Purchasing Divison
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

State of West Virginia
Request for Quotation
26 — Medical

Proc Folder: 128946

Doc Description: Microcuvettes and Analyzers for WIC Clinic Use

Proc Type: Central Master Agreement

Date Issued	Solicitation Closes	Solicitation No	Version
2015-12-07	2016-01-08 13:30:00	CRFQ 0506 WIC1600000001	1

BID RECEIVING LOCATION

BID CLERK
DEPARTMENT OF ADMINISTRATION
PURCHASING DIVISION
2019 WASHINGTON ST E
CHARLESTON WV 25305
US

VENDOR

Vendor Name, Address and Telephone Number:

EKF Diagnostics
1261 North Main
Boerne, Texas
(830) 249-0772

01/20/16 09:22:10
WV Purchasing Division

FOR INFORMATION CONTACT THE BUYER

April Battle
(304) 558-0067
april.e.battle@wv.gov

Signature X [signature] **FEIN #** 45-3356270 **DATE** 1-18-2016

All offers subject to all terms and conditions contained in this solicitation

ADDITIONAL INFORMATION:

The West Virginia Purchasing Division is soliciting bids on behalf of the West Virginia Department of Health and Human Resources (WVDHHR), Bureau for Public Health (BPH), Office of Nutrition Services (ONS) to establish an open-end contract for Hemocue HB201+ Analyzers, or equal, and Hemocue Microuvettes, or equal.

INVOICE TO	SHIP TO
PURCHASING DIRECTOR - 304-356-4095 HEALTH AND HUMAN RESOURCES BPH - NUTRITION SERVICES 350 CAPITOL ST, RM 519 CHARLESTON WV25301-3717 US	PURCHASING DIRECTOR - 304-356-4095 HEALTH AND HUMAN RESOURCES BPH - NUTRITION SERVICES (WIC) C/O DHHR MATERIALS MANAGEMENT 900 BULLITT ST CHARLESTON WV 25301 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
1	Clinical and diagnostic analyzers and accessories & supplies	100.00000	EA		

Comm Code	Manufacturer	Specification	Model #
41115800			

Extended Description :

Section 3.1.1 - Contract Item #1: Hemocue HB201+ Hemoglobin Analyzers, or equal

100 Each

INVOICE TO	SHIP TO
PURCHASING DIRECTOR - 304-356-4095 HEALTH AND HUMAN RESOURCES BPH - NUTRITION SERVICES 350 CAPITOL ST, RM 519 CHARLESTON WV25301-3717 US	PURCHASING DIRECTOR - 304-356-4095 HEALTH AND HUMAN RESOURCES BPH - NUTRITION SERVICES (WIC) C/O DHHR MATERIALS MANAGEMENT 900 BULLITT ST CHARLESTON WV 25301 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
2	Medical Equipment and Accessories and Supplies	1000.00000	BOX		

Comm Code	Manufacturer	Specification	Model #
42000000			

Extended Description :

Section 3.1.2 - Contract Item #2: Microcuvettes for use with the Hemocue HB201+ Analyzer, or compatible with the Analyzer bid under Section 3.1.1

1,000 Boxes

Must be individually wrapped with 25 per package and 4 packages per box of 100, or equal.

INVOICE TO	SHIP TO
PURCHASING DIRECTOR - 304-356-4095 HEALTH AND HUMAN RESOURCES BPH - NUTRITION SERVICES 350 CAPITOL ST, RM 519 CHARLESTON WV25301-3717 US	PURCHASING DIRECTOR - 304-356-4095 HEALTH AND HUMAN RESOURCES BPH - NUTRITION SERVICES (WIC) C/O DHHR MATERIALS MANAGEMENT 900 BULLITT ST CHARLESTON WV 25301 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
3	Training planning, facilitation and delivery services	8.00000	EA		

Comm Code	Manufacturer	Specification	Model #
86132100			

Extended Description :

Section 3.1.3 - Contract Item #3: Vendor Training, Support, and Ongoing Assistance, or equal, over the life of the contract must be included in the quoted price

Minimum 8 Trainings

SCHEDULE OF EVENTS

Line	Event	Event Date
1	TQ due	2015-12-22

ADDITIONAL TERMS AND CONDITIONS

See attached document(s) for additional Terms and Conditions

INSTRUCTIONS TO VENDORS SUBMITTING BIDS

1. REVIEW DOCUMENTS THOROUGHLY: The attached documents contain a solicitation for bids. Please read these instructions and all documents attached in their entirety. These instructions provide critical information about requirements that if overlooked could lead to disqualification of a Vendor's bid. All bids must be submitted in accordance with the provisions contained in these instructions and the Solicitation. Failure to do so may result in disqualification of Vendor's bid.

2. MANDATORY TERMS: The Solicitation may contain mandatory provisions identified by the use of the words "must," "will," and "shall." Failure to comply with a mandatory term in the Solicitation will result in bid disqualification.

3. PREBID MEETING: The item identified below shall apply to this Solicitation.

☑ A pre-bid meeting will not be held prior to bid opening

☐ A **NON-MANDATORY PRE-BID** meeting will be held at the following place and time:

☐ A **MANDATORY PRE-BID** meeting will be held at the following place and time:

All Vendors submitting a bid must attend the mandatory pre-bid meeting. Failure to attend the mandatory pre-bid meeting shall result in disqualification of the Vendor's bid. No one person attending the pre-bid meeting may represent more than one Vendor.

An attendance sheet provided at the pre-bid meeting shall serve as the official document verifying attendance. The State will not accept any other form of proof or documentation to verify attendance. Any person attending the pre-bid meeting on behalf of a Vendor must list on the attendance sheet his or her name and the name of the Vendor he or she is representing.

Additionally, the person attending the pre-bid meeting should include the Vendor's E-Mail address, phone number, and Fax number on the attendance sheet. It is the Vendor's responsibility to locate the attendance sheet and provide the required information. Failure to complete the attendance sheet as required may result in disqualification of Vendor's bid.

All Vendors should arrive prior to the starting time for the pre-bid. Vendors who arrive after the starting time but prior to the end of the pre-bid will be permitted to sign in, but are charged with knowing all matters discussed at the pre-bid.

Questions submitted at least five business days prior to a scheduled pre-bid will be discussed at the pre-bid meeting if possible. Any discussions or answers to questions at the pre-bid meeting

are preliminary in nature and are non-binding. Official and binding answers to questions will be published in a written addendum to the Solicitation prior to bid opening.

4. VENDOR QUESTION DEADLINE: Vendors may submit questions relating to this Solicitation to the Purchasing Division. Questions must be submitted in writing. All questions must be submitted on or before the date listed below and to the address listed below in order to be considered. A written response will be published in a Solicitation addendum if a response is possible and appropriate. Non-written discussions, conversations, or questions and answers regarding this Solicitation are preliminary in nature and are nonbinding.

Submitted e-mails should have solicitation number in the subject line.

Question Submission Deadline: December 22, 2015

Submit Questions to: April Battle, Buyer 51
2019 Washington Street, East
Charleston, WV 25305
Fax: (304) 558-4115 (Vendors should not use this fax number for bid submission)
Email: april.e.battle@wv.gov

5. VERBAL COMMUNICATION: Any verbal communication between the Vendor and any State personnel is not binding, including verbal communication at the mandatory pre-bid conference. Only information issued in writing and added to the Solicitation by an official written addendum by the Purchasing Division is binding.

6. BID SUBMISSION: All bids must be submitted electronically through wvOASIS or signed and delivered by the Vendor to the Purchasing Division at the address listed below on or before the date and time of the bid opening. Any bid received by the Purchasing Division staff is considered to be in the possession of the Purchasing Division and will not be returned for any reason. The Purchasing Division will not accept bids, modification of bids, or addendum acknowledgment forms via e-mail. Acceptable delivery methods include electronic submission via wvOASIS, hand delivery, delivery by courier, or facsimile.

The bid delivery address is:
Department of Administration, Purchasing Division
2019 Washington Street East
Charleston, WV 25305-0130

A bid that is not submitted electronically through wvOASIS should contain the information listed below on the face of the envelope or the bid may be rejected by the Purchasing Division.:

SEALED BID: Hemocue HB201+ Analyzer & Hemocue Microcuvettes
BUYER: April Battle, Buyer 51
SOLICITATION NO.: CRFQ 0506 WIC1600000001
BID OPENING DATE: January 8, 2016
BID OPENING TIME: 1:30 PM EST

FAX NUMBER: (304) 558-3970

In the event that Vendor is responding to a request for proposal, the Vendor shall submit one original technical and one original cost proposal plus convenience copies of each to the Purchasing Division at the address shown above. Submission of a response to a request for proposal is not permitted in wvOASIS. Additionally, the Vendor should identify the bid type as either a technical or cost proposal on the face of each bid envelope submitted in response to a request for proposal as follows:

BID TYPE: (This only applies to CRFP)
☐ Technical
☐ Cost

7. BID OPENING: Bids submitted in response to this Solicitation will be opened at the location identified below on the date and time listed below. Delivery of a bid after the bid opening date and time will result in bid disqualification. For purposes of this Solicitation, a bid is considered delivered when confirmation of delivery is provided by wvOASIS (in the case of electronic submission) or when the bid is time stamped by the official Purchasing Division time clock (in the case of hand delivery).

Bid Opening Date and Time: January 8, 2016, at 1:30 PM EST

Bid Opening Location: Department of Administration, Purchasing Division
2019 Washington Street East
Charleston, WV 25305-0130

8. ADDENDUM ACKNOWLEDGEMENT: Changes or revisions to this Solicitation will be made by an official written addendum issued by the Purchasing Division. Vendor should acknowledge receipt of all addenda issued with this Solicitation by completing an Addendum Acknowledgment Form, a copy of which is included herewith. Failure to acknowledge addenda may result in bid disqualification. The addendum acknowledgement should be submitted with the bid to expedite document processing.

9. BID FORMATTING: Vendor should type or electronically enter the information onto its bid to prevent errors in the evaluation. Failure to type or electronically enter the information may result in bid disqualification.

10. ALTERNATES: Any model, brand, or specification listed in this Solicitation establishes the acceptable level of quality only and is not intended to reflect a preference for, or in any way favor, a particular brand or vendor. Vendors may bid alternates to a listed model or brand provided that the alternate is at least equal to the model or brand and complies with the required specifications. The equality of any alternate being bid shall be determined by the State at its sole discretion. Any Vendor bidding an alternate model or brand should clearly identify the alternate items in its bid and should include manufacturer's specifications, industry literature, and/or any other relevant documentation demonstrating the equality of the alternate items. Failure to provide information for alternate items may be grounds for rejection of a Vendor's bid.

11. EXCEPTIONS AND CLARIFICATIONS: The Solicitation contains the specifications that shall form the basis of a contractual agreement. Vendor shall clearly mark any exceptions, clarifications, or other proposed modifications in its bid. Exceptions to, clarifications of, or modifications of a requirement or term and condition of the Solicitation may result in bid disqualification.

12. COMMUNICATION LIMITATIONS: In accordance with West Virginia Code of State Rules §148-1-6.6, communication with the State of West Virginia or any of its employees regarding this Solicitation during the solicitation, bid, evaluation or award periods, except through the Purchasing Division, is strictly prohibited without prior Purchasing Division approval. Purchasing Division approval for such communication is implied for all agency delegated and exempt purchases.

13. REGISTRATION: Prior to Contract award, the apparent successful Vendor must be properly registered with the West Virginia Purchasing Division and must have paid the $125 fee, if applicable.

14. UNIT PRICE: Unit prices shall prevail in cases of a discrepancy in the Vendor's bid.

15. PREFERENCE: Vendor Preference may only be granted upon written request and only in accordance with the West Virginia Code § 5A-3-37 and the West Virginia Code of State Rules. A Vendor Preference Certificate form has been attached hereto to allow Vendor to apply for the preference. Vendor's failure to submit the Vendor Preference Certificate form with its bid will result in denial of Vendor Preference. Vendor Preference does not apply to construction projects.

16. SMALL, WOMEN-OWNED, OR MINORITY-OWNED BUSINESSES: For any solicitations publicly advertised for bid, in accordance with West Virginia Code §5A-3-37(a)(7) and W. Va. CSR § 148-22-9, any non-resident vendor certified as a small, women-owned, or minority-owned business under W. Va. CSR § 148-22-9 shall be provided the same preference made available to any resident vendor. Any non-resident small, women-owned, or minority-owned business must identify itself as such in writing, must submit that writing to the Purchasing Division with its bid, and must be properly certified under W. Va. CSR § 148-22-9 prior to contract award to receive the preferences made available to resident vendors. Preference for a non-resident small, women-owned, or minority owned business shall be applied in accordance with W. Va. CSR § 148-22-9.

17. WAIVER OF MINOR IRREGULARITIES: The Director reserves the right to waive minor irregularities in bids or specifications in accordance with West Virginia Code of State Rules § 148-1-4.6.

18. ELECTRONIC FILE ACCESS RESTRICTIONS: Vendor must ensure that its submission in wvOASIS can be accessed by the Purchasing Division staff immediately upon bid opening. The Purchasing Division will consider any file that cannot be immediately opened and/or viewed at the time of the bid opening (such as, encrypted files, password protected files, or incompatible files) to be blank or incomplete as context requires, and are therefore

unacceptable. A vendor will not be permitted to unencrypt files, remove password protections, or resubmit documents after bid opening if those documents are required with the bid.

19. NON-RESPONSIBLE: The Purchasing Division Director reserves the right to reject the bid of any vendor as Non-Responsible in accordance with W. Va. Code of State Rules § 148-1-5.3, when the Director determines that the vendor submitting the bid does not have the capability to fully perform, or lacks the integrity and reliability to assure good-faith performance."

20. ACCEPTANCE/REJECTION: The State may accept or reject any bid in whole, or in part in accordance with W. Va. Code of State Rules § 148-1-4.5. and § 148-1-6.4.b."

21. YOUR SUBMISSION IS A PUBLIC DOCUMENT: Vendor's entire response to the Solicitation and the resulting Contract are public documents. As public documents, they will be disclosed to the public following the bid/proposal opening or award of the contract, as required by the competitive bidding laws of West Virginia Code §§ 5A-3-1 et seq., 5-22-1 et seq., and 5G-1-1 et seq. and the Freedom of Information Act West Virginia Code §§ 29B-1-1 et seq.

DO NOT SUBMIT MATERIAL YOU CONSIDER TO BE CONFIDENTIAL, A TRADE SECRET, OR OTHERWISE NOT SUBJECT TO PUBLIC DISCLOSURE.

Submission of any bid, proposal, or other document to the Purchasing Division constitutes your explicit consent to the subsequent public disclosure of the bid, proposal, or document. The Purchasing Division will disclose any document labeled "confidential," "proprietary," "trade secret," "private," or labeled with any other claim against public disclosure of the documents, to include any "trade secrets" as defined by West Virginia Code § 47-22-1 et seq. All submissions are subject to public disclosure without notice.

GENERAL TERMS AND CONDITIONS:

1. CONTRACTUAL AGREEMENT: Issuance of a Award Document signed by the Purchasing Division Director, or his designee, and approved as to form by the Attorney General's office constitutes acceptance of this Contract made by and between the State of West Virginia and the Vendor. Vendor's signature on its bid signifies Vendor's agreement to be bound by and accept the terms and conditions contained in this Contract.

2. DEFINITIONS: As used in this Solicitation/Contract, the following terms shall have the meanings attributed to them below. Additional definitions may be found in the specifications included with this Solicitation/Contract.

2.1. "Agency" or **"Agencies"** means the agency, board, commission, or other entity of the State of West Virginia that is identified on the first page of the Solicitation or any other public entity seeking to procure goods or services under this Contract.

2.2. "Bid" or **"Proposal"** means the vendors submitted response to this solicitation.

2.3. "Contract" means the binding agreement that is entered into between the State and the Vendor to provide the goods or services requested in the Solicitation.

2.4. "Director" means the Director of the West Virginia Department of Administration, Purchasing Division.

2.5. "Purchasing Division" means the West Virginia Department of Administration, Purchasing Division.

2.6. "Award Document" means the document signed by the Agency and the Purchasing Division, and approved as to form by the Attorney General, that identifies the Vendor as the contract holder.

2.7. "Solicitation" means the official notice of an opportunity to supply the State with goods or services that is published by the Purchasing Division.

2.8. "State" means the State of West Virginia and/or any of its agencies, commissions, boards, etc. as context requires.

2.9. "Vendor" or **"Vendors"** means any entity submitting a bid in response to the Solicitation, the entity that has been selected as the lowest responsible bidder, or the entity that has been awarded the Contract as context requires.

3. CONTRACT TERM; RENEWAL; EXTENSION: The term of this Contract shall be determined in accordance with the category that has been identified as applicable to this Contract below:

☑ **Term Contract**

Initial Contract Term: This Contract becomes effective on Upon Award and extends for a period of one (1) year(s).
Renewal Term: This Contract may be renewed upon the mutual written consent of the Agency, and the Vendor, with approval of the Purchasing Division and the Attorney General's office (Attorney General approval is as to form only). Any request for renewal should be submitted to the Purchasing Division thirty (30) days prior to the expiration date of the initial contract term or appropriate renewal term. A Contract renewal shall be in accordance with the terms and conditions of the original contract. Renewal of this Contract is limited to three (3) successive one (1) year periods or multiple renewal periods of less than one year, provided that the multiple renewal periods do not exceed thirty six (36) months in total. Automatic renewal of this Contract is prohibited. Notwithstanding the foregoing, Purchasing Division approval is not required on agency delegated or exempt purchases. Attorney General approval may be required for vendor terms and conditions.

Delivery Order Limitations: In the event that this contract permits delivery orders, a delivery order may only be issued during the time this Contract is in effect. Any delivery order issued within one year of the expiration of this Contract shall be effective for one year from the date the delivery order is issued. No delivery order may be extended beyond one year after this Contract has expired.

☐ **Fixed Period Contract:** This Contract becomes effective upon Vendor's receipt of the notice to proceed and must be completed within _____ days.

☐ **Fixed Period Contract with Renewals:** This Contract becomes effective upon Vendor's receipt of the notice to proceed and part of the Contract more fully described in the attached specifications must be completed within _____ days.

Upon completion, the vendor agrees that maintenance, monitoring, or warranty services will be provided for one year thereafter with an additional _____ successive one year renewal periods or multiple renewal periods of less than one year provided that the multiple renewal periods do not exceed _____ months in total. Automatic renewal of this Contract is prohibited.

☐ **One Time Purchase:** The term of this Contract shall run from the issuance of the Award Document until all of the goods contracted for have been delivered, but in no event will this Contract extend for more than one fiscal year.

☐ **Other:** See attached.

4. NOTICE TO PROCEED: Vendor shall begin performance of this Contract immediately upon receiving notice to proceed unless otherwise instructed by the Agency. Unless otherwise specified, the fully executed Award Document will be considered notice to proceed.

5. QUANTITIES: The quantities required under this Contract shall be determined in accordance with the category that has been identified as applicable to this Contract below.

☑ **Open End Contract:** Quantities listed in this Solicitation are approximations only, based on estimates supplied by the Agency. It is understood and agreed that the Contract shall cover the quantities actually ordered for delivery during the term of the Contract, whether more or less than the quantities shown.

☐ **Service:** The scope of the service to be provided will be more clearly defined in the specifications included herewith.

☐ **Combined Service and Goods:** The scope of the service and deliverable goods to be provided will be more clearly defined in the specifications included herewith.

☐ **One Time Purchase:** This Contract is for the purchase of a set quantity of goods that are identified in the specifications included herewith. Once those items have been delivered, no additional goods may be procured under this Contract without an appropriate change order approved by the Vendor, Agency, Purchasing Division, and Attorney General's office.

6. PRICING: The pricing set forth herein is firm for the life of the Contract, unless specified elsewhere within this Solicitation/Contract by the State. A Vendor's inclusion of price adjustment provisions in its bid, without an express authorization from the State in the Solicitation to do so, may result in bid disqualification.

7. EMERGENCY PURCHASES: The Purchasing Division Director may authorize the Agency to purchase goods or services in the open market that Vendor would otherwise provide under this Contract if those goods or services are for immediate or expedited delivery in an emergency. Emergencies shall include, but are not limited to, delays in transportation or an unanticipated increase in the volume of work. An emergency purchase in the open market, approved by the Purchasing Division Director, shall not constitute of breach of this Contract and shall not entitle the Vendor to any form of compensation or damages. This provision does not excuse the State from fulfilling its obligations under a One Time Purchase contract.

8. REQUIRED DOCUMENTS: All of the items checked below must be provided to the Purchasing Division by the Vendor as specified below.

☐ **BID BOND:** All Vendors shall furnish a bid bond in the amount of five percent (5%) of the total amount of the bid protecting the State of West Virginia. The bid bond must be submitted with the bid.

☐ **PERFORMANCE BOND:** The apparent successful Vendor shall provide a performance bond in the amount of _____. The performance bond must be received by the Purchasing Division prior to Contract award. On construction contracts, the performance bond must be 100% of the Contract value.

☐ **LABOR/MATERIAL PAYMENT BOND:** The apparent successful Vendor shall provide a labor/material payment bond in the amount of 100% of the Contract value. The labor/material payment bond must be delivered to the Purchasing Division prior to Contract award.

In lieu of the Bid Bond, Performance Bond, and Labor/Material Payment Bond, the Vendor may provide certified checks, cashier's checks, or irrevocable letters of credit. Any certified check, cashier's check, or irrevocable letter of credit provided in lieu of a bond must be of the same amount and delivered on the same schedule as the bond it replaces. A letter of credit submitted in lieu of a performance and labor/material payment bond will only be allowed for projects under $100,000. Personal or business checks are not acceptable.

☐ **MAINTENANCE BOND:** The apparent successful Vendor shall provide a two (2) year maintenance bond covering the roofing system. The maintenance bond must be issued and delivered to the Purchasing Division prior to Contract award.

☐ **INSURANCE:** The apparent successful Vendor shall furnish proof of the following insurance prior to Contract award and shall list the state as a certificate holder:

☐ **Commercial General Liability Insurance:** In the amount of _____ _____ or more.

☐ **Builders Risk Insurance:** In an amount equal to 100% of the amount of the Contract.

☐

☐

☐

☐

☐

The apparent successful Vendor shall also furnish proof of any additional insurance requirements contained in the specifications prior to Contract award regardless of whether or not that insurance requirement is listed above.

☐ **LICENSE(S) / CERTIFICATIONS / PERMITS:** In addition to anything required under the Section entitled Licensing, of the General Terms and Conditions, the apparent successful Vendor shall furnish proof of the following licenses, certifications, and/or permits prior to Contract award, in a form acceptable to the Purchasing Division.

☐

The apparent successful Vendor shall also furnish proof of any additional licenses or certifications contained in the specifications prior to Contract award regardless of whether or not that requirement is listed above.

9. WORKERS' COMPENSATION INSURANCE: The apparent successful Vendor shall comply with laws relating to workers compensation, shall maintain workers' compensation insurance when required, and shall furnish proof of workers' compensation insurance upon request.

10. LITIGATION BOND: The Director reserves the right to require any Vendor that files a protest of an award to submit a litigation bond in the amount equal to one percent of the lowest bid submitted or $5,000, whichever is greater. The entire amount of the bond shall be forfeited if the hearing officer determines that the protest was filed for frivolous or improper purpose, including but not limited to, the purpose of harassing, causing unnecessary delay, or needless expense for the Agency. All litigation bonds shall be made payable to the Purchasing Division. In lieu of a bond, the protester may submit a cashier's check or certified check payable to the Purchasing Division. Cashier's or certified checks will be deposited with and held by the State Treasurer's office. If it is determined that the protest has not been filed for frivolous or improper purpose, the bond or deposit shall be returned in its entirety.

11. LIQUIDATED DAMAGES: Vendor shall pay liquidated damages in the amount of N/A

for N/A.

This clause shall in no way be considered exclusive and shall not limit the State or Agency's right to pursue any other available remedy.

12. ACCEPTANCE: Vendor's signature on its bid, or on the certification and signature page, constitutes an offer to the State that cannot be unilaterally withdrawn, signifies that the product or service proposed by vendor meets the mandatory requirements contained in the Solicitation for that product or service, unless otherwise indicated, and signifies acceptance of the terms and conditions contained in the Solicitation unless otherwise indicated.

13. FUNDING: This Contract shall continue for the term stated herein, contingent upon funds being appropriated by the Legislature or otherwise being made available. In the event funds are not appropriated or otherwise made available, this Contract becomes void and of no effect beginning on July 1 of the fiscal year for which funding has not been appropriated or otherwise made available.

14. PAYMENT: Payment in advance is prohibited under this Contract. Payment may only be made after the delivery and acceptance of goods or services. The Vendor shall submit invoices, in arrears.

15. TAXES: The Vendor shall pay any applicable sales, use, personal property or any other taxes arising out of this Contract and the transactions contemplated thereby. The State of West Virginia is exempt from federal and state taxes and will not pay or reimburse such taxes.

16. CANCELLATION: The Purchasing Division Director reserves the right to cancel this Contract immediately upon written notice to the vendor if the materials or workmanship supplied do not conform to the specifications contained in the Contract. The Purchasing Division Director may also cancel any purchase or Contract upon 30 days written notice to the Vendor in accordance with West Virginia Code of State Rules §§ 148-1-6.1.e.

17. TIME: Time is of the essence with regard to all matters of time and performance in this Contract.

18. APPLICABLE LAW: This Contract is governed by and interpreted under West Virginia law without giving effect to its choice of law principles. Any information provided in specification manuals, or any other source, verbal or written, which contradicts or violates the West Virginia Constitution, West Virginia Code or West Virginia Code of State Rules is void and of no effect.

19. COMPLIANCE: Vendor shall comply with all applicable federal, state, and local laws, regulations and ordinances. By submitting a bid, Vendor acknowledges that it has reviewed, understands, and will comply with all applicable laws, regulations, and ordinances.

20. PREVAILING WAGE: Vendor shall be responsible for ensuring compliance with prevailing wage requirements and determining when prevailing wage requirements are applicable.

21. ARBITRATION: Any references made to arbitration contained in this Contract, Vendor's bid, or in any American Institute of Architects documents pertaining to this Contract are hereby deleted, void, and of no effect.

22. MODIFICATIONS: This writing is the parties' final expression of intent. Notwithstanding anything contained in this Contract to the contrary no modification of this Contract shall be binding without mutual written consent of the Agency, and the Vendor, with approval of the Purchasing Division and the Attorney General's office (Attorney General approval is as to form only). Any change to existing contracts that adds work or changes contract cost, and were not included in the original contract, must be approved by the Purchasing Division and the Attorney General's Office (as to form) prior to the implementation of the change or commencement of work affected by the change.

23. WAIVER: The failure of either party to insist upon a strict performance of any of the terms or provision of this Contract, or to exercise any option, right, or remedy herein contained, shall not be construed as a waiver or a relinquishment for the future of such term, provision, option, right, or remedy, but the same shall continue in full force and effect. Any waiver must be expressly stated in writing and signed by the waiving party.

24. SUBSEQUENT FORMS: The terms and conditions contained in this Contract shall supersede any and all subsequent terms and conditions which may appear on any form documents submitted by Vendor to the Agency or Purchasing Division such as price lists, order forms, invoices, sales agreements, or maintenance agreements, and includes internet websites or other electronic documents. Acceptance or use of Vendor's forms does not constitute acceptance of the terms and conditions contained thereon.

25. ASSIGNMENT: Neither this Contract nor any monies due, or to become due hereunder, may be assigned by the Vendor without the express written consent of the Agency, the Purchasing Division, the Attorney General's office (as to form only), and any other government agency or office that may be required to approve such assignments. Notwithstanding the foregoing, Purchasing Division approval may or may not be required on certain agency delegated or exempt purchases.

26. WARRANTY: The Vendor expressly warrants that the goods and/or services covered by this Contract will: (a) conform to the specifications, drawings, samples, or other description furnished or specified by the Agency; (b) be merchantable and fit for the purpose intended; and (c) be free from defect in material and workmanship.

27. STATE EMPLOYEES: State employees are not permitted to utilize this Contract for personal use and the Vendor is prohibited from permitting or facilitating the same.

28. BANKRUPTCY: In the event the Vendor files for bankruptcy protection, the State of West Virginia may deem this Contract null and void, and terminate this Contract without notice.

29. PRIVACY, SECURITY, AND CONFIDENTIALITY: The Vendor agrees that it will not disclose to anyone, directly or indirectly, any such personally identifiable information or other confidential information gained from the Agency, unless the individual who is the subject of the information consents to the disclosure in writing or the disclosure is made pursuant to the Agency's policies, procedures, and rules. Vendor further agrees to comply with the Confidentiality Policies and Information Security Accountability Requirements, set forth in http://www.state.wv.us/admin/purchase/privacy/default.html.

30. YOUR SUBMISSION IS A PUBLIC DOCUMENT: Vendor's entire response to the Solicitation and the resulting Contract are public documents. As public documents, they will be disclosed to the public following the bid/proposal opening or award of the contract, as required by the competitive bidding laws of West Virginia Code §§ 5A-3-1 et seq., 5-22-1 et seq., and 5G-1-1 et seq. and the Freedom of Information Act West Virginia Code §§ 29B-1-1 et seq.

DO NOT SUBMIT MATERIAL YOU CONSIDER TO BE CONFIDENTIAL, A TRADE SECRET, OR OTHERWISE NOT SUBJECT TO PUBLIC DISCLOSURE.

Submission of any bid, proposal, or other document to the Purchasing Division constitutes your explicit consent to the subsequent public disclosure of the bid, proposal, or document. The Purchasing Division will disclose any document labeled "confidential," "proprietary," "trade secret," "private," or labeled with any other claim against public disclosure of the documents, to

include any "trade secrets" as defined by West Virginia Code § 47-22-1 et seq. All submissions are subject to public disclosure without notice.

31. LICENSING: In accordance with West Virginia Code of State Rules § 148-1-6.1.e, Vendor must be licensed and in good standing in accordance with any and all state and local laws and requirements by any state or local agency of West Virginia, including, but not limited to, the West Virginia Secretary of State's Office, the West Virginia Tax Department, West Virginia Insurance Commission, or any other state agency or political subdivision. Upon request, the Vendor must provide all necessary releases to obtain information to enable the Purchasing Division Director or the Agency to verify that the Vendor is licensed and in good standing with the above entities.

32. ANTITRUST: In submitting a bid to, signing a contract with, or accepting a Award Document from any agency of the State of West Virginia, the Vendor agrees to convey, sell, assign, or transfer to the State of West Virginia all rights, title, and interest in and to all causes of action it may now or hereafter acquire under the antitrust laws of the United States and the State of West Virginia for price fixing and/or unreasonable restraints of trade relating to the particular commodities or services purchased or acquired by the State of West Virginia. Such assignment shall be made and become effective at the time the purchasing agency tenders the initial payment to Vendor.

33. VENDOR CERTIFICATIONS: By signing its bid or entering into this Contract, Vendor certifies (1) that its bid or offer was made without prior understanding, agreement, or connection with any corporation, firm, limited liability company, partnership, person or entity submitting a bid or offer for the same material, supplies, equipment or services; (2) that its bid or offer is in all respects fair and without collusion or fraud; (3) that this Contract is accepted or entered into without any prior understanding, agreement, or connection to any other entity that could be considered a violation of law; and (4) that it has reviewed this Solicitation in its entirety; understands the requirements, terms and conditions, and other information contained herein. Vendor's signature on its bid or offer also affirms that neither it nor its representatives have any interest, nor shall acquire any interest, direct or indirect, which would compromise the performance of its services hereunder. Any such interests shall be promptly presented in detail to the Agency. The individual signing this bid or offer on behalf of Vendor certifies that he or she is authorized by the Vendor to execute this bid or offer or any documents related thereto on Vendor's behalf; that he or she is authorized to bind the Vendor in a contractual relationship; and that, to the best of his or her knowledge, the Vendor has properly registered with any State agency that may require registration.

34. PURCHASING CARD ACCEPTANCE: The State of West Virginia currently utilizes a Purchasing Card program, administered under contract by a banking institution, to process payment for goods and services. The Vendor must accept the State of West Virginia's Purchasing Card for payment of all orders under this Contract unless the box below is checked.
☐ Vendor is not required to accept the State of West Virginia's Purchasing Card as payment for all goods and services.

35. VENDOR RELATIONSHIP: The relationship of the Vendor to the State shall be that of an independent contractor and no principal-agent relationship or employer-employee relationship is contemplated or created by this Contract. The Vendor as an independent contractor is solely liable for the acts and omissions of its employees and agents. Vendor shall be responsible for selecting, supervising, and compensating any and all individuals employed pursuant to the terms of this Solicitation and resulting contract. Neither the Vendor, nor any employees or subcontractors of the Vendor, shall be deemed to be employees of the State for any purpose whatsoever. Vendor shall be exclusively responsible for payment of employees and contractors for all wages and salaries, taxes, withholding payments, penalties, fees, fringe benefits, professional liability insurance premiums, contributions to insurance and pension, or other deferred compensation plans, including but not limited to, Workers' Compensation and Social Security obligations, licensing fees, etc. and the filing of all necessary documents, forms, and returns pertinent to all of the foregoing.
Vendor shall hold harmless the State, and shall provide the State and Agency with a defense against any and all claims including, but not limited to, the foregoing payments, withholdings, contributions, taxes, Social Security taxes, and employer income tax returns.

36. INDEMNIFICATION: The Vendor agrees to indemnify, defend, and hold harmless the State and the Agency, their officers, and employees from and against: (1) Any claims or losses for services rendered by any subcontractor, person, or firm performing or supplying services, materials, or supplies in connection with the performance of the Contract; (2) Any claims or losses resulting to any person or entity injured or damaged by the Vendor, its officers, employees, or subcontractors by the publication, translation, reproduction, delivery, performance, use, or disposition of any data used under the Contract in a manner not authorized by the Contract, or by Federal or State statutes or regulations; and (3) Any failure of the Vendor, its officers, employees, or subcontractors to observe State and Federal laws including, but not limited to, labor and wage and hour laws.

37. PURCHASING AFFIDAVIT: In accordance with West Virginia Code § 5A-3-10a, all Vendors are required to sign, notarize, and submit the Purchasing Affidavit stating that neither the Vendor nor a related party owe a debt to the State in excess of $1,000. The affidavit must be submitted prior to award, but should be submitted with the Vendor's bid. A copy of the Purchasing Affidavit is included herewith.

38. ADDITIONAL AGENCY AND LOCAL GOVERNMENT USE: This Contract may be utilized by other agencies, spending units, and political subdivisions of the State of West Virginia; county, municipal, and other local government bodies; and school districts ("Other Government Entities"). Any extension of this Contract to the aforementioned Other Government Entities must be on the same prices, terms, and conditions as those offered and agreed to in this Contract, provided that such extension is in compliance with the applicable laws, rules, and ordinances of the Other Government Entity. If the Vendor does not wish to extend the prices, terms, and conditions of its bid and subsequent contract to the Other Government Entities, the Vendor must clearly indicate such refusal in its bid. A refusal to extend this Contract to the Other Government Entities shall not impact or influence the award of this Contract in any manner.

39. CONFLICT OF INTEREST: Vendor, its officers or members or employees, shall not presently have or acquire an interest, direct or indirect, which would conflict with or compromise the performance of its obligations hereunder. Vendor shall periodically inquire of its officers, members and employees to ensure that a conflict of interest does not arise. Any conflict of interest discovered shall be promptly presented in detail to the Agency.

40. REPORTS: Vendor shall provide the Agency and/or the Purchasing Division with the following reports identified by a checked box below:

☑ Such reports as the Agency and/or the Purchasing Division may request. Requested reports may include, but are not limited to, quantities purchased, agencies utilizing the contract, total contract expenditures by agency, etc.

☐ Quarterly reports detailing the total quantity of purchases in units and dollars, along with a listing of purchases by agency. Quarterly reports should be delivered to the Purchasing Division via email at purchasing.requisitions@wv.gov.

41. BACKGROUND CHECK: In accordance with W. Va. Code § 15-2D-3, the Director of the Division of Protective Services shall require any service provider whose employees are regularly employed on the grounds or in the buildings of the Capitol complex or who have access to sensitive or critical information to submit to a fingerprint-based state and federal background inquiry through the state repository. The service provider is responsible for any costs associated with the fingerprint-based state and federal background inquiry.

After the contract for such services has been approved, but before any such employees are permitted to be on the grounds or in the buildings of the Capitol complex or have access to sensitive or critical information, the service provider shall submit a list of all persons who will be physically present and working at the Capitol complex to the Director of the Division of Protective Services for purposes of verifying compliance with this provision. The State reserves the right to prohibit a service provider's employees from accessing sensitive or critical information or to be present at the Capitol complex based upon results addressed from a criminal background check.

Service providers should contact the West Virginia Division of Protective Services by phone at (304) 558-9911 for more information.

42. PREFERENCE FOR USE OF DOMESTIC STEEL PRODUCTS: Except when authorized by the Director of the Purchasing Division pursuant to W. Va. Code § 5A-3-56, no contractor may use or supply steel products for a State Contract Project other than those steel products made in the United States. A contractor who uses steel products in violation of this section may be subject to civil penalties pursuant to W. Va. Code § 5A-3-56. As used in this section:

a. "State Contract Project" means any erection or construction of, or any addition to, alteration of or other improvement to any building or structure, including, but not limited to, roads or highways, or the installation of any heating or cooling or ventilating plants or other equipment,

or the supply of and materials for such projects, pursuant to a contract with the State of West Virginia for which bids were solicited on or after June 6, 2001.
b. "Steel Products" means products rolled, formed, shaped, drawn, extruded, forged, cast, fabricated or otherwise similarly processed, or processed by a combination of two or more or such operations, from steel made by the open heath, basic oxygen, electric furnace, Bessemer or other steel making process. The Purchasing Division Director may, in writing, authorize the use of foreign steel products if:
c. The cost for each contract item used does not exceed one tenth of one percent (.1%) of the total contract cost or two thousand five hundred dollars ($2,500.00), whichever is greater. For the purposes of this section, the cost is the value of the steel product as delivered to the project; or
d. The Director of the Purchasing Division determines that specified steel materials are not produced in the United States in sufficient quantity or otherwise are not reasonably available to meet contract requirements.

43. PREFERENCE FOR USE OF DOMESTIC ALUMINUM, GLASS, AND STEEL: In Accordance with W. Va. Code § 5-19-1 et seq., and W. Va. CSR § 148-10-1 et seq., for every contract or subcontract, subject to the limitations contained herein, for the construction, reconstruction, alteration, repair, improvement or maintenance of public works or for the purchase of any item of machinery or equipment to be used at sites of public works, only domestic aluminum, glass or steel products shall be supplied unless the spending officer determines, in writing, after the receipt of offers or bids, (1) that the cost of domestic aluminum, glass or steel products is unreasonable or inconsistent with the public interest of the State of West Virginia, (2) that domestic aluminum, glass or steel products are not produced in sufficient quantities to meet the contract requirements, or (3) the available domestic aluminum, glass, or steel do not meet the contract specifications. This provision only applies to public works contracts awarded in an amount more than fifty thousand dollars ($50,000) or public works contracts that require more than ten thousand pounds of steel products.

The cost of domestic aluminum, glass, or steel products may be unreasonable if the cost is more than twenty percent (20%) of the bid or offered price for foreign made aluminum, glass, or steel products. If the domestic aluminum, glass or steel products to be supplied or produced in a "substantial labor surplus area", as defined by the United States Department of Labor, the cost of domestic aluminum, glass, or steel products may be unreasonable if the cost is more than thirty percent (30%) of the bid or offered price for foreign made aluminum, glass, or steel products. This preference shall be applied to an item of machinery or equipment, as indicated above, when the item is a single unit of equipment or machinery manufactured primarily of aluminum, glass or steel, is part of a public works contract and has the sole purpose or of being a permanent part of a single public works project. This provision does not apply to equipment or machinery purchased by a spending unit for use by that spending unit and not as part of a single public works project.

All bids and offers including domestic aluminum, glass or steel products that exceed bid or offer prices including foreign aluminum, glass or steel products after application of the preferences provided in this provision may be reduced to a price equal to or lower than the lowest bid or offer price for foreign aluminum, glass or steel products plus the applicable preference. If the reduced bid or offer prices are made in writing and supersede the prior bid or offer prices, all

bids or offers, including the reduced bid or offer prices, will be reevaluated in accordance with this rule.

CERTIFICATIONAND SIGNATURE PAGE

By signing below, or submitting documentation through wvOASIS, I certify that I have reviewed this Solicitation in its entirety; that I understand the requirements, terms and conditions, and other information contained herein; that this bid, offer or proposal constitutes an offer to the State that cannot be unilaterally withdrawn; that the product or service proposed meets the mandatory requirements contained in the Solicitation for that product or service, unless otherwise stated herein; that the Vendor accepts the terms and conditions contained in the Solicitation, unless otherwise stated herein; that I am submitting this bid, offer or proposal for review and consideration; that I am authorized by the vendor to execute and submit this bid, offer, or proposal, or any documents related thereto on vendor's behalf; that I am authorized to bind the vendor in a contractual relationship; and that to the best of my knowledge, the vendor has properly registered with any State agency that may require registration.

EKF Diagnostics
(Company)

(Authorized Signature) (Representative Name, Title)

(830) 249-0772 fax (830) 249-1851
(Phone Number) (Fax Number) (Date) 1-19-2016

ADDENDUM ACKNOWLEDGEMENT FORM
SOLICITATION NO.: WIC160000001

Instructions: Please acknowledge receipt of all addenda issued with this solicitation by completing this addendum acknowledgment form. Check the box next to each addendum received and sign below. Failure to acknowledge addenda may result in bid disqualification.

Acknowledgment: I hereby acknowledge receipt of the following addenda and have made the necessary revisions to my proposal, plans and/or specification, etc.

Addendum Numbers Received:
(Check the box next to each addendum received)

- [x] Addendum No. 1
- [x] Addendum No. 2
- [x] Addendum No. 3
- [ ] Addendum No. 4
- [ ] Addendum No. 5
- [ ] Addendum No. 6
- [ ] Addendum No. 7
- [ ] Addendum No. 8
- [ ] Addendum No. 9
- [ ] Addendum No. 10

I understand that failure to confirm the receipt of addenda may be cause for rejection of this bid. I further understand that any verbal representation made or assumed to be made during any oral discussion held between Vendor's representatives and any state personnel is not binding. Only the information issued in writing and added to the specifications by an official addendum is binding.

BKF Diagnostics
Company

Pat Burkey
Authorized Signature

1-19-2016
Date

NOTE: This addendum acknowledgement should be submitted with the bid to expedite document processing.

3.1.1.2 Analyzers must be capable of blood samples of 8 ul to 10 ul.

3.1.1.3 Each analyzer unit shall come complete with: software (capable of storing a minimum of 500 patient results), cable(s), connection device(s), and be ready to connect to a State-owned computer.

3.1.1.4 Analyzers must connect to a personal computer via a USB and serial ports to allow for the transfer of data to the WIC Crossroads SAM System.

3.1.1.4.1 Successful Vendors bidding an "equal to" product must provide an in-person demonstration to the ONS staff, at the Vendor's expense, showing that the alternate product fully functional within the WIC Crossroads SAM System.

3.1.1.4.2 The WIC Crossroads SAM System has a communication protocol that was developed to automatically transmit the hematological value from the analyzer to the specific computer screens located within the Crossroads Application, which is used in each WIC Clinic, to minimize data entry errors and increase data input rates.

3.1.1.5 Analyzers must be factory calibrated or have a data control lockout feature to prevent the modification or change of control parameters.

3.1.1.5.1 Analyzers must be factory calibrated against the ICSH (International Council for Standardization in Hematology) Reference and will need no further calibration post-delivery.

3.1.1.6 Analyzers must have a feature that allows for operator comments.

3.1.1.7 Analyzers must have a Linearity of up to 25.6 g/dL.

3.1.1.8 Analyzers must have a Total Precision CV of 1.3% or 1.5%.

3.1.1.9 Analyzers must have an internal self-test that verifies the performance of the optronic unit and a minimum of 4 points of a linearity range when it is turned on and a minimum of every 2 hours subsequently to ensure it is working properly.

3.1.1.10 Analyzer must be capable of sampling capillary, venous, or arterial whole blood.

3.1.1.11 Analyzer must be capable of operation with an AC adaptor or four (4) type AA batteries for backup.

3.1.1.12 Analyzer must be capable of producing results in g/dL within a minimum of 15 seconds and a maximum of 60 seconds.

3.1.1.13 Analyzers must come with a hard shell carrying case.

3.1.1.14 Analyzers must include tools such as: operators manual, suggested evaluations, and validation ad operating procedure templates for the hemoglobin systems.

3.1.1.15 A total of 56 analyzers must be provided by the successful Vendor at no cost to ONS, in order to replace existing equipment.

3.1.1.15.1 Analyzers in excess of 56 will be purchased by the ONS per the price listing on Exhibit A of the Pricing Pages.

3.1.1.16 Vendor should provide with their bid a copy of any hardware or software licensing and/or support terms and conditions to which the State of West Virginia or the Agency must agree to or accept, either in writing or digitally, in order to order and receive the commodities or services offered as part of this contract. Written terms will be required prior to the award of any contract resulting from this solicitation. Failure of vendor to provide additional terms and conditions with their submitted solicitation may result in disqualification of the vendor's bid.

3.1.2 Contract Item #2: Microcuvettes for use with the Hemocue HB201+ Analyzer, or compatible with the Analyzer bid under Section 3.1.1 or equal

3.1.2.1 Microcuvettes must be compatible with the Hemocue HB201+ Hemoglobin Analyzers, or equal, that are currently owned and in use by the ONS field offices.

3.1.2.1.1 Successful Vendors bidding an "equal to" product must provide an in-person demonstration to the ONS staff, at the Vendor's expense, showing that the alternate microcuvettes can be operated in the Hemocue HB201+ Hemoglobin Analyzers, or equal, and the Vendor will provide test results that are accurate to less than two (2) percent.

3.1.2.1.2 Successful Vendors must also show that any brand microcuvettes will work with the Hemocue HB201+ Hemoglobin Analyzers, or equal, due to a communication protocol that was developed to automatically transmit the hematological value from the analyzer to the specific computer screens located within the Crossroads Application, which is used in each WIC Clinic, to minimize data entry errors and increase data input rates.

3.1.2.2 Microcuvettes must be individually wrapped with 25 per package and 4 packages per box of 100, or equal.

3.1.2.3 Microcuvettes must have an expiration date in the future of at least twelve (12) months for unopened vials and three (3) months for opened vials.

3.1.2.4 Vendor must be able to supply the estimated annual usage of 1,000 boxes with 100 microcuvettes per box (i.e. 100,000 microcuvettes), whether it is less or more.

3.1.2.5 The Vendor must be able to provide a quantity of 100 boxes within a thirty-day period.

3.1.2.6 Vendor must include shipping and handling costs for all Microcuvette shipments over the life of the contract in the quoted price.

3.1.3 Contract Item #3: Vendor Training, Support, and Ongoing Assistance, or equal, over the life of the contract must be included in the quoted price

3.1.3.1 Vendor must provide eight (8) days of on-site training support per year. ONS will coordinate the training dates, times, and locations with the Vendor upon award of the Contract.

3.1.3.2 Vendor must provide annual on-site instrument in-process verification to ensure the equipment is still in good working order.

3.1.3.3 Vendor must provide online training and annual certification for all State Staff.

3.1.3.4 Upon receipt of the Analyzers bid under 3.1.1 to the State and/or Field Offices, the Vendor must provide site visits within 45 days to support the implementation and reinforce training. Vendor will also provide on-going online training to staff at no charge per ONS requests.

3.1.3.5 Vendor must provide telephone and/or email technical support available during the WIC Clinic Hours of 8:00 AM – 5:00 PM EST Monday through Friday.

4. CONTRACT AWARD:

4.1 **Contract Award:** The Contract is intended to provide Agencies with a purchase price on all Contract Items. The Contract shall be awarded to the Vendor that provides the Contract Items meeting the required specifications for the lowest overall Grand Total cost as shown on the Pricing Pages.

4.2 **Pricing Pages:** Vendor should complete the Pricing Pages by completing the Unit Price and Extended Price for each of the Contract Items, Grand Total, and Vendor Section. Vendor should complete the Pricing Pages in their entirety as failure to do so may result in Vendor's bids being disqualified.

The Pricing Pages contain a list of the Contract Items and estimated purchase volume. The estimated purchase volume for each item represents the approximate volume of anticipated purchases only. No future use of the Contract or any individual item is guaranteed or implied.

Vendor should electronically enter the information into the Pricing Pages through wvOASIS, if available, or as an electronic document.

5. ORDERING AND PAYMENT:

5.1 Ordering: Vendor shall accept orders through wvOASIS, regular mail, facsimile, e-mail, or any other written form of communication. Vendor may, but is not required to, accept on-line orders through a secure internet ordering portal/website. If Vendor has the ability to accept on-line orders, it should include in its response a brief description of how Agencies may utilize the on-line ordering system. Vendor shall ensure that its on-line ordering system is properly secured prior to processing Agency orders on-line.

5.2 Payment: Vendor shall accept payment in accordance with the payment procedures of the State of West Virginia.

6. DELIVERY AND RETURN:

6.1 Delivery Time: Vendor shall deliver standard orders within thirty (30) working days after orders are received. Vendor shall deliver emergency orders within ten (10) working day(s) after orders are received. Vendor shall deliver all applicable contract items to the WIC Storage Area at the WVDHHR Materials Management, 900 Bullitt Street, Charleston, WV 25301. Vendor shall ship all orders in accordance with the above schedule and shall not hold orders until a minimum delivery quantity is met.

6.2 Late Delivery: The Agency placing the order under this Contract must be notified in writing if orders will be delayed for any reason. Any delay in delivery that could cause harm to an Agency will be grounds for cancellation of the delayed order, and/or obtaining the items ordered from a third party.

Any Agency seeking to obtain items from a third party under this provision must first obtain approval of the Purchasing Division.

6.3 Delivery Payment/Risk of Loss: Standard order delivery shall be F.O.B.

destination to the Agency's location. Vendor shall include the cost of standard order delivery charges in its bid pricing/discount and is not permitted to charge the Agency separately for such delivery. The Agency will pay delivery charges on all emergency orders provided that Vendor invoices those delivery costs as a separate charge with the original freight bill attached to the invoice.

6.4 **Return of Unacceptable Items:** If the Agency deems the Contract Items to be unacceptable, the Contract Items shall be returned to Vendor at Vendor's expense and with no restocking charge. Vendor shall either make arrangements for the return within five (5) days of being notified that items are unacceptable, or permit the Agency to arrange for the return and reimburse Agency for delivery expenses. If the original packaging cannot be utilized for the return, Vendor will supply the Agency with appropriate return packaging upon request. All returns of unacceptable items shall be F.O.B. the Agency's location. The returned product shall either be replaced, or the Agency shall receive a full credit or refund for the purchase price, at the Agency's discretion.

6.5 **Return Due to Agency Error**: Items ordered in error by the Agency will be returned for credit within 30 days of receipt, F.O.B. Vendor's location. Vendor shall not charge a restocking fee if returned products are in a resalable condition. Items shall be deemed to be in a resalable condition if they are unused and in the original packaging. Any restocking fee for items not in a resalable condition shall be the lower of the Vendor's customary restocking fee or 5% of the total invoiced value of the returned items.

7. VENDOR DEFAULT:

7.1 The following shall be considered a vendor default under this Contract.

7.1.1 Failure to provide Contract Items in accordance with the requirements contained herein.

7.1.2 Failure to comply with other specifications and requirements contained herein.

7.1.3 Failure to comply with any laws, rules, and ordinances applicable to the Contract Services provided under this Contract.

7.1.4 Failure to remedy deficient performance upon request.

7.2 The following remedies shall be available to Agency upon default.

7.2.1 Immediate cancellation of the Contract.

7.2.2 Immediate cancellation of one or more release orders issued under this Contract.

7.2.3 Any other remedies available in law or equity.

8. MISCELLANEOUS:

8.1 **No Substitutions:** Vendor shall supply only Contract Items submitted in response to the Solicitation unless a contract modification is approved in accordance with the provisions contained in this Contract.

8.2 **Vendor Supply:** Vendor must carry sufficient inventory of the Contract Items being offered to fulfill its obligations under this Contract. By signing its bid, Vendor certifies that it can supply the Contract Items contained in its bid response.

8.3 **Reports:** Vendor shall provide quarterly reports and annual summaries to the Agency showing the Agency's items purchased, quantities of items purchased, and total dollar value of the items purchased. Vendor shall also provide reports, upon request, showing the items purchased during the term of this Contract, the quantity purchased for each of those items, and the total value of purchases for each of those items. Failure to supply such reports may be grounds for cancellation of this Contract.

8.4 **Contract Manager:** During its performance of this Contract, Vendor must designate and maintain a primary contract manager responsible for overseeing Vendor's responsibilities under this Contract. The Contract manager must be available during normal business hours to address any customer service or other issues related to this Contract. Vendor should list its Contract manager and his or her contact information below.

Contract Manager: Pat Breheny
Telephone Number: 330 249-0772
Fax Number: 330 249-0851
Email Address: PatBreheny@EKFDiagnostics.com

Exhibit A
Pricing Pages
CRQM – WIC1600000001

Contract Item #	Description	Estimated Quantity	Unit Price	Extended Price
3.1.1	Hemocue HB201+ Hemoglobin Analyzers, or equal	100 Each	$0.00	$ $0.00
3.1.2	Microcuvettes for use with the Hemocue HB201+ Analyzer, or compatible with the Analyzer bid under Section 3.1.1 ** Must be individually wrapped with 25 per package and 4 packages per box of 100, or equal.	1,000 Boxes	$76.00= 1 Box of 50 Microcuvettes $152.00= 2 Hemopoint#12 boxes = 100 Microcuvettes	$
3.1.3	Vendor Training, Support, and Ongoing Assistance, or equal, over the life of the contract must be included in the quoted price	Minimum 8 Trainings	$ 0.00	$ $0.00
			Grand Total	$ 152,000

Contract will be awarded to the Vendor that provides the Service Items meeting the required specifications for the lowest overall Grand Total cost.

Delivery of orders will be F.O.B. Destination.

The estimated quantity for each Service Item represents the approximate volume of anticipated purchases only. No future use of the Contract or any individual Service Item is guaranteed or implied.

Vendor Name: EKF Diagnostics
Physical Address: 1261 North Main Boerne, Texas 78006
Remit to Address: 1261 North Main Boerne, Texas 78006
Telephone: (830) 249-0772
Fax: (830) 249-0851
Email: patbreheny@EKFdiagnostics.com
Vendor Representative (print name): Pat Breheny

Signature: Pat Breheny	**Date:** 1-18-16

ATTACHMENT 1

Provisions Required for Federally Funded Procurements

1. **Federal Funds:** This purchase is being funded in whole or in part with Federal Funds and is subject to the requirements established in 2 CFR § 200. Pursuant to 2 CFR § 200.317 the provisions of 2 CFR §§ 200.322 and 200.326 are expressly included in this solicitation below and incorporated into any contract resulting from this solicitation by reference.

2. **2 CFR §200.322 Procurement of recovered materials:** A non-Federal entity that is a state agency or agency of a political subdivision of a state and its contractors must comply with section 6002 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act. The requirements of Section 6002 include procuring only items designated in guidelines of the Environmental Protection Agency (EPA) at 40 CFR part 247 that contain the highest percentage of recovered materials practicable, consistent with maintaining a satisfactory level of competition, where the purchase price of the item exceeds $10,000 or the value of the quantity acquired during the preceding fiscal year exceeded $10,000; procuring solid waste management services in a manner that maximizes energy and resource recovery; and establishing an affirmative procurement program for procurement of recovered materials identified in the EPA guidelines.

3. **§200.326 Contract provisions:** Pursuant to the requirements contained in 2 CFR §§ 200.317 and 200.326, the following provisions are included any contract resulting from this solicitation, to the extent that the provisions are applicable.

   (A) At a minimum, the administrative, contractual, or legal remedies contained in W. Va. CSR § 148-1-5 and the applicable definitions contained in W. Va. CSR § 148-1-2 apply to any contract resulting from this solicitation in instances where contractors violate or breach contract terms for contracts for more than the simplified acquisition threshold currently set at $150,000 (which is the inflation adjusted amount determined by the Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (Councils) as authorized by 41 U.S.C. 1908).,

   West Virginia Code of State Rules § 148-1-5 states:

   § 148-1-5. Remedies.

   5.1. The Director may require that the spending unit attempt to resolve any issues that it may have with the vendor prior to pursuing a remedy contained herein. The spending unit must document any resolution efforts and provide copies of those documents to the Purchasing Division.

   5.2. Contract Cancellation.

5.2.a. Cancellation. The Director may cancel a purchase or contract immediately under any one of the following conditions including, but not limited to:

5.2.a.1. The vendor agrees to the cancellation;

5.2.a.2. The vendor has obtained the contract by fraud, collusion, conspiracy, or is in conflict with any statutory or constitutional provision of the State of West Virginia;

5.2.a.3. Failure to honor any contractual term or condition or to honor standard commercial practices;

5.2.a.4. The existence of an organizational conflict of interest is identified;

5.2.a.5. Funds are not appropriated or an appropriation is discontinued by the legislature for the acquisition.

5.2.a.6. Violation of any federal, state, or local law, regulation, or ordinance.

5.2.b. The Director may cancel a purchase or contract for any reason or no reason, upon providing the vendor with 30 days' notice of the cancellation.

5.2.c. Opportunity to Cure. In the event that a vendor fails to honor any contractual term or condition, or violates any provision of federal, state, or local law, regulation, or ordinance, the Director may request that the vendor remedy the contract breach or legal violation within a time frame the Director determines to be appropriate. If the vendor fails to remedy the contract breach or legal violation or the Director determines, at his or her sole discretion, that such a request is unlikely to yield a satisfactory result, then he or she may cancel immediately without providing the vendor an opportunity to perform a remedy.

5.2.d. Re-Award. The Director may award the cancelled contract to the next lowest responsible bidder (or next highest scoring bidder if best value procurement) without a subsequent solicitation if the following conditions are met:

5.2.d.1. The next lowest responsible bidder (or next highest scoring bidder if best value procurement) is able to perform at the price contained in its original bid submission, and

5.2.d.2. The contract is an open-end contract, a one-time purchase contract, or a contract for work which has not yet commenced.

Award to the next lowest responsible bidder (or next highest scoring bidder if best value procurement) will not be an option if the vendor's failure has in any way increased or significantly changed the scope of the original contract. The vendor failing to honor contractual and legal obligations is responsible for any increase in cost the state incurs as a result of the re-award.

5.3. Non-Responsible. If the Director believes that a vendor may be non-responsible, the Director may request that a vendor or spending unit provide evidence that the vendor either does or does not have the capability to fully perform the contract requirements, and the integrity and reliability necessary to assure good faith performance. If the Director determines that the vendor is non-responsible, the Director shall reject that vendor's bid and shall not award the contract to that vendor. A determination of non-responsibility must be evaluated on a case-by-case basis and can only be made after the vendor in question has submitted a bid. A determination of non-responsibility will only extend to the contract for which the vendor has submitted a bid and does not operate as a bar against submitting future bids.

5.4. Suspension.

5.4.a. The Director may suspend, for a period not to exceed one (1) year, the right of a vendor to bid on procurements issued by the Purchasing Division or any state spending unit under its authority if:

5.4.a.1. The vendor has exhibited a pattern of submitting bids and then requesting that its bid be withdrawn after bids have been publicly opened. For purposes of this provision, a pattern is two or more instances in any 12 month period.

5.4.a.2. The vendor has exhibited a pattern of poor performance in fulfilling his or her contractual obligations to the State. Poor performance includes, but is not limited to, two or more instances of any of the following: violations of law, regulation, or ordinance; failure to deliver timely; failure to deliver quantities ordered; poor performance reports; and failure to deliver commodities, services, or printing at the quality level required by the contract.

5.4.a.3. The vendor has breached a contract issued by the Purchasing Division or any state spending unit under its authority and refuses to remedy that breach.

5.4.a.4. The vendor's actions have given rise to one or more of the grounds for debarment listed in section 5A-3-33d.

5.4.c. A vendor may appeal a decision of the Director to the Secretary of Administration. The appeal must be in writing and served on the Secretary no later than five (5) working days of receipt of the Director's decision.

5.4.d. The Secretary, or his or her designee, will schedule an appeal hearing and serve on the vendor, a notice of hearing that includes the date, time and place of the hearing. The appeal hearing will be recorded and an official record prepared. Within ten (10) working days of the conclusion of the appeal hearing, the Secretary will issue and serve on the vendor a written decision either confirming or reversing the suspension.

5.4.e. Any notice or service related to suspension actions or proceedings must be provided by certified mail, return receipt requested.

5.5. Vendor Debarment. The Director may debar a vendor on the basis of one or more of the grounds for debarment contained in West Virginia Code § 5A-3-33d or if the vendor has been declared ineligible to participate in procurement related activities under federal laws and regulation.

5.5.a. Debarment proceedings shall be conducted in accordance with West Virginia Code § 5A-3-33e and these rules. A vendor that has received notice of the proposed debarment by certified mail, return receipt requested, must respond to the proposed debarment within 30 working days after receipt of notice or the debarment will be instituted without further notice. A vendor is deemed to have received notice, notwithstanding the vendor's failure to accept the certified mail, if the letter is addressed to the vendor at its last known address. After considering the matter and reaching a decision, the Director shall notify the vendor of his or her decision by certified mail, return receipt requested.

5.5.b. Any vendor, other than a vendor prohibited from participating in federal procurement, undergoing debarment proceedings is permitted to continue participating in the state's procurement process until a final debarment decision has been reached. Any contract that a debarred vendor obtains prior to a final debarment decision shall remain in effect for the current term, but may not be extended or renewed. Notwithstanding the foregoing, the Director may cancel a contract held by a debarred vendor if the Director determines, in his or her sole discretion, that doing so is in the best interest of the State. A vendor prohibited from participating in federal procurement will not be permitted to participate in the state's procurement process during debarment proceedings.

5.5.c. If the Director's final debarment decision is that debarment is warranted and notice of the final debarment decision is mailed, the Purchasing Division shall reject any bid submitted by the debarred vendor,

including any bid submitted prior to the final debarment decision if that bid has not yet been accepted and a contract consummated. 5.5.d. Pursuant to West Virginia Code section 5A-3-33e(e), the length of the debarment period will be specified in the debarment decision and will be for a period of time that the Director finds necessary and proper to protect the public from an irresponsible vendor.

5.5.e. List of Debarred Vendors. The Director shall maintain and publicly post a list of debarred vendors on the Purchasing Division's website.

5.6. Damages.

5.6.a. A vendor who fails to perform as required under a contract shall be liable for actual damages and costs incurred by the state.

5.6.b. If any commodities delivered under a contract have been used or consumed by a spending unit and on testing the commodities are found not to comply with specifications, no payment may be approved by the Spending Unit for the merchandise until the amount of actual damages incurred has been determined.

5.6.c. The Spending Unit shall seek to collect damages by following the procedures established by the Office of the Attorney General for the collection of delinquent obligations.

(B) At a minimum, the termination for cause and for convenience provisions contained in W. Va. CSR § 148-1-5.2 and the applicable definitions contained in W. Va. CSR § 148-1-2 apply to any contract in excess of $10,000 resulting from this solicitation.

West Virginia Code of State Rules § 148-1-5.2 states:

5.2. Contract Cancellation.

5.2.a. Cancellation. The Director may cancel a purchase or contract immediately under any one of the following conditions including, but not limited to:

5.2.a.1. The vendor agrees to the cancellation;

5.2.a.2. The vendor has obtained the contract by fraud, collusion, conspiracy, or is in conflict with any statutory or constitutional provision of the State of West Virginia;

5.2.a.3. Failure to honor any contractual term or condition or to honor standard commercial practices;

5.2.a.4. The existence of an organizational conflict of interest is identified;

5.2.a.5. Funds are not appropriated or an appropriation is discontinued by the legislature for the acquisition.

5.2.a.6. Violation of any federal, state, or local law, regulation, or ordinance.

5.2.b. The Director may cancel a purchase or contract for any reason or no reason, upon providing the vendor with 30 days' notice of the cancellation.

5.2.c. Opportunity to Cure. In the event that a vendor fails to honor any contractual term or condition, or violates any provision of federal, state, or local law, regulation, or ordinance, the Director may request that the vendor remedy the contract breach or legal violation within a time frame the Director determines to be appropriate. If the vendor fails to remedy the contract breach or legal violation or the Director determines, at his or her sole discretion, that such a request is unlikely to yield a satisfactory result, then he or she may cancel immediately without providing the vendor an opportunity to perform a remedy.

(C) **Equal Employment Opportunity.** Except as otherwise provided under 41 CFR Part 60, all contracts that meet the definition of **"federally assisted construction contract"** in 41 CFR Part 60–1.3 must include the equal opportunity clause provided under 41 CFR 60–1.4(b), in accordance with Executive Order 11246, "Equal Employment Opportunity" (30 FR 12319, 12935, 3 CFR Part, 1964–1965 Comp., p. 339), as amended by Executive Order 11375, "Amending Executive Order 11246 Relating to Equal Employment Opportunity," and implementing regulations at 41 CFR part 60, "Office of Federal Contract Compliance Programs, Equal Employment Opportunity, Department of Labor."

41 CFR § 60-1.3 defines "Federally assisted construction contract" as any agreement or modification thereof between any applicant and a person for construction work which is paid for in whole or in part with funds obtained from the Government or borrowed on the credit of the Government pursuant to any Federal program involving a grant, contract, loan, insurance, or guarantee, or undertaken pursuant to any Federal program involving such grant, contract, loan, insurance, or guarantee, or any application or modification thereof approved by the Government for a grant, contract, loan, insurance, or guarantee under which the applicant itself participates in the construction work.

Accordingly, to the extent that this contract meets the definition of a "federally assisted construction contract" under 41 CFR Part 60-1.3, the following clause is included:

41 CFR 60-1.4 - Equal opportunity clause. (b) *Federally assisted construction contracts.*

In accordance with the requirements of described above, and except as otherwise provided in the applicable regulations, the following language is hereby incorporated into any contract resulting from this solicitation involving federally assisted construction which is not exempt from the requirements of the equal opportunity clause:

> The applicant hereby agrees that it will incorporate or cause to be incorporated into any contract for construction work, or modification thereof, as defined in the regulations of the Secretary of Labor at 41 CFR Chapter 60, which is paid for in whole or in part with funds obtained from the Federal Government or borrowed on the credit of the Federal Government pursuant to a grant, contract, loan insurance, or guarantee, or undertaken pursuant to any Federal program involving such grant, contract, loan, insurance, or guarantee, the following equal opportunity clause:
>
> During the performance of this contract, the contractor agrees as follows:

(1) The contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin. The contractor will take affirmative action to ensure that applicants are employed, and that employees are treated during employment without regard to their race, color, religion, sex, or national origin. such action shall include, but not be limited to the following: Employment, upgrading, demotion, or transfer; recruitment or recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship. The contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices to be provided setting forth the provisions of this nondiscrimination clause.

(2) The contractor will, in all solicitations or advertisements for employees placed by or on behalf of the contractor, state that all qualified applicants will receive considerations for employment without regard to race, color, religion, sex, or national origin.

(3) The contractor will send to each labor union or representative of workers with which he has a collective bargaining agreement or other contract or understanding, a notice to be provided advising the said labor union or workers' representatives of the contractor's commitments under this section, and shall post copies of the notice in conspicuous places available to employees and applicants for employment.

(4) The contractor will comply with all provisions of Executive Order 11246 of September 24, 1965, and of the rules, regulations, and relevant orders of the Secretary of Labor.

(5) The contractor will furnish all information and reports required by Executive Order 11246 of September 24, 1965, and by rules, regulations, and orders of the Secretary of Labor, or pursuant thereto, and will permit access to his books, records, and accounts by the administering agency and the Secretary of Labor for purposes of investigation to ascertain compliance with such rules, regulations, and orders.

(6) In the event of the contractor's noncompliance with the nondiscrimination clauses of this contract or with any of the said rules, regulations, or orders, this contract may be canceled, terminated, or suspended in whole or in part and the contractor may be declared ineligible for further Government contracts or federally assisted construction contracts in accordance with procedures authorized in Executive Order 11246 of September 24, 1965, and such other sanctions may be imposed and remedies invoked as provided in Executive Order 11246 of September 24, 1965, or by rule, regulation, or order of the Secretary of Labor, or as otherwise provided by law.

(7) The contractor will include the portion of the sentence immediately preceding paragraph (1) and the provisions of paragraphs (1) through (7) in every subcontract or purchase order unless exempted by rules, regulations, or orders of the Secretary of Labor issued pursuant to section 204 of Executive Order 11246 of September 24, 1965, so that such provisions will be binding upon each subcontractor or vendor. The contractor will take such action with respect to any subcontract or purchase order as the administering agency may direct as a means of enforcing such provisions, including sanctions for noncompliance: *Provided, however,* That in the event a contractor becomes involved in, or is threatened with, litigation with a subcontractor or vendor as a result of such direction by the administering agency the contractor may

request the United States to enter into such litigation to protect the interests of the United States.

The applicant further agrees that it will be bound by the above equal opportunity clause with respect to its own employment practices when it participates in federally assisted construction work: *Provided,* That if the applicant so participating is a State or local government, the above equal opportunity clause is not applicable to any agency, instrumentality or subdivision of such government which does not participate in work on or under the contract.

The applicant agrees that it will assist and cooperate actively with the administering agency and the Secretary of Labor in obtaining the compliance of contractors and subcontractors with the equal opportunity clause and the rules, regulations, and relevant orders of the Secretary of Labor, that it will furnish the administering agency and the Secretary of Labor such information as they may require for the supervision of such compliance, and that it will otherwise assist the administering agency in the discharge of the agency's primary responsibility for securing compliance.

The applicant further agrees that it will refrain from entering into any contract or contract modification subject to Executive Order 11246 of September 24, 1965, with a contractor debarred from, or who has not demonstrated eligibility for, Government contracts and federally assisted construction contracts pursuant to the Executive order and will carry out such sanctions and penalties for violation of the equal opportunity clause as may be imposed upon contractors and subcontractors by the administering agency or the Secretary of Labor pursuant to Part II, Subpart D of the Executive order. In addition, the applicant agrees that if it fails or refuses to comply with these undertakings, the administering agency may take any or all of the following actions: Cancel, terminate, or suspend in whole or in part this grant (contract, loan, insurance, guarantee); refrain from extending any further assistance to the applicant under the program with respect to which the failure or refund occurred until satisfactory assurance of future compliance has been received from such applicant; and refer the case to the Department of Justice for appropriate legal proceedings.

(D) **Davis-Bacon Act, as amended (40 U.S.C.3141–3148).** Any construction contract resulting from this solicitation hereby requires compliance with the Davis-Bacon Act (40 U.S.C.3141–3144, and 3146–3148) as supplemented by Department of Labor regulations (29 CFR Part 5, "Labor

Standards Provisions Applicable to Contracts Covering Federally Financed and Assisted Construction"). In accordance with the statute, contractors are required to pay wages to laborers and mechanics at a rate not less than the prevailing wages specified in a wage determination made by the Secretary of Labor. In addition, contractors are required to pay wages not less than once a week.

Any construction contract resulting from this solicitation hereby requires compliance with the Copeland "Anti-Kickback" Act (40 U.S.C. 3145), as supplemented by Department of Labor regulations (29 CFR Part 3, "Contractors and Subcontractors on Public Building or Public Work Financed in Whole or in Part by Loans or Grants from the United States"). The Act provides that each contractor or subrecipient are prohibited from inducing, by any means, any person employed in the construction, completion, or repair of public work, to give up any part of the compensation to which he or she is otherwise entitled.

(E) **Contract Work Hours and Safety Standards Act (40 U.S.C. 3701–3708).** Where applicable, any contract resulting from this solicitation in excess of $100,000 that involve the employment of mechanics or laborers hereby requires compliance with 40 U.S.C. 3702 and 3704, as supplemented by Department of Labor regulations (29 CFR Part 5). Under 40 U.S.C. 3702 of the Act, each contractor is required to compute the wages of every mechanic and laborer on the basis of a standard work week of 40 hours. Work in excess of the standard work week is permissible provided that the worker is compensated at a rate of not less than one and a half times the basic rate of pay for all hours worked in excess of 40 hours in the work week. The requirements of 40 U.S.C. 3704 are applicable to construction work and provide that no laborer or mechanic must be required to work in surroundings or under working conditions which are unsanitary, hazardous or dangerous. These requirements do not apply to the purchases of supplies or materials or articles ordinarily available on the open market, or contracts for transportation or transmission of intelligence.

(F) **Rights to Inventions Made Under a Contract or Agreement.** If the Federal award meets the definition of "funding agreement' 'under 37 CFR § 401.2 (a) and the recipient or subrecipient wishes to enter into a contract with a small business firm or nonprofit organization regarding the substitution of parties, assignment or performance of experimental, developmental, or research work under that "funding agreement," the recipient or subrecipient must comply with the requirements of 37 CFR Part 401, "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements," and any implementing regulations issued by the awarding agency.

(G) **Clean Air Act (42 U.S.C. 7401–7671q.) and the Federal Water Pollution Control Act (33 U.S.C. 1251–1387), as amended**— Any contract resulting from this solicitation in excess of $150,000 hereby requires compliance with all applicable standards, orders or regulations issued pursuant to the Clean Air Act (42 U.S.C. 7401–7671q) and the Federal Water Pollution Control Act as amended (33 U.S.C.1251–1387).

(H) **Debarment and Suspension (Executive Orders 12549 and 12689)**— Any contract resulting from this solicitation will not be awarded to parties listed on the government wide Excluded Parties List System in the System for Award Management (SAM), in accordance with the OMB guidelines at 2 CFR 180 that implement Executive Orders 12549 (3 CFR Part 1986 Comp., p. 189) and 12689 (3 CFR Part 1989 Comp., p. 235), "Debarment and Suspension."

(I) **Byrd Anti-Lobbying Amendment (31 U.S.C. 1352)**— Any contract resulting from this solicitation requires compliance with the Byrd Anti-Lobbying Amendment (31 U.S.C. 1352). Contractors that apply or bid for an award of $100,000 or more must file the required certification. Each tier certifies to the tier above that it will not and has not used Federal appropriated funds to pay any person or organization for influencing or attempting to influence an officer or employee of any agency, a member of Congress, officer or employee of Congress, or an employee of a member of Congress in connection with obtaining any Federal contract, grant or any other award covered by 31 U.S.C. 1352. Each tier must also disclose any lobbying with non-Federal funds that takes place in connection with obtaining any Federal award. Such disclosures are forwarded from tier to tier up to the non-Federal award.

ADDENDUM ACKNOWLEDGEMENT FORM
SOLICITATION NO.: WIC1600000001

Instructions: Please acknowledge receipt of all addenda issued with this solicitation by completing this addendum acknowledgment form. Check the box next to each addendum received and sign below. Failure to acknowledge addenda may result in bid disqualification.

Acknowledgment: I hereby acknowledge receipt of the following addenda and have made the necessary revisions to my proposal, plans and/or specification, etc.

Addendum Numbers Received:
(Check the box next to each addendum received)

[X]	Addendum No. 1	[ ]	Addendum No. 6
[X]	Addendum No. 2	[ ]	Addendum No. 7
[X]	Addendum No. 3	[ ]	Addendum No. 8
[ ]	Addendum No. 4	[ ]	Addendum No. 9
[ ]	Addendum No. 5	[ ]	Addendum No. 10

I understand that failure to confirm the receipt of addenda may be cause for rejection of this bid. I further understand that any verbal representation made or assumed to be made during any oral discussion held between Vendor's representatives and any state personnel is not binding. Only the information issued in writing and added to the specifications by an official addendum is binding.

EKF Diagnostics
Company

Pat Buck
Authorized Signature

1-18-16
Date

NOTE: This addendum acknowledgement should be submitted with the bid to expedite document processing.
Revised 6/8/2012

SOLICITATION NUMBER: CRFQ – CME1600000001
Addendum Number: 1

The purpose of this addendum is to modify the solicitation identified as CRFQ CME1600000001 ("Solicitation") to reflect the change(s) identified and described below.

Applicable Addendum Category:

[X] Modify bid opening date and time

[ ] Modify specifications of product or service being sought

[ ] Attachment of vendor questions and responses

[ ] Attachment of pre-bid sign-in sheet

[ ] Correction of error

[ ] Other

Description of Modification to Solicitation:

1. To move bid opening date from 1/8/2016 to 1/7/2016

Additional Documentation: Documentation related to this Addendum (if any) has been included herewith as Attachment A and is specifically incorporated herein by reference.

Terms and Conditions:

1. All provisions of the Solicitation and other addenda not modified herein shall remain in full force and effect.

2. Vendor should acknowledge receipt of all addenda issued for this Solicitation by completing an Addendum Acknowledgment, a copy of which is included herewith. Failure to acknowledge addenda may result in bid disqualification. The addendum acknowledgement should be submitted with the bid to expedite document processing.

Purchasing Divison
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

State of West Virginia
Request for Quotation
34 — Service - Prof

Proc Folder: 44604

Doc Description: Addendum No. 1 - to change bid opening date to 1/7/2016

Proc Type: Central Master Agreement

Date Issued	Solicitation Closes	Solicitation No	Version
2015-12-07	2016-01-07 13:30:00	CRFQ 0506 CME1600000001	2

BID RECEIVING ADDRESS

BID CLERK
DEPARTMENT OF ADMINISTRATION
PURCHASING DIVISION
2019 WASHINGTON ST E
CHARLESTON WV 25305
US

VENDOR

Vendor Name, Address and Telephone Number:

EKF Diagnostics
12601 North Main Street
Boerne, TX 78006
830-249-0772

FOR INFORMATION CONTACT THE BUYER
April Battle
(304) 558-0067
april.e.battle@wv.gov

Signature X Pat Duckett **FEIN #** 45 33 56 270 **DATE** 1-18-16

All offers subject to all terms and conditions contained in this solicitation

ADDITIONAL INFORMATION

Addendum No. 1 - To change bid opening date from 1/8/2016 to 1/7/2016.

INVOICE TO	SHIP TO
PURCHASING DIRECTOR - 304-356-4095 HEALTH AND HUMAN RESOURCES BUREAU FOR PUBLIC HEALTH OFFICE CHIEF MEDICAL EXAMINER 619 VIRGINIA ST WEST CHARLESTON WV25302 US	PURCHASING DIRECTOR - 304-356-4095 HEALTH AND HUMAN RESOURCES BUREAU FOR PUBLIC HEALTH OFFICE CHIEF MEDICAL EXAMINER 619 VIRGINIA ST W CHARLESTON WV 25302 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
1	Toxicology test kits or supplies	1.00000	EA		

Comm Code	Manufacturer	Specification	Model #
41116146			

Extended Description :
Grand Total from the Pricing Page

SCHEDULE OF EVENTS

Line	Event	Event Date
1	TQ due	2015-12-22

SOLICITATION NUMBER: CRFQ 0506 WIC1600000001
Addendum Number: 2

The purpose of this addendum is to modify the solicitation identified as ("Solicitation") to reflect the change(s) identified and described below.

Applicable Addendum Category:

[✓] Modify bid opening date and time

[ ] Modify specifications of product or service being sought

[ ] Attachment of vendor questions and responses

[ ] Attachment of pre-bid sign-in sheet

[ ] Correction of error

[ ] Other

Description of Modification to Solicitation:

1) To extend the bid opening date from January 7, 2016, at 1:30 PM EST to January 21, 2016, at 1:30 PM EST.

Additional Documentation: Documentation related to this Addendum (if any) has been included herewith as Attachment A and is specifically incorporated herein by reference.

Terms and Conditions:

1. All provisions of the Solicitation and other addenda not modified herein shall remain in full force and effect.

2. Vendor should acknowledge receipt of all addenda issued for this Solicitation by completing an Addendum Acknowledgment, a copy of which is included herewith. Failure to acknowledge addenda may result in bid disqualification. The addendum acknowledgement should be submitted with the bid to expedite document processing.

Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

State of West Virginia
Request for Quotation
26 — Medical

Proc Folder: 128946

Doc Description: Addendum No. 2 - To move bid opening date to 1/21/16.

Proc Type: Central Master Agreement

Date Issued	Solicitation Closes	Solicitation No	Version
2015-12-31	2016-01-21 13:30:00	CRFQ 0506 WIC1600000001	3

BID CLERK
DEPARTMENT OF ADMINISTRATION
PURCHASING DIVISION
2019 WASHINGTON ST E
CHARLESTON WV 25305
US

VENDOR

Vendor Name, Address and Telephone Number:

EKF Diagnostics
1261 North Main
Boerne, TX 78006
830-249-0772

FOR INFORMATION CONTACT THE BUYER

April Battle
(304) 558-0067
april.e.battle@wv.gov

Signature X Pat Duhy **FEIN #** 45-3354270 **DATE** 1-18-16

All offers subject to all terms and conditions contained in this solicitation

ADDITIONAL INFORMATION

Addendum No. 2 - To move bid opening date from 1/7/2016 to 1/21/2016.

INVOICE TO	SHIP TO
PURCHASING DIRECTOR - 304-356-4095 HEALTH AND HUMAN RESOURCES BPH - NUTRITION SERVICES 350 CAPITOL ST, RM 519 CHARLESTON WV25301-3717 US	PURCHASING DIRECTOR - 304-356-4095 HEALTH AND HUMAN RESOURCES BPH - NUTRITION SERVICES (WIC) C/O DHHR MATERIALS MANAGEMENT 900 BULLITT ST CHARLESTON WV 25301 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
1	Clinical and diagnostic analyzers and accessories & supplies	100.00000	EA		

Comm Code	Manufacturer	Specification	Model #
41115800			

Extended Description :

Section 3.1.1 - Contract Item #1: Hemocue HB201+ Hemoglobin Analyzers, or equal

100 Each

INVOICE TO	SHIP TO
PURCHASING DIRECTOR - 304-356-4095 HEALTH AND HUMAN RESOURCES BPH - NUTRITION SERVICES 350 CAPITOL ST, RM 519 CHARLESTON WV25301-3717 US	PURCHASING DIRECTOR - 304-356-4095 HEALTH AND HUMAN RESOURCES BPH - NUTRITION SERVICES (WIC) C/O DHHR MATERIALS MANAGEMENT 900 BULLITT ST CHARLESTON WV 25301 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
2	Medical Equipment and Accessories and Supplies	1000.00000	BOX		

Comm Code	Manufacturer	Specification	Model #
42000000			

Extended Description :

Section 3.1.2 - Contract Item #2: Microcuvettes for use with the Hemocue HB201+ Analyzer, or compatible with the Analyzer bid under Section 3.1.1

1,000 Boxes

Must be individually wrapped with 25 per package and 4 packages per box of 100, or equal.

BILL TO	SHIP TO
PURCHASING DIRECTOR - 304-356-4095 HEALTH AND HUMAN RESOURCES BPH - NUTRITION SERVICES 350 CAPITOL ST, RM 519 CHARLESTON WV25301-3717 US	PURCHASING DIRECTOR - 304-356-4095 HEALTH AND HUMAN RESOURCES BPH - NUTRITION SERVICES (WIC) C/O DHHR MATERIALS MANAGEMENT 900 BULLITT ST CHARLESTON WV 25301 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
3	Training planning, facilitation and delivery services	8.00000	EA		

Comm Code	Manufacturer	Specification	Model #
86132100			

Extended Description :

Section 3.1.3 - Contract Item #3: Vendor Training, Support, and Ongoing Assistance, or equal, over the life of the contract must be included in the quoted price

Minimum 8 Trainings

SCHEDULE OF EVENTS

Line	Event	Event Date
1	TQ due	2015-12-22

ADDITIONAL TERMS AND CONDITIONS

See attached document(s) for additional Terms and Conditions

SOLICITATION NUMBER: CRFQ 0506 WIC1600000001
Addendum Number: 3

The purpose of this addendum is to modify the solicitation identified as ("Solicitation") to reflect the change(s) identified and described below.

Applicable Addendum Category:

[ ] Modify bid opening date and time

[ ] Modify specifications of product or service being sought

[✓] Attachment of vendor questions and responses

[ ] Attachment of pre-bid sign-in sheet

[ ] Correction of error

[ ] Other

Description of Modification to Solicitation:

1) To answer the technical questions submitted by vendors.

Additional Documentation: Documentation related to this Addendum (if any) has been included herewith as Attachment A and is specifically incorporated herein by reference.

Terms and Conditions:

1. All provisions of the Solicitation and other addenda not modified herein shall remain in full force and effect.

2. Vendor should acknowledge receipt of all addenda issued for this Solicitation by completing an Addendum Acknowledgment, a copy of which is included herewith. Failure to acknowledge addenda may result in bid disqualification. The addendum acknowledgement should be submitted with the bid to expedite document processing.

ATTACHMENT A

ATTACHMENT A
CRFQ WIC1600000001

ADDENDUM #3 – TO RESPOND TO VENDOR QUESTIONS

Vendor Question #1:
We have a question in regards to item 3.1.1.6 which reads 3.1.1.6 "Analyzers must have a feature that allows for operator comments."

Agency Response to Vendor Question #1:
Delete Item 3.1.1.6. The product HemoCue HB201+ Analyzers, or equal, does not have or need this capability of allowing for operator comments.

Vendor Question #2:
HemoCue analyzers have the ability to connect via Crossroads SAM in place with the state of West Virginia. Can you please clarify this question as we prepare to submit our bid response?

Agency Response to Vendor Question #2
The HemoCue analyzers connect to the Crossroads SAM system via a USB cable and works through an existing interface between the analyzer and the Crossroads application. This interface is designed to ensure the correct hematological value is automatically transmitted from the analyzer to the specific computer screens located within the Crossroads Application.

Vendor Question #3:
Section 3.1.2.2 states that Microcuvettes must be individually wrapped. The package size need be 25 Microcuvettes per package and 4 packages per box of 100, or equal. EKF Diagnostics dba Stanbio Laboratory offers individually wrapped Microcuvettes in a box of 50 count. We would provide two boxes of 50 count to the equal the 100 that are requested. Would this be acceptable to State of West Virginia (WV DHHR)?

Agency Response to Vendor Question #3
Yes, the packing of 50 individually wrapped microcuvettes for one box and two boxes count towards the 100 requirement is acceptable, as long as the microcuvettes are individually wrapped. However, this will require a change with our local clinic ordering form and the shipment of microcuvettes from our WIC Storage Area located at WVDHHR's Materials Management Warehouse.

Vendor Question #4:
Is the State of West Virginia (WVDHHR) currently utilizing the Crossroads system at this time? If not, when is the WV DHHR planning to implement their system? Are any of the HemoCue HB-201 + analyzers currently in use by your facilities connected to your Crossroads system? If

not, when will the Crossroads system be implemented and what is the timeline for the connection of the HemoCue HB-201+ analyzers?

Agency Response to Vendor Question #4
Yes, WVDHHR is currently utilizing the Crossroads system. Our current HemoCue HB201+ Analyzers are an older model. We have tested the newer models of HB201+ Analyzers that are currently available, and the functionality of the interface between the Analyzers and the Crossroads system does work. However, based on financial constraints and the age of our current analyzers, we are not using the functionality at this time, but need it to be available under this new Contract using the newer models of HemoCue HB201+ Analyzers, or equal.

Vendor Question #5
In section 3.1.2.6 regarding the Freight on Board, will there be multiple ship sites? If yes, how many locations are there? Additionally, how often does the State of West Virginia order Microcuvettes for these locations (e.g. monthly, quarterly, etc.)?

Agency Response to Vendor Question #5
There will not be multiple ship sites needed under this Contract. All microcuvettes and analyzers will be shipped directly to the WIC Storage Area at the WVDHHR Materials Management Warehouse only. Microcuvettes are ordered on an as needed basis since they are used in daily WIC clinics across the State, but normal usage is approximately done on a monthly basis.

Vendor Question #6
What are the current payment terms for the State of West Virginia? Is it net 30, or some other terms?

Agency Response to Vendor Question #6
Payment in advance is prohibited under this Contract. Payment may only be made after the delivery and acceptance of any goods. The Vendor shall submit invoices, in arrears.

Vendor Question #7
In section 6.4, regarding Return of Unacceptable Items, what is considered unacceptable by the State? How often during the previous contract was the product returned as unacceptable and for what reason(s)?

Agency Response to Vendor Question #7
Unacceptable product for both the analyzers and the microcuvettes would include: inoperable or non-functioning, damaged, close-to or past the expiration date, wrong item, and/or not individually wrapped microcuvettes. WVDHHR has not had a current contract for microcuvettes

in the last 6 months, but under the old contract there was one instance of unacceptable product due to the microcuvettes being defective and too close to the expiration date. This issue was addressed and corrected by the vendor and new microcuvettes with a longer expiration date were sent.

Vendor Question #8
During the previous contract, how often was the product ordered in error and returned to vendor?

Agency Response to Vendor Question #8
Under the previous contract, WVDHHR did not order in error in product and therefore, none needed to be returned to the vendor.

Vendor Question #9
Bid Opening Date and Time is January 8th, 2016 at 1:30 PM EST. Is this opening a private opening or a public opening where vendors can attend?

Agency Response to Vendor Question #9:
The bid opening date has been updated via Addendum #2 to January 21, 2016 at 1:30PM. It is not a private opening and vendors may attend.

Purchasing Divison
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

State of West Virginia
Request for Quotation
26 — Medical

Proc Folder: 128946

Doc Description: Addendum No. 3 - To provide responses to vendors questions.

Proc Type: Central Master Agreement

Date Issued	Solicitation Closes	Solicitation No	Version
2016-01-06	2016-01-21 13:30:00	CRFQ 0506 WIC1600000001	4

BID RECEIVING LOCATION

BID CLERK
DEPARTMENT OF ADMINISTRATION
PURCHASING DIVISION
2019 WASHINGTON ST E
CHARLESTON WV 25305
US

VENDOR

Vendor Name, Address and Telephone Number:

EKF DIAGNOSTICS.
12611 NORTH MAIN ST
BOERNE, TX 78006
830-249-0772

FOR INFORMATION CONTACT THE BUYER

April Battle
(304) 558-0067
april.e.battle@wv.gov

Signature X Pat Bailey **FEIN #** 45 3356270 **DATE** 1-18-16

All offers subject to all terms and conditions contained in this solicitation

ADDITIONAL INFORMATION:

Addendum No. 3 - To provide responses to vendors questions.

INVOICE TO	SHIP TO
PURCHASING DIRECTOR - 304-356-4095 HEALTH AND HUMAN RESOURCES BPH - NUTRITION SERVICES 350 CAPITOL ST, RM 519 CHARLESTON WV25301-3717 US	PURCHASING DIRECTOR - 304-356-4095 HEALTH AND HUMAN RESOURCES BPH - NUTRITION SERVICES (WIC) C/O DHHR MATERIALS MANAGEMENT 900 BULLITT ST CHARLESTON WV 25301 US

Line	Comm Ln Desc	Qty	Unit issue	Unit Price	Total Price
1	Clinical and diagnostic analyzers and accessories & supplies	100.00000	EA		

Comm Code	Manufacturer	Specification	Model #
41115800			

Extended Description :

Section 3.1.1 - Contract Item #1: Hemocue HB201+ Hemoglobin Analyzers, or equal

100 Each

INVOICE TO	SHIP TO
PURCHASING DIRECTOR - 304-356-4095 HEALTH AND HUMAN RESOURCES BPH - NUTRITION SERVICES 350 CAPITOL ST, RM 519 CHARLESTON WV25301-3717 US	PURCHASING DIRECTOR - 304-356-4095 HEALTH AND HUMAN RESOURCES BPH - NUTRITION SERVICES (WIC) C/O DHHR MATERIALS MANAGEMENT 900 BULLITT ST CHARLESTON WV 25301 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
2	Medical Equipment and Accessories and Supplies	1000.00000	BOX		

Comm Code	Manufacturer	Specification	Model #
42000000			

Extended Description :

Section 3.1.2 - Contract Item #2: Microcuvettes for use with the Hemocue HB201+ Analyzer, or compatible with the Analyzer bid under Section 3.1.1

1,000 Boxes

Must be individually wrapped with 25 per package and 4 packages per box of 100, or equal.

INVOICE TO	SHIP TO
PURCHASING DIRECTOR - 304-356-4095 HEALTH AND HUMAN RESOURCES BPH - NUTRITION SERVICES 350 CAPITOL ST, RM 519 CHARLESTON WV25301-3717 US	PURCHASING DIRECTOR - 304-356-4095 HEALTH AND HUMAN RESOURCES BPH - NUTRITION SERVICES (WIC) C/O DHHR MATERIALS MANAGEMENT 900 BULLITT ST CHARLESTON WV 25301 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
3	Training planning, facilitation and delivery services	8.00000	EA		

Comm Code	Manufacturer	Specification	Model #
86132100			

Extended Description :

Section 3.1.3 - Contract Item #3: Vendor Training, Support, and Ongoing Assistance, or equal, over the life of the contract must be included in the quoted price

Minimum 8 Trainings

SCHEDULE OF EVENTS

Line	Event	Event Date
1	TQ due	2015-12-22

ADDITIONAL TERMS AND CONDITIONS

See attached document(s) for additional Terms and Conditions

EKF DIAGNOSTICS STANBIO®

Safety Data Sheet

HemoPoint® H2 n•x•t MicroCuvettes

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Identification: HemoPoint® H2 n•x•t MicroCuvettes
Ref No. 3015, 3015-100, etc.

Test kit contains HemoPoint® H2 n•x•t MicroCuvettes.

Company Identification: Stanbio Laboratory
1261 North Main Street
Boerne, TX 78006

Telephone Number: (830) 249-0772
Website: http://www.stanbio.com

SECTION 2 – HAZARDS IDENTIFICATION

Routes of Exposure: Only when used as directed.
Classification system: In compliance with OSHA's Hazard Communication Standard (29CFR 1910.1200), a chemical mixture is considered hazardous if it contains 1.0% or more of a hazardous compound or 0.1% or more of a carcinogen. The product contains hazardous material(s) in excess of these amounts, therefore, precautions adequate for the pure form of the material(s) are presented here.
National Fire Protection Association (NFPA) ratings (scale 0-4):

Health=0
Fire=0
Reactivity=0

Hazard Overview
Health: Minimal risk if used as directed.
Fire: Not considered a fire hazard.
Reactivity: Minimal risk.
Special Hazards: Avoid ingestion of reagents, as toxicity has not been determined. The following general guidelines are given should reagents be inhaled, ingested, or exposed to eyes or skin.
Carcinogenicity information
OSHA (Occupational Safety and Health Administration): None of the ingredients is listed.
NTP (National Toxicology Program): None of the ingredients is listed.
IARC (International Agency for Research on Cancer): None of the ingredients is listed.

SECTION 3 – PRODUCT COMPOSITION

The test kit is composed of HemoPoint® H2 n•x•t MicroCuvettes.

HemoPoint® H2 n•x•t MicroCuvettes/3016 (The reagent contains by percentage the following amounts of chemicals)

Chemical Name	CAS No.	Concentration
Sodium Azide	26628-22-8	20 %
Sodium Nitrite	7632-00-0	20 %
Sodium Desoxycholate	361-09-1	40 %

SECTION 4 – FIRST AID MEASURES

After inhalation: Provide fresh air. Restore or support breathing. Keep victim warm and quiet. Get medical attention.

After skin contact: Flush skin with water for 15 minutes. Wash affected area thoroughly with soap and water. Remove contaminated clothing and shoes. Get medical attention if irritation develops or persists.

After eye contact: Flush eyes including under the eyelids with water for 15 minutes. Get medical attention.

After swallowing: Wash out mouth with generous amounts of water. Do not give anything by mouth to an unconscious person. Get medical attention.

SECTION 5 – FIRE FIGHTING MEASURES

Suitable extinguishing agents:

Sodium Azide: Not considered a fire hazard.

Sodium Nitrite: Not considered a fire hazard.

Sodium Desoxycholate: Not considered a fire hazard.

Protective equipment: Wear a self-contained breathing apparatus and protective clothing.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Safe work practices: Disposal should be made in accordance with existing disposal practices employed for infectious waste.

Measures for environmental protection: Prevent liquid and vapor from entering sewage system, storm drains, surface waters, and soil.

Measures for cleaning/ collecting: Wash spill area with appropriate cleaning materials. Dispose of in a manner consistent with federal, state and local regulation.

SECTION 7 – HANDLING AND STORAGE

Information for safe handling: Refer to the package insert or product label for additional information on storage conditions.

Information about protection against explosions and fires: No special measures required.

Requirements to be met by storerooms and receptacles: Refer to the package insert or product label for additional information on storage conditions.

Information about storage in one common storage facility: Store product in original packaging.

Further information about storage conditions: Protect from heat and direct sunlight.

SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with Occupational Exposure Limits: The product does not contain any hazardous ingredients with occupational exposure limits established by OSHA, ACGIH, or NIOSH.

General protective and hygienic measures: Always maintain good housekeeping. Do not eat, drink or store food and beverages in areas where chemicals are used. Wash hands before breaks and at the end of the work shift.

Breathing equipment: Use adequate protection to prevent inhalation, as well as good ventilation.

HemoPoint® H2 n•x•t MicroCuvettes

Hand protection: Wear necessary gloves when handling.
Eye protection: Wear appropriate safety glasses or other protective eyewear.
Body protection: Wear apron, laboratory coat or appropriate protective clothing when handling.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Form: Solid
Color: Not applicable
Odor: Not identified
Boiling point/Boiling range:
Sodium Azide: NA/NA
Sodium Nitrite: NA/NA
Sodium Desoxycholate: NA/NA
Flash point: NA
Auto igniting: Not self-igniting
Danger of explosion: Not applicable
Density at 20°C (68°F): Not applicable
Solubility in/Miscibility with Water: Not applicable
PH-value at 20°C (68°F): Not applicable
Water: Not applicable

SECTION 10 – STABILITY AND REACTIVITY

Microcuvettes contain Sodium Azide, Sodium Nitrite, Sodium Desoxycholate and inert ingredients.
Dangerous reactions: No dangerous reactions known.
Stability: Stable.
Incompatibility: None.
Hazardous Polymerization: Will not occur.
Dangerous reactions: No dangerous decomposition products known.

SECTION 11 – TOXICOLOGICAL INFORMATION

LD50/50LC values for hazardous ingredients per OSHA criteria:
Ingredients (100% pure substance/s)
Sodium Azide: Not established.
Sodium Nitrite: Not established.
Sodium Desoxycholate: Not established.
Primary toxicological effects of the final product
Skin irritation: Not determined.
Eye irritation: Not determined.
Sensitization: No sensitizing effects known.
Target organs/systems: Not determined.

SECTION 12 – ECOLOGICAL INFORMATION

Toxicity: Further details: no data available
Persistence and degradability: Further details: no data available
Bioaccumulative potential: Partition coefficient: n-octanol/water: no data available

Mobility in soil: no data available
Results of PBT and vPvB assessment: no data available
General information: Do not allow to enter into ground-water, surface water or drains.

SECTION 13 – DISPOSAL CONSIDERATIONS

Dispose of in a manner consistent with federal, state, and local regulations.

SECTION 14 – TRANSPORT INFORMATION

DOT Class - Not restricted for transportation.
IMDG Class - Marine pollutant: No, not restricted for transportation.
ICAO/IATA Class - Not restricted for transportation.

SECTION 15 – REGULATORY INFORMATION

SARA (Superfund Amendments and Reauthorization Act of 1986 – USA):
Section 302/304 (40CFR355.40): The product does not contain listed substances.
Section 313 (40CFR372.65): The product does not contain listed substances.
California Proposition 65 (USA)
Chemicals known to cause cancer: The product does not contain listed substances.
Chemicals known to cause female reproductive toxicity: None of the ingredients is listed.
Chemicals known to cause male reproductive toxicity: None of the ingredients is listed.
Chemicals known to cause developmental reproductive toxicity: None of the ingredients is listed.
Markings according to European guidelines: observe the general safety regulations when handling chemicals. The product does not require any hazard warnings according the respective European Community (EC) Directives.

SECTION 16 – OTHER INFORMATION

The information contained in this SDS is believed to be accurate and represents the best information currently available. Stanbio Laboratory makes no warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should determine suitability of the information contained in SDS for their particular purpose.
In no way shall Stanbio Laboratory be liable for any claims, losses or damages resulting from using information contained in SDS.

EKF DIAGNOSTICS STANBIO®

Safety Data Sheet

HemoPoint® H2 Optics Cleaner

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Identification: HemoPoint® H2 Optics Cleaner
Ref No. 3050, 3050-003, etc.

Test kit contains name of Optics Cleaner.

Company Identification: Stanbio Laboratory
1261 North Main Street
Boerne, TX 78006

Telephone Number: (830) 249-0772
Website: http://www.stanbio.com

SECTION 2 – HAZARDS IDENTIFICATION

Routes of Exposure: Only when used as directed.
Classification system: In compliance with OSHA's Hazard Communication Standard (29CFR 1910.1200), a chemical mixture is considered hazardous if it contains 1.0% or more of a hazardous compound or 0.1% or more of a carcinogen. The product does NOT contain hazardous material(s) in excess of these amounts; therefore, no SDS is required under the standard.
National Fire Protection Association (NFPA) ratings (scale 0-4):

Health=0
Fire=0
Reactivity=0

Hazard Overview
Health: Minimal risk if used as directed.
Fire: Not considered a fire hazard.
Reactivity: Reagents do not contain hazardous materials according to the standard. Minimal risk.
Special Hazards: Avoid ingestion of reagents, as toxicity has not been determined. Although no SDS is required by the standard, the following general guidelines are given should reagents be inhaled, ingested, or exposed to eyes or skin.
Carcinogenicity information
OSHA (Occupational Safety and Health Administration): None of the ingredients is listed.
NTP (National Toxicology Program): None of the ingredients is listed.
IARC (International Agency for Research on Cancer): None of the ingredients is listed.

SECTION 3 – PRODUCT COMPOSITION

The test kit is composed of Optics Cleaner.

Optics Cleaner/3051 (The reagent contains by percentage the following amounts of chemicals)

Chemical Name	CAS No.	Concentration
None determined to be hazardous.		

HemoPoint® H2 Optics Cleaner

SECTION 4 – FIRST AID MEASURES

After inhalation: Provide fresh air. Restore or support breathing. Keep victim warm and quiet. Get medical attention.

After skin contact: Flush skin with water for 15 minutes. Wash affected area thoroughly with soap and water. Remove contaminated clothing and shoes. Get medical attention if irritation develops or persists.

After eye contact: Flush eyes including under the eyelids with water for 15 minutes. Get medical attention.

After swallowing: Wash out mouth with generous amounts of water. Do not give anything by mouth to an unconscious person. Get medical attention.

SECTION 5 – FIRE FIGHTING MEASURES

Suitable extinguishing agents: Not considered a fire hazard.

Protective equipment: Wear a self-contained breathing apparatus and protective clothing.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Safe work practices: Disposal should be made in accordance with existing disposal practices employed for infectious waste.

Measures for environmental protection: Prevent liquid and vapor from entering sewage system, storm drains, surface waters, and soil.

Measures for cleaning/ collecting: Wash spill area with appropriate cleaning materials. Dispose of in a manner consistent with federal, state and local regulation.

SECTION 7 – HANDLING AND STORAGE

Information for safe handling: Refer to the package insert or product label for additional information on storage conditions.

Information about protection against explosions and fires: No special measures required.

Requirements to be met by storerooms and receptacles: Refer to the package insert or product label for additional information on storage conditions.

Information about storage in one common storage facility: Store product in original packaging.

Further information about storage conditions: Protect from heat and direct sunlight.

SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with Occupational Exposure Limits: The product does not contain any hazardous ingredients with occupational exposure limits established by OSHA, ACGIH, or NIOSH.

General protective and hygienic measures: Always maintain good housekeeping. Do not eat, drink or store food and beverages in areas where chemicals are used. Wash hands before breaks and at the end of the work shift.

Breathing equipment: Use adequate protection to prevent inhalation, as well as good ventilation.

Hand protection: Wear necessary gloves when handling.

Eye protection: Wear appropriate safety glasses or other protective eyewear.

Body protection: Wear apron, laboratory coat or appropriate protective clothing when handling.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Form: Liquid
Color: Not applicable
Odor: Not identified
Boiling point/Boiling range: NA/NA
Flash point: NA
Auto igniting: Not self-igniting
Danger of explosion: Not applicable
Density at 20°C (68°F): Not applicable
Solubility in/Miscibility with Water: Not applicable
PH-value at 20°C (68°F): Not applicable
Water: Not applicable

SECTION 10 – STABILITY AND REACTIVITY

Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications
Dangerous reactions: No dangerous reactions known.
Stability: Stable.
Incompatibility: None.
Hazardous Polymerization: Will not occur.
Dangerous reactions: No dangerous decomposition products known.

SECTION 11 – TOXICOLOGICAL INFORMATION

LD50/50LC values for hazardous ingredients per OSHA criteria:
Ingredients (100% pure substance/s)
Not applicable.
Primary toxicological effects of the final product
Skin irritation: Not determined.
Eye irritation: Not determined.
Sensitization: No sensitizing effects known.
Target organs/systems: Not determined.

SECTION 12 – ECOLOGICAL INFORMATION

Toxicity: Further details: no data available
Persistence and degradability: Further details: no data available
Bioaccumulative potential: Partition coefficient: n-octanol/water: no data available
Mobility in soil: no data available
Results of PBT and vPvB assessment: no data available
General information: Do not allow to enter into ground-water, surface water or drains.

SECTION 13 – DISPOSAL CONSIDERATIONS

Dispose of in a manner consistent with federal, state, and local regulations.

SECTION 14 – TRANSPORT INFORMATION

DOT Class - Not restricted for transportation.
IMDG Class - Marine pollutant: No, not restricted for transportation.
ICAO/IATA Class - Not restricted for transportation.

SECTION 15 – REGULATORY INFORMATION

SARA (Superfund Amendments and Reauthorization Act of 1986 – USA):
Section 302/304 (40CFR355.40): The product does not contain listed substances.
Section 313 (40CFR372.65): The product does not contain listed substances.
California Proposition 65 (USA)
Chemicals known to cause cancer: The product does not contain listed substances.
Chemicals known to cause female reproductive toxicity: None of the ingredients is listed.
Chemicals known to cause male reproductive toxicity: None of the ingredients is listed.
Chemicals known to cause developmental reproductive toxicity: None of the ingredients is listed.
Markings according to European guidelines: observe the general safety regulations when handling chemicals. The product does not require any hazard warnings according the respective European Community (EC) Directives.

SECTION 16 – OTHER INFORMATION

The information contained in this SDS is believed to be accurate and represents the best information currently available. Stanbio Laboratory makes no warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should determine suitability of the information contained in SDS for their particular purpose.
In no way shall Stanbio Laboratory be liable for any claims, losses or damages resulting from using information contained in SDS.

1 Purpose of this document

This document describes the structure of an exported data file of the software InterLink light. The style and structure of the exported data is defined in an EDD-File, so the representation of data can vary significantly depending on the chosen EDD-File. Furthermore QC and Patient related tests will be handled in different EDD-Files.

Software	InterLink light
EDD Group	H3
Test Type	PAT (Patient)
EDD Version	1.1

2 EDD Versioning structure

X.Y	
X	Type and structure of layout in the created data file, e.g. comma separated line or XML like style or number and type of data
Y	Version of customized changes in relation to the default of the initial version e.g. Hb value in mmol/L instead of g/L

3 Data

Table 1: Attributes

Row	Attribute	Format	Description
1	EDD Group	Text	EDD group, value is fix on "H3"
2	Test Type	Text	Test type, value is fix on "PAT"
3	EDD Version	Text	EDD version, value is fix on "1.1"
4	Reserved	-	Value is left empty
5	Date	Date	The date the test was performed
6	Time	Time	The time the test was performed
7	Patient ID	Text	The unique identifier for the patient
8	Laboratory ID	Text	The unique identifier for the place of operation
9	Hb Value	Numeric	Hemoglobin value
10	Hb Unit	Text	Hemoglobin unit "g/dL"
11	Hct Value	Numeric	Hematocrit value
12	Hct Unit	Text	Hematocrit unit "%"
13	Patient Type	Table 2	The type of patient
14	Hb Range Flag	Table 3	Range evaluation flag
15	Stat Sample Flag	Table 4	Was this test performed normally or under override conditions?
16	Rejected Flag	Table 5	Rejected flag
17	Adapted Flag	Table 6	Adapted flag
18	Operator Name	Text	Name of operator
19	Cuvette Lot Number	Text	LOT number
20	Comment	Text	Comment, entered after a test
21	Serial No	Text	Unique serial identifier
22	Device Description	Text	A convenient name for a device (e.g. Team-1)

Table 2 : patient_type values

Code	Description
no	Type is unknown
male	Male
female	Female
child	Child

Table 3 : range_flag values

Code	Description
OK	Inside normal range
L	Below lower limit of normal range
H	Above upper limit of normal range
---	Below absolute low-off device scale
+++	Above absolute high-off device scale

Table 4 : stat_sample_flag values

Code	Description
left empty	This test was performed under normal conditions
STAT	This test was performed in an override circumstance

Table 5 : rejected_flag values

Code	Description
left empty	The result was accepted
rejected	The result was not accepted

Table 6 : adapted_flag values

Code	Description
left empty	The value was not changed
adapted	The value was adapted, that means an additional calculation with specific data

OCT 2 4 2003

K032482

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 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 vs. 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)

HemoPoint® H2 Controls

A bi-level reference control set intended for use on **HemoPoint® H2** *Hemoglobin testing system.*

Summary and Principle

Controls, when assayed as actual specimens, help a laboratory evaluate whether a given procedure is performing with acceptable accuracy and precision. **HemoPoint® H2** Hemoglobin Controls, Ref. No. 3065, may be used as one would use whole blood in obtaining the stated parameters for the **HemoPoint® H2** hemolobin testing system.

Reagents

Hemoglobin Control, Ref. No. 3061, Low Level (1.5 mL)
Purified bovine hemoloysate solution, containing a low level of hemoglobin.

Hemoglobin Control, Ref. No. 3063, High Level (1.5 mL)
Purified bovine hemoloysate solution, containing a high level of hemoglobin.

Warning and Precautions

For In Vitro Diagnostic Use.

HemoPoint® H2 Hemoglobin Controls are animal blood products. Bovine based materials do not carry biohazards for man, such as hepatitis B surface antigen (HBsAg), hepatitis B core (HBc), antibody, hepatitis C virus, and anti-HIV-1, as well as for anti-HIV-2 and the human T-cell lymphotrophic virus type 1 (HTLV-1).

It is recommended that **HemoPoint® H2** Hemoglobin Control be handled with the same precautions used for patient specimens.

HemoPoint® H2 Hemoglobin Control should be treated the same as a patient specimen and run in accordance with the instructions accompanying the instrument being used.

HemoPoint® H2 Hemoglobin Controls are intended solely for *in vitro* diagnostic use for the purpose described on the labeling. The manufacturer shall not be liable for any claimed damages arising from any other usage.

Storage and Stability

Control is stable until expiration date, when stored unopened at 35° - 46°F (2-8C). After opening, control may be used for up to 60 days stored at 35° - 46°F (2-8°C), or 30 days stored at room temperature, 59° - 86°F (15°-30°C).

Specific Performance Characteristics

HemoPoint® H2 Hemoglobin Controls are reliable liquid products manufactured under rigid quality control standards. To obtain good results, the product requires proper storage and handling as described.

Preparation

1. Allow the vials to come to room temperature 59° - 86°F (15-30°C) for 15 minutes.
2. Mix thoroughly but gently by inverting the vials and repeatedly rolling them between the palms (**approximately 60 seconds**). **Do not shake the vial.**
3. Remove the cap from the vial. Dispense and discard the 1st drop. Place 2nd drop of control onto a clean non-absorbent material such as plastic film. Fill the microcuvette with the control as you would a patient sample.

HemoPoint® H2 Controls

A bi-level reference control set intended for use on **HemoPoint® H2** *Hemoglobin testing system.*

Summary and Principle

Controls, when assayed as actual specimens, help a laboratory evaluate whether a given procedure is performing with acceptable accuracy and precision. **HemoPoint® H2** Hemoglobin Controls, Ref. No. 3065, may be used as one would use whole blood in obtaining the stated parameters for the **HemoPoint® H2** hemolobin testing system.

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3. Remove the cap from the vial. Dispense and discard the 1st drop. Place 2nd drop of control onto a clean non-absorbent material such as plastic film. Fill the microcuvette with the control as you would a patient sample.

4. **After filling microcuvette, wait a minimum of 60 seconds before closing the cuvette holder. The filled microcuvette should be read within 5 minutes.** Follow the instrument manufacture's instructions for testing.
5. While waiting for results, clean the threads of the vial and threads of the cap with a cotton or polyester gauze. Snugly recap the vial immediately. After testing, return the vial to its proper storage.

Limitations of the Procedure

1. HemoPoint® H2 Hemoglobin Controls may not be appropriate for certain instruments other than the HemoPoint® H2 Hemoglobin System.
2. Inaccuracies in test results may occur as a result of inappropriate mixing procedures. Precisely follow all mixing instructions before testing.

Results

An expected range is given for each level based on data generated from multiple lab analyses using the HemoPoint® H2 Hemoglobin System. Variations between labs will be greater than the precision for any one instrument. Results depend upon differences in equipment, reagents, supplies and techniques. Therefore, a laboratory should establish its own acceptable ranges. If the controls fail to perform consistently within expected ranges, contact Stanbio Technical Service at (800) 531-5535.

Control Values		Exp. Date: Dec 12
Level	Lot No.	Expected Range
Low	196-1-B122	4.4 - 5.4 g/dL
High	196-3-B122	14.4 - 17.5 g/dL

Index of Symbols

	Attention, see instructions for use	Σ	Tests per kit		Manufactured by
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
	Store between temperature indicated	LOT	Lot Number	REF	Reference No.

Stanbio Laboratory • 1261 North Main Street • Boerne, Texas 78006 USA
For Technical Service call: 1-800-531-5535 • (830) 249-0772
Fax (830) 249-0851 • e-mail: stanbio@stanbio.com
http: //www.stanbio.com
RBR.3065.601.24 • Last Revision: 07/18/2011 • Procedure No. 3065

STANBIO LABORATORY

4. **After filling microcuvette, wait a minimum of 60 seconds before closing the cuvette holder. The filled microcuvette should be read within 5 minutes.** Follow the instrument manufacture's instructions for testing.
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STANBIO LABORATORY

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HemoPoint® H2 Optics Cleaner
Limpiador Óptico para el HemoPoint® H2
Reference No./No. de Referencia 3050-003

Intended Use: This cleaner is intended for cleaning the optical system of the **HemoPoint® H2** photometer.

Description: The **HemoPoint® H2** Optical Cleaner consists of a spatula partially covered by a foam cushion impregnated with a special cleaning solution.

Storage and Stability: The Optical Cleaner is stable until the expiration date, when stored unopened at 59° - 86°F (15-30°C). After opening, the cleaner must be used within 10 minutes.

Uso: El limpiador óptico es utilizado para limpiar la unidad óptica del fotometro **HemoPoint® H2.**

Descripción: El Limpiador Óptico para el **HemoPoint® H2** consiste en una espátula parcialmente cubierto por un almohadilla impregnada con una solución de limpieza especial.

Almacenamiento y Estabilidad: El Limpiador Óptico es estable hasta la fecha de caducidad a ser almacenado cerrado de 59 a 86°F (15 a 30°C). Una vez abierto, el limpiador se debe utilizar en 10 minutos.

Procedure/Procedimiento:

1. To safely clean the **HemoPoint® H2** photometer optics, disconnect the power adaptor from the electrical connection before proceeding

1. Con el fin de limpiar de forma segura la unidad óptica del fotómetro **HemoPoint® H2,** desconecte el adaptador de la conexión eléctrica antes de proceder.

2. With the **HemoPoint® H2** in the ready mode, open the cuvette holder until you feel a resistance and the holder will not extend further.

2. Con el **HemoPoint® H2** en el estado operativo, abra el sostenedor de la cubeta hasta que se sienta una resistencia y no se extenderá más allá

3. Locate the silver pin on the left-hand side of the cuvette holder.

3. Localice la clavija plateada en el lado izquierdo del sostenedor de la cubeta.

4. While depressing the silver pin with a pointed object, slide the cuvette holder towards you and away from the **HemoPoint® H2**.

4. Oprima la clavija plateada con un bolígrafo o objeto puntiagudo y deslice el sostenedor hacia enfrente y fuera del **HemoPoint® H2** al mismo tiempo.

5. Remove the cleaner from the foil pouch. Check to be sure the pad is moist with cleaner.

5. Retire el limpiador de la bolsa de aluminio. Verifique que la almohadilla está húmeda con limpiador

(Continued on next page)
(Continúa en la página proxima)

6. Insert the cleaner slowly into the opening of the cuvette holder until you feel a smooth resistance. Slowly push the cleaner deeper into the opening until it stops.

7. Move the optics cleaner in an in-and-out motion for at least 5 times.

8. Remove the cleaner from the **HemoPoint® H2**. If the used cleaner is discolored or dirty, repeat the procedure using a new cleaner.

9. Dispose of all used cleaners as potentially infectious waste in accordance with the current regulations applicable to your establishment.

10. Clean and dry the cuvette holder (see the **HemoPoint® H2** Users Guide, maintenance section). Wait at least 15 minutes after cleaning to re-insert the cuvette holder into the **HemoPoint® H2**.

11. Replace the cuvette holder then re-open the **HemoPoint® H2** cuvette holder and ensure that the silver pin is locked in place.

6. Inserte el limpiador lentamente en la apertura del sostenedor de la cubeta hasta que se sienta una resistencia suave. Empuje lentamente el limpiador profundizar en la apertura hasta que se detenga.

7. Mueve el limpiador óptico en un movimiento hacia dentro y hacia fuera por lo menos 5 veces

8. Retire el limpiador del fotometro **HemoPoint® H2**. Si el limpiador utilizado está descolorida o sucia, repita el procedimiento con un limpiador nuevo

9. Deseche todos los limpiadores usados como desechos potencialmente infecciosos de acuerdo con la normativa vigente aplicable a su establecimiento.

10. Limpie y seque el sostenedor de la cubeta (consulte la sección de Mantenimiento en la Guía Para el Usuario del fotometro **HemoPoint® H2**). Espere al menos 15 minutos después de la limpieza para volver a insertar el sostenedor de la cubeta en el **HemoPoint® H2**.

11. Vuelva a colocar el sostenedor de la cubeta en el el **HemoPoint® H2**. Luego, vuelva a abrir el sostenedor para asegurarse de que la clavija plateada está enganchada en su lugar.

STANBIO LABORATORY
An EKF Diagnostics Company

The HemoPoint® H2 is now ready to resume operation...
Ahora, el HemoPoint® H2 está listo para usar...

Stanbio Laboratory
1261 N. Main Street
Boerne, Texas 78006 USA

For Technical Service call/
Para asistencia técnica llame:
800-531-5535 830-249-0772
E-mail: lab@stanbio.com

RBR.3050.03 Rev. 08/11

HemoPoint® H2 n•x•t Microcuvettes

Procedure No. 3025

For the quantitative determination of hemoglobin in capillary, venous or arterial whole blood.

CLIA Complexity: Waived

Intended Use

The HemoPoint® n•x•t H2 microcuvettes are intended to be used in the HemoPoint® H2 Photometer. The reagents/ microcuvettes and the photometer form an analytical system.

Summary and Principle

The HemoPoint® H2 system is intended to be used for the quantitative determination of hemoglobin (Hgb) concentration in human blood. It consists of a photometer instrument and individual single-use microcuvettes filled with reagents. Using the microcuvette, a small amount of capillary, venous or arterial blood is taken up by capillary action. The microcuvettes are intended to be used once only and must be disposed of after use as potentially infectious waste, in accordance with the current regulations applicable to your establishment. The HemoPoint® H2 system is designed for use in medical practices and in clinical laboratories to assist in medical diagnostics. In addition it can be used in emergency and intensive care units and in medical facilities such as blood donor sessions and blood banks. Blood sampling and operating the HemoPoint® H2 system should be carried out by trained personnel with sound knowledge of the system.

The recognized reference method for 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 hemolyzed and the bivalent iron in oxyhemoglobin and desoxyhemoglobin are oxidized 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 Hgb concentration. In 1966, Vanzetti suggested to replace KCN by NaN_3 and thus he was able to reduce the toxicity of the reagent mixture considerably[2]. Vanzetti's method is also known as the azide methemogobin method. A modified azide methemoglobin method is used in the HemoPoint® H2 system.

Principles of the Procedure

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

For this purpose, light is directed through the blood sample and the absorption is measured. From the amount of light absorbed by the sample, the concentration of the hemoglobin in the cuvette can be calculated using the Beers-Lambert Law. Light emitting diodes (LED's) are used as light sources and a photodiode is used to detect the light. The light emitting diodes utilize the central wavelengths 570 nm (for measurement) and 880 nm (for turbidity compensation).

The n•x•t Microcuvette

The plastic microcuvette consists of a clear body with a cavity which takes up approximately 8 µL of blood which combines with the dry reagent chemistry. The optical distance between the cuvette walls is fixed and permits photometric determination of the hemoglobin in undiluted blood samples.

The Chemistry Principle

In order to use the azide methemoglobin method in undiluted blood, three reagents are necessary: sodium deoxycholate dissolves and disperses the cell walls of the red blood corpuscles. Hence the hemoglobin formerly contained in the erythrocytes is now available free in the solution. The bivalent iron of the oxyhemoglobin and the deoxyhemoglobin becomes oxidized by sodium nitrite $NaNO_2$ to trivalent iron, in methemoglobin. Existing and formed methemoglobin and azide ions from sodium azide NaN_3 form a colored complex which exhibits maximal absorption at 540 and 575 nm and hence it can be quantitatively determined photometrically.

Reagents

HemoPoint® H2 n•x•t Microcuvettes, Cat. No. 3025

40% w/w sodium deoxycholate, 20% sodium azide, 20% w/w sodium nitrite and 20% w/w non-reactive ingredients.

Warnings and Precautions

Microcuvettes are designed for *in-vitro* diagnostic use only. The reagents which coat the inner walls of the microcuvettes are harmful and must not be swallowed. Wear suitable protection (gloves) at all times when handling blood samples. Please note that all human blood samples or products must be handled as potential infectious waste per your local regulations.

Storage

HemoPoint® H2 n•x•t microcuvettes are to be stored solely in the original pouches and at room temperature 59 – 86°F (15–30°C). DO NOT refrigerate! Only remove one microcuvette at a time from the pouch. The microcuvettes are analyzed optically in the HemoPoint® H2 photometer. Measurement light must pass through the sample cuvette to the photo detector with the least possible interference. It is therefore crucial not to touch the optical eye of the cuvette with fingers, dirty or sharp objects.

Sample Collection and Preparation

The HemoPoint® H2 Photometer can be used with capillary, venous, or arterial blood. Use EDTA, heparin or heparin/ fluoride as anticoagulants, preferably in solid form, to avoid dilutional effects. Venous and arterial blood samples may be used if the blood collected is not more than 24 hours old and the samples have been stored refrigerated 35 – 46°F (2-8°C).

Prepare stored samples for measurement as follows:

1) Remove sample tube from the refrigerator and bring it to room temperature.
2) Mix the sample tube well. (i.e. by a mechanical rotator or hand inversion at least 10 times).

Procedure

Refer to the HemoPoint® H2 User's Guide for proper use of the photometer.

Materials Provided

HemoPoint® H2 n•x•t Microcuvettes, Cat.No. 3025-001 (single cuvette); 3025-050 (test box of 50 cuvettes)

Materials Required But Not Provided

HemoPoint® H2 Photometer[3]
HemoPoint® H2 Control Cuvette (optional)
HemoPoint® H2 Hemoglobin Controls, (Cat. No. 3065-601) (optional)
Disposable pipettes (venous or arterial blood only)
Plastic film (venous or arterial blood only, lint-free material

Instructions For Use (Capillary)

1. Make sure that the Photometer is ready for use.
2. Make sure that your patient is sitting comfortably.
3. There should be a good blood circulation in the hand from which you wish to take blood, e.g., it should be warm and relaxed.
4. Lightly massage the fingers, in order to stimulate circulation.
5. Disinfect the puncture site and allow to dry.
6. Take out a microcuvette from the pouch.
7. Press lightly on the fingertip and puncture with a suitable sampling device on the side of the fingertip.
8. Blot away the first drop of blood then, if necessary, press gently once again to get a 2nd drop of blood which is large enough to fill the microcuvette completely. Avoid "milking" the finger.
9. Hold the center of the microcuvette in the middle of the drop of blood and let the cavity fill in one step. In case of air bubbles in the optical eye, discard the microcuvette and take another sample using a new microcuvette.

(over)

STANBIO LABORATORY

10. In order to avoid contamination of the cuvette holder, remove surplus blood from the outside of the microcuvette.
11. The microcuvette sample prepared in this way can now be measured immediately or within 10 minutes at the latest.

Instructions For Use (Venous or Arterial)

1. Make sure that the Photometer is ready for use. See the **HemoPoint® H2** User's Guide for additional information.

2. Remove sample tube from the refrigerator and bring it to room temperature.

3. Mix the sample tube well (i.e. by a mechanical rotator or mixing by hand at least 10 times).

4. Take out a microcuvette from the container and close the lid immediately.

5. Pipette a sufficient drop of blood on a non-absorbent material (i.e. plastic film).

6. Hold the center of the microcuvette in the middle of the drop of blood and let the cavity fill in one step. In case of air bubbles in the optical eye, discard the microcuvette and take another sample using a new microcuvette.

7. In order to avoid contamination of the cuvette holder, remove surplus blood from the outside of the microcuvette.

8. The cuvette sample prepared in this way can now be measured immediately or within 10 minutes at the latest.

Limitations of the Procedure

1. The microcuvette sample can be measured immediately or within 10 minutes at the latest, otherwise false results may be obtained.

2. Air bubbles in the optical eye, caused by inadequate filling of the microcuvette cavity, may cause false results. Discard the microcuvette and take another sample using a new microcuvette.

3. Ensure that you do not hold the microcuvette at its filling end, because this may contaminate the optical eye.

4. In order to avoid contamination of the cuvette holder, remove surplus blood from the outside of the microcuvette.

5. All results above 23.5 g/dL or equivalent must be confirmed by laboratory method.

6. Sulfhemoglobin is not measured by this method. Carboxyhemoglobin and turbidity due to leukocytosis or hyperlipemia do not interfere.

7. Always place cuvette right side up in holder. Placing cuvette upside down can lead to erroneous results.

Expected Values[4,5,6,7,8]

The following hemoglobin values are considered normal:

Adult males:	13.0 – 18.0 g/dL
Adult females:	11.0 – 16.0 g/dL
Children:	11.0 – 16.0 g/dL
Infants (postnatal):	10.0 – 14.0 g/dL

Due to a wide range of conditions which affect normal values, it is recommended that each laboratory establish its own "normal" range.

Quality Control

The **HemoPoint® H2** AutoCheck performs an internal check of the photometer's optic system every time the cuvette holder is opened. If additional regulatory quality control is required in your facility, the following checks may be performed: (1) The control cuvette supplied with the photometer can be used for a simple check of the photometer's calibration. (2) Use of external controls to assure that the microcuvettes and the photometer are performing correctly. For this purpose, we recommend the use of Stanbio's **HemoPoint® H2** Hemoglobin Tri-level Controls, Cat. No. 3060-601 or **HemoPoint® H2** Hemoglobin Bi-level Controls, Cat. No. 3065-601
Do not use cyanmethemoglobin standards with this test.

Results

The test result is displayed directly on the screen of the **HemoPoint® H2** photometer. No calculations are necessary. The test is linear up to 23.5 g/dL.

Performance Characteristics

Precision

Within-run precision using the **HemoPoint® H2** with the **HemoPoint® H2** next microcuvettes is 2%. The precision evaluation was carried out in accordance with NCCLS EP5-A[9]. On each of 20 testing days, two separate runs with duplicate measurements within each run were carried out. Three commercially available control materials were used. The test was carried out using: (6) **HemoPoint® H2** devices; (16) lots of **HemoPoint® H2** microcuvettes and (3) operators.

Correlation

Correlation coefficient of the **HemoPoint® H2** System compared to the NCCLS H15-A3 reference method.
Venous blood: r = 0.998

NCCLS 6 EP5-A Protocol	H2 next cuvette measured in HemoPoint® H2 device
Hgb/Low (8.0 g/dL): Within-run Precision Total Precision	S_w 0.068 g/dL, CV 0.7% S_t 0.122 g/dL, CV 1.5%
Hgb/Normal (11.8 g/dL) Within-run Precision Total Precision	S_w 0.070 g/dL, CV 0.6% S_t 0.162 g/dL, CV 1.4%
Hgb/High (15.7 g/dL): Within-run Precision Total Precision	S_w 0.087 g/dL, CV 0.6% S_t 0.174 g/dL, CV 1.2%
Day-to-Day Precision	8.0 g/dL: SD 0.111 g/dL, CV 1.4% 11.8 g/dL: SD 0.176 g/dL, CV 1.5% 15.7 g/dL: SD 0.179 g/dL, CV 1.1%

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

Regression line and correlation coefficients compared to NCCLS H15A3 reference method (g/dL), venous blood	1. Y = 0.2929 + 1.0086x 2. R = 0.998 3. N = 100, duplicate measurements 4. Summary of results

References

1. NCCLS, Reference and selected procedures for the quantitative determination of hemoglobin in blood – second edition; approved standard, NCCLS Document H15-A3, 2000.
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5. DeMott Wayne R., Tilzer Lowell L, Hematology. In: Jacobs DS, DeMott WR, Finley PR, Horvat RT, Kasten Jr BL., Tilzer LL, eds. Laboratory Test Handbook. Hudson: Lexi-comp, 1992: 517-626.
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8. Tietz N, ed. Clinical Guide To Laboratory Tests, WB Saunders, 1983:258-259.
9. NCCLS, Evaluation of Precision Performance of Clinical Chemistry Devices; Document EP5-A, Vol 19 No. 2, February 1999.

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DN: RBR.3025.01 • Last Revision: 01/15 • Procedure No. 3025

STANBIO LABORATORY

Your Patient's Health:

The Point of What We Do.

HemoPoint® H2

Efficient

The **Hemo**Point® **H2** uses a smaller sample size, simplified sample drawing, and has a 4,000 test result memory. These features allow you to improve your participant work flow — more participant testing means better nutritional support.

Less Invasive

...than other testing methods. The **Hemo**Point® **H2** only requires the 2nd drop of blood — the competition requires the 3rd or 4th.

Cost Effective

Stanbio Laboratory understands your need for conservative spending, which is why we want to help. The **Hemo**Point® **H2** is even designed with a rechargeable battery, so you spend less money on disposables.

Know that we stand by our product and warranty the instrument, so that reliability can be the last thought on your mind.

Competitive Matrix

	Stanbio Laboratory HemoPoint® H2	The Competition** HemoCue
Measuring Range	Hgb: 0-25.6 g/dL Hct: 36% - 54%	Hgb: 0-25.6 g/dL
Sample Size	8 µL	10 µL
Measuring Time	In as little as 30 seconds	60 seconds
Cuvette Expiration Dating	Unopened: 24 mos. from date of manufacture Opened: 90 days	Unopened: 24 mos. from date of manufacture Opened: 90 days
Memory	4,000 test results	NONE
Battery Power	100 hrs. rechargeable battery	Variable, disposable batteries
Hematocrit* Function	YES	NO
Blood Drop Sampled	2nd drop	3rd or 4th drop
Internal Self Check	Each time cuvette loader is opened	At power & every 2nd hour
Touch Screen	YES	NO

** Hematocrit result is calculated when hemoglobin result is within 12-18 g/dL.*
*** Competitive information taken from competitor's website (04/29/09) and operator's manual.*

CLIA'88 WAIVED

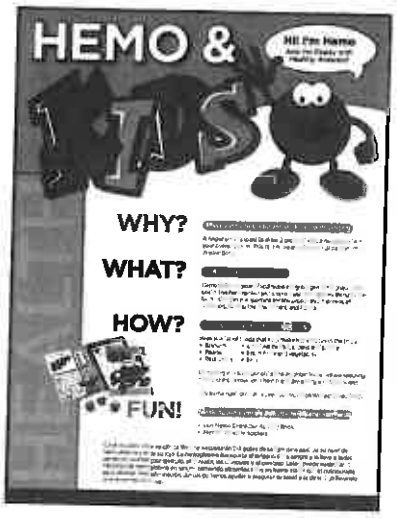
STANBIO LABORATORY

Public Health Clinics

We Think You'll Get the Point.

HemoPoint® H2

Make your participant's testing experience fun and educational with Stanbio Laboