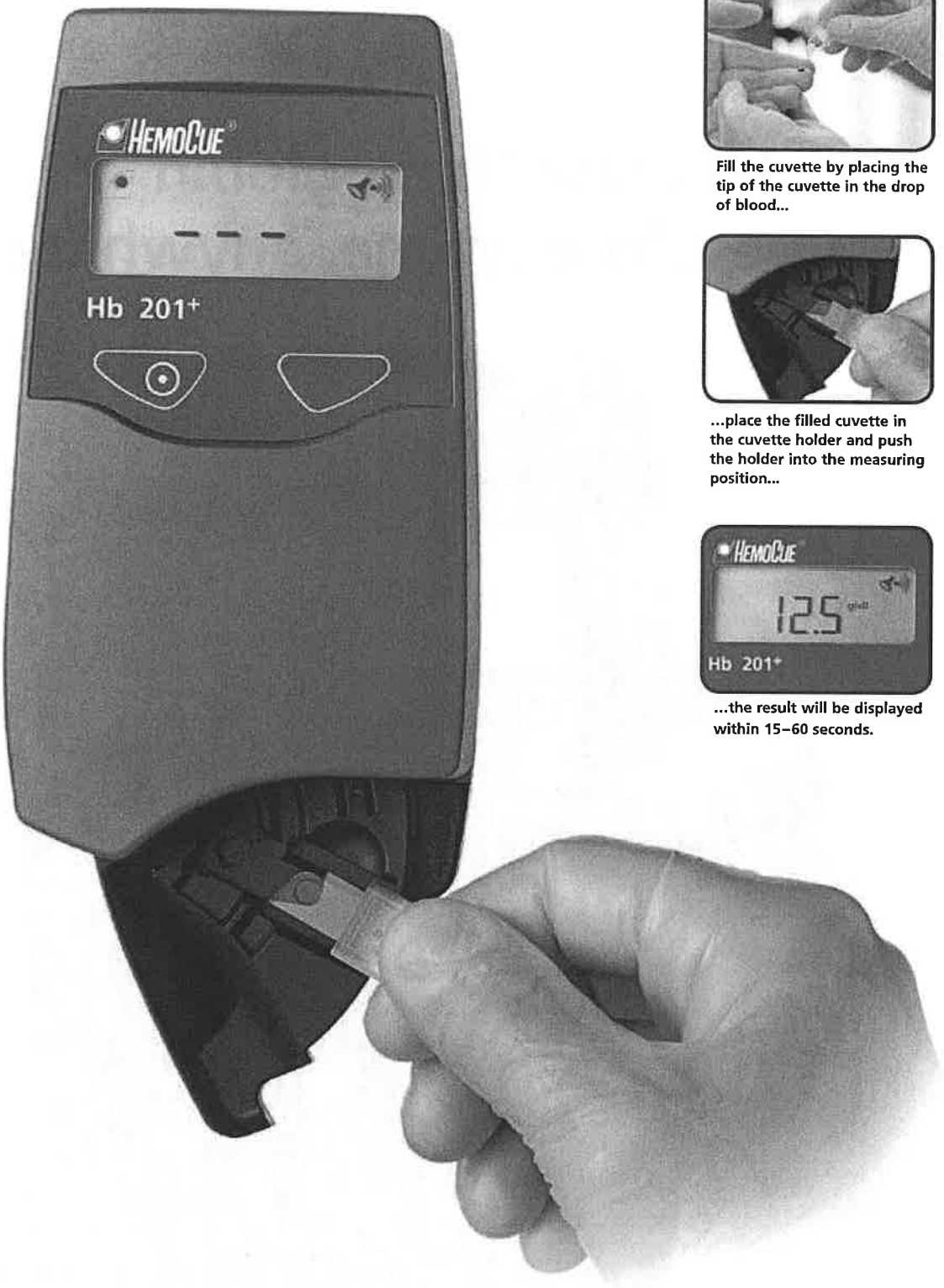
HemoCue Hb 201+ System

Accurate Hemoglobin results anytime, anywhere.

HEMOCUE®
A Quest Diagnostics Company

EXHIBIT 7



Fill the cuvette by placing the tip of the cuvette in the drop of blood...

...place the filled cuvette in the cuvette holder and push the holder into the measuring position...

...the result will be displayed within 15–60 seconds.

Excellent Precision and Accuracy.

Appreciated by users all over the world for simplicity, speed, and small sample volume, the HemoCue Hemoglobin testing systems are the long-standing original choice for lab quality hemoglobin testing at the point-of-care. The system uses a specially designed analyzer with specially designed microcuvettes.

As a hand-held analyzer, the HemoCue Hb 201+ System offers various features and benefits. The optimal cuvette packaging allows the flexibility and mobility for use of the system anytime, anywhere.

Laboratory precision and accuracy

The accuracy of the Hb 201+ System is ±1.5% when compared to the international reference method for hemoglobin (the ICSH method). Many studies also show excellent correlation with different laboratory systems. There is no need to recalibrate the instrument when new batches of cuvettes are put into use. Additionally, by measuring at two wavelengths, the system automatically compensates for turbidity (e.g. high WBC and lipids) in the sample, improving accuracy.

Lab-Accurate Performance

The HemoCue hemoglobin systems achieve precision and accuracy matching that of a central laboratory. We ensure that all products leaving our production facility meet or exceed rigorous specifications for: within lot variation, lot-to-lot variation, calibration, instrument-to-instrument variation, and total system variation.

Each of more than 400,000[1] cuvettes produced each day are inspected. Our analyzers require no recalibration. Throughout the lifetime of the analyzers, and from one cuvette lot to the next, HemoCue's testing systems remain as accurate as the day they left the factory.

Microcuvettes

Microcuvettes are packaged either in 4 vials of 50 or 4 boxes of 25 individually packaged microcuvettes.

The unique, disposable microcuvette is the heart of the HemoCue system. The correct volume of blood is drawn into the cuvette by capillary action, which initiates the reaction.

User friendly and minimal maintenance

The system is easy to learn and easy to use. After a brief instruction, even non-laboratory personnel can perform the test safely and accurately. The analyzer is factory calibrated, which is automatically verified every time the instrument is switched on. The "selftest" eliminates the need for a control cuvette. The cuvette holder design reduces the need for cleaning by minimizing the contamination of the optronic unit.

*Reimbursement

CPT Code 85018QW - $3.46 (national ceiling)

*The CPT Codes provided are for informational purposes only. CPT coding is the sole responsibility of the billing party.

[1]This number is reflective of all products.

HemoCue Hb 201+ System Specifications

System
The HemoCue Hb 201+ System consists of two parts: a disposable microcuvette containing dry reagent and a factory-calibrated analyzer. The HemoCue Hb 201+ Analyzer should only be used with HemoCue Hb 201 Microcuvettes.

Method
The Hb 201+ System uses a modification of Vanzetti's reagents, utilizing an azidemethemoglobin reaction yielding results within one minute. This method correlates well with the international reference method for hemoglobin determination (ICSH).

Analyzer
Measurements are made at two wavelengths, 570 nm for hemoglobin measurement and 880 nm for turbidity compensation.

Specimen requirement
10 µL of capillary, venous, or arterial blood are needed for the assay.

Results
Results are displayed in g/dL within 15–60 seconds depending on the hemoglobin concentration.

Measuring range
The measuring range is 0-25.6 g/dL.

Quality control
The HemoCue Hb 201+ has an internal electronic "selftest" which automatically verifies that the optronic unit of the instrument is working properly each time the analyzer is switched on and every second hour thereafter. If additional quality control testing is required for regulatory reasons, contact HemoCue, Inc. for control information.

CLIA WAIVED CLIA

Lab Quality At Your Fingertips®

HEMOCUE®
A Quest Diagnostics Company

HemoCue, Inc. • 40 Empire Drive • Lake Forest, California 92630
(800) 323-1674 • Fax (800) 333-7043 • www.hemocue.com • www.questdiagnostics.com

LIT1001 090909

CE
IVD

151712 160127

US

For US and Canadian markets only.
For other markets see last page.

HemoCue® Hb 201 Microcuvettes

The HemoCue Hb 201 Microcuvettes are designed for use with the HemoCue Hb 201+ Analyzer and the HemoCue Hb 201 DM Analyzer (referred to as the HemoCue Hb 201 Analyzer in this document). HemoCue Hb 201 Microcuvettes are available in individual packages or in vials. Please read the relevant Operating Manual for proper use of the system[1].

Intended Purpose/Intended Use

Quantitative determination of hemoglobin in capillary, venous and arterial whole blood, using a specially designed analyzer, the HemoCue Hb 201 Analyzer, and specially designed microcuvettes, the HemoCue Hb 201 Microcuvettes. HemoCue Hb 201 Microcuvettes are for *In Vitro* Diagnostic use only. The HemoCue Hb 201 Analyzer is only to be used with HemoCue Hb 201 Microcuvettes.

IVD Medical Device Directive

The HemoCue Hb 201 Microcuvettes comply with the IVD Medical Device Directive 98/79/EC and carry the CE mark

Principles of the method/procedure

Principle of the method

The reaction in the microcuvette is a modified azidemethemoglobin reaction. The erythrocytes are hemolyzed to release the hemoglobin. The hemoglobin is converted to methemoglobin and then combined with azide to form azidemethemoglobin. The measurement takes place in the analyzer in which the transmittance is measured and the absorbance and hemoglobin level is calculated. The absorbance is directly proportional to the hemoglobin concentration.

Principle of the procedure

The system consists of an analyzer together with microcuvettes. The microcuvette serves both as a pipette and as a measuring cuvette and is for single-use only. A blood sample of approximately 10 µL is drawn into the cavity by capillary action. The analyzer measures at two wavelengths in order to compensate for turbidity, and the hemoglobin level is calculated and presented. The HemoCue Hb 201 system is calibrated against the international reference method for hemoglobin determination, ICSH[3] and needs no further calibration.

Composition

The microcuvette is made of polystyrene plastic. Reagents; <600 µg/g microcuvette sodium deoxycholate, <300 µg/g microcuvette sodium azide, <300 µg/g microcuvette sodium nitrite, <350 µg/g microcuvette nonreactive ingredients.

Warning and precautions

The microcuvettes are for *In Vitro* Diagnostic use only. Always handle blood specimens with care as they may be infectious. Consult local environmental authorities for proper disposal.

Storage and handling

Use the HemoCue Hb 201 Microcuvettes prior to their expiry date. The expiry date is printed on each package.

Storage for microcuvettes kept in a vial

The microcuvettes are to be stored at room temperature (15–30 °C, 59–86 °F) and in a dry place. Once the seal is broken the microcuvettes are stable for three months. Always keep the vial properly closed.

Storage for individually packaged cuvettes

The microcuvettes are to be stored at room temperature (15–30 °C, 59–86 °F) and in a dry place.

Specimen collection and preparation

Capillary, venous or arterial blood may be used. Appropriate anticoagulants (e.g. EDTA or heparin) may be used, preferably in solid form to avoid dilutional effects. Mix all specimen tubes thoroughly on a mechanical mixer for at least 2 minutes or invert the tube 8-10 times by hand. Hemoglobin remains unchanged for days, provided that the blood does not become infected. If the specimen has been stored in a refrigerator, it will be viscid and should reach room temperature before mixing[2].

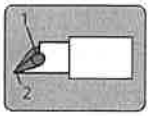
Directions for use

Materials required

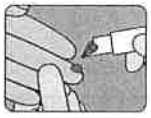
- HemoCue Hb 201 Analyzer
- HemoCue Hb 201 Microcuvettes
- Lancet (for capillary samples)
- Pipette or other transfer device (for venous, arterial or control material samples)
- Lint-free wipe (non-fraying)
- Hydrophobic surface (for venous, arterial or control material samples)

Procedure

The operating temperature of the HemoCue Hb 201 system is 15-30 °C (59-86 °F). Please read the Operating Manual for proper use of the system[1]. See relevant manual for information on repeat capillary sampling. For further information please contact HemoCue.



1. Optical eye
2. Filling end



Remove the microcuvette from the package. Close the vial. Hold the microcuvette opposite the filling end and bring into contact with the specimen, allowing the cavity to fill completely. Always avoid touching the optical eye. Do not refill the cavity of the microcuvette. Note: The microcuvette should be filled whitin 3 minutes after the microcuvette has been taken out of its package.

When collection tubes or control material are used, dispense an aliquot of the well-mixed specimen onto a hydrophobic surface. Note: The microcuvette should be filled whitin 3 minutes after the microcuvette has been taken out of its package.

Wipe off the outside of the microcuvette with a clean lint-free wipe, being careful not to touch the open end. If air bubbles are seen in the optical eye of the microcuvette, discard the microcuvette and take a new sample. Small air bubbles around the edge do not influence the result.

Place the microcuvette into the cuvette holder and start measurement as soon as possible but no later than 10 minutes after filling the microcuvette by gently pushing the cuvette holder to its measuring position. Close the cuvette holder. The measuring time is 15-60 seconds for Hb values below 20 g/dL. Pull the cuvette holder out to its loading position and discard the used microcuvette.

Quality control

The HemoCue Hb 201 Analyzer has an internal electronic selftest. Every time the analyzer is turned on, it will automatically verify the measurement performance. This test is performed at regular intervals if the analyzer remains switched on. Follow local guidelines regarding quality control procedures. If a quality control test is required by local or other regulations and therefore should be performed, only use controls recommended by HemoCue. For further information regarding controls contact HemoCue AB.

Pearson, Kevin

From:	Spetz, Mary L <Mary.L.Spetz@hemocue.com>
Sent:	Wednesday, March 31, 2021 1:08 PM
To:	Pearson, Kevin; Nelson, Johnny
Cc:	Bellwood, Mark C; Dayton, Sara X
Subject:	RFx 3140002081
Attachments:	RFx 3140002081 Specification Sheet (Hb301).docx; RFx 3140002081 Specification Sheet (Hb201+).docx

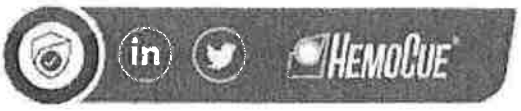
Hi Kevin-

In response to your request of yesterday, please find a specification sheet for each unit submitted in MSDH-Rfx#314000208. Please let us know if this meets your expectations, as all supporting documentation was submitted previously. If this response is not in line with what you are looking for, please make us aware and we will submit anything additional that you are in need of by Friday April 2.

Please Note: Please reply to my email address, rather than the customerservice@hemocue.com , as that is a generic email which is not monitored as closely.

Warm Regards,

Mary Spetz
Key Account Representative
585-353-3648
Mary.l.spetz@hemocue.com



MSDH-RFx # 3140002081 SPECIFICATION SHEET

Hemoglobin Analyzer and Microcuvettes

Hb 301

A.
A.1 Prospective device must be CLIA Waived. Yes

B. General Specifications-Analyzer
B.1 All devices purchased must be new and model currently in production. Refurbished or demonstrator units are not acceptable. Instrument name and model must be listed. Yes
B.2 The vendor must guarantee manufacturer replacement units for defective units for first 5 years. Yes
B.3 All units must include a physical set of operating manual and brochures. Yes
B.4 All units must include training and education program to all sites as well as refresher trainings at no cost. Yes
B. 5 Testing sample size must be 10µl or less. Yes
B. 6 Measuring range must be Hgb: 0-25.6 g/dL. Yes
B.7 Measuring time must be 30 seconds or less. Yes
B. 8 Unit must provide memory for no less than 100 test results. Yes, with included Basic Connect package.
B. 9 Unit must include AC adapters and DC battery options. Yes
B. 10 Unit must have internal self check no less than each time unit is powered on. Yes
B. 11 Units will be delivered to WIC Central Office, Ridgeland, MS with no shipping cost. Yes

C. General Specifications-Microcuvettes
C.1 Expiration date at time of shipment must be greater than 18 months. Yes
C.2 Expiration date after opening must be greater than or equal to 90 days. Yes
C. 3 Guaranteed pricing of microcuvette supplies for 5 years. Yes

The specifications listed are the minimum required for this RFQ-F Reverse Auction. They are not intended to limit competition nor specify any particular bidder/respondent, but to ensure that the MSDH receives a quality product meeting the needs of the agency.

MSDH-RFx # 3140002081 SPECIFICATION SHEET

Hemoglobin Analyzer and Microcuvettes

Hb 201+

A.
A.1 Prospective device must be CLIA Waived. Yes

B. General Specifications-Analyzer
B.1 All devices purchased must be new and model currently in production. Refurbished or demonstrator units are not acceptable. Instrument name and model must be listed. Yes
B.2 The vendor must guarantee manufacturer replacement units for defective units for first 5 years. Yes
B.3 All units must include a physical set of operating manual and brochures. Yes
B.4 All units must include training and education program to all sites as well as refresher trainings at no cost. Yes
B. 5 Testing sample size must be 10µl or less. Yes
B. 6 Measuring range must be Hgb: 0-25.6 g/dL. Yes
B.7 Measuring time must be 30 seconds or less. No
B. 8 Unit must provide memory for no less than 100 test results. Yes, with included Basic Connect package.
B. 9 Unit must include AC adapters and DC battery options. Yes
B. 10 Unit must have internal self check no less than each time unit is powered on. Yes
B. 11 Units will be delivered to WIC Central Office, Ridgeland, MS with no shipping cost. Yes

C. General Specifications-Microcuvettes
C.1 Expiration date at time of shipment must be greater than 18 months. Yes
C.2 Expiration date after opening must be greater than or equal to 90 days. Yes
C. 3 Guaranteed pricing of microcuvette supplies for 5 years. Yes

The specifications listed are the minimum required for this RFQ-F Reverse Auction. They are not intended to limit competition nor specify any particular bidder/respondent, but to ensure that the MSDH receives a quality product meeting the needs of the agency.

Order Granting Protest In Part

In the matter of the Mississippi State Department of Health

RFX Number: 3140002081

Contract Number 8200056689

Date Signed: 10/21/2021

BEFORE THE PUBLIC PROCUREMENT REVIEW BOARD

IN THE MATTER OF THE MISSISSIPPI STATE DEPARTMENT OF HEALTH
RFX Number: 3140002081
Contract Number: 8200056689
REQUEST FOR QUOTES AND REVERSE AUCTION FOR HEMOGLOBIN ANALYZERS AND MICROCUVETTES

ORDER GRANTING PROTEST IN PART

THIS MATTER, HemoCue America's ("HemoCue") protest of the Mississippi State Department of Health's ("MSDH") Intent to Award a contract to EKF Diagnostics, Inc. ("EKF") as a result of the MSDH Request for Quotes ("RFQ") and Reverse Auction for hemoglobin analyzers and microcuvettes, came on to be administratively reviewed and heard September 9, 2021, at a Special Called Meeting of the Public Procurement Review Board ("PPRB") pursuant to Rule 6.204 "Protest of Solicitation or Awards"[1] of the PPRB Office of Purchasing, Travel and Fleet Management (OPTFM) Procurement Manual. This Decision is based on evidence presented for the record including oral arguments and the written pleadings referenced below:

1) April 26, 2021 HemoCue's Protest,
2) June 22, 2021 MSDH's Protest Decision,
3) July 1, 2021 HemoCue's Appeal of Protest Decision, and
4) July 30, 2021 EKF's Response to Appeal.

Board Members Billy Morehead (Chair), Norman McLeod (Interim Vice Chair), Rita Wray, David Russell and ex officio nonvoting member Liz Welch, met via video conference establishing a proper quorum throughout the proceedings. Counsel appearing via video conference on behalf of HemoCue were Orlando "Rod" Richmond, Mark Garriga, Hunter Bennett, and Evan Sherwood. Appearing via video conference on behalf of MSDH were Special Assistant Attorney General, LaTeshya Martin, Director of Procurement, Jennifer Dotson, Project Director, Kevin Pearson, Chief Finance Officer, Sharon Dowdy, Procurement Coordinator, Teselyn Funches, and Director of Public Health Nursing, Laura Tucker. Appearing via video conference on behalf of EKF were Pat Breheny, Public Health Sales Specialist, Jami Meeks, Vice President of Strategic Business Development, and as counsel were John Lassiter and Josh Stover. Oral arguments were presented by counsel and representatives for all parties.

After having considered the written submissions and oral arguments in support of and in opposition to the Protest, and being fully advised of the premises, this Board finds that MSDH's determination that the EKF product met the procurement's specifications was not in accordance with the terms and conditions of the solicitation.

[1]Unless indicated otherwise, all references to rules and regulations are to the PPRB's Office of Purchasing, Travel and Fleet Management (OPTFM) Procurement Manual.

STANDARD OF REVIEW

Appeals of agency protest decisions before the PPRB are reviewed de novo.[2] Pursuant to Rule 6.204(3), the PPRB must decide "whether the solicitation or award was in accordance with the Constitution, statutes, regulations, and the terms and conditions of the solicitation."

DISCUSSION

MSDH issued a solicitation for hemoglobin analyzers and microcuvettes and received two responses from HemoCue and one from EKF. After reviewing all three submissions, the agency sent both respondents the list of specifications and asked that they "provide a response for each specification...."[3] Based on the responses provided, MSDH determined HemoCue's Model Hb 301 and EKF's Hemo Control Analyzer Model # 3040-0010-0218 both met the specifications, but rejected HemoCue's Model Hb 201+. HemoCue's arguments focus on the responses to specification B.7 which stated, "Measuring time must be 30 seconds or less."[4] HemoCue references the B.7 requirement and argues, "[t]here was no exception to that requirement for samples with high concentrations of hemoglobin."[5] HemoCue references EKF's April 1, 2021 response to MSDH, and reasons "that its [EKF] analyzer will take as long as one minute – i.e., 100% longer than the solicitation allows – to measure samples with high hemoglobin levels."[6] HemoCue argues, EKF "stated only that the measurement time 'can be...as quick as 25 seconds' – indicating that it can also take longer to measure such samples in some instances."[7] HemoCue points to EKF's "qualifier on its measurement times" to argue that "even the possibility of meeting the 30-seconds or less requirement depends on the measurement being "performed correctly."[8]

MSDH did not respond to HemoCue's Appeal of its Protest Decision, however it argued in response to the initial protest, "[t]he decision regarding responsiveness of each product submitted was based on certifications and clarifications provided by each vendor."[9] The agency's decision referenced the March 31, 2021 email sent to both vendors and argues its representative "proactively requested additional information from each vendor."[10] MSDH points to EKF's April 1, 2021 response and maintains, "[a]fter consideration of EKF's statement, MSDH determined the EKF product met MSDH specifications."[11]

Pursuant to Rule 3.106.13.1, "the contract is to be awarded to the lowest and best responsible/responsive bidder whose bid meets the requirements and criteria set forth in the Invitation for Bids ... [the IFB] shall set forth the requirements and criteria which will be used ... No bid shall be evaluated for any requirement or criterion not disclosed in the [IFB]." In this instance, MSDH's March 31, 2021 request sent to both vendors was an attempt by the agency to

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[2] PPRB OPTFM Procurement Manual Rule 6.204(3)
[3] See 3-31-21 MSDH emails to both HemoCue and EKF
[4] See RFQ 3140002081 Specification Sheet
[5] See HemoCue Appeal, Paragraph III
[6] *Id.*, Paragraph V
[7] *Id.*
[8] *Id.*
[9] See MSDH Protest Decision, page 2
[10] *Id.*, page 3
[11] *Id.*

certify that each device met the bid's specifications. In response to B.7, HemoCue answered in the affirmative for the Hb 301 model and in the negative for the Hb 201+ model. EKF's response is an explanation of the device's ability to meet the required specification in certain instances. In response to the B.7 specification, EKF stated, "...The measuring time for one sample *can be as quick* as 25 seconds, if performed correctly, or *up to 60 seconds* if performed incorrectly or if the hemoglobin concentration is high."[12] (emphasis added).

Pursuant to rule 3.101.01(6), a responsive bid is one which "conforms in all material respects to the Invitation for Bids." MSDH's Specification Sheet stated that "Measuring time *must* be 30 seconds or less" and that "the specifications listed are the *minimum* required ..." (emphasis added)." Additionally, in the Questions and Answers document posted as Amendment #3 to RFx Number 3140002081, MSDH affirmed that the specifications are "mandatory." EKF's qualifying statement regarding its product's capabilities is nonresponsive on its face, and inconsistent with the agency's three (3) statements above regarding the requirements. Accordingly, this Board finds the agency's determination that EKF's model met its specification was not in accordance with the terms of the solicitation.

This Board finds the agency shall either award a contract to HemoCue for the 301 product or cancel this solicitation and reissue it after careful research of the product and revisions to specifications to clarify the minimum requirements. Specifically, if the agency chooses to reissue the solicitation, it shall determine whether the B.7 requirement for "measuring time" to be "30 seconds or less," is truly a requirement or whether there are acceptable qualifiers.

Because this Board finds the issue of responsiveness to the solicitation dispositive, this Order does not address arguments regarding the alleged disparate treatment of the respondents during the prequalification phase of the solicitation.

NOW THEREFORE,

IT IS ORDERED, that HemoCue's Protest of MSDH's Intent to Award to EKF is hereby granted in part. The Mississippi State Department of Health is directed to either award a contract to HemoCue for the 301 product or reissue this procurement as directed herein.

IT IS FURTHER ORDERED that the stay pursuant to Rules 6.101(5) and 6.101.05 lifted when this Board approved a finding in favor of HemoCue.

SO ORDERED, this the 21st day of October 2021.

W S Morehead

Billy Morehead, PPRB CHAIR

[12] *Id.*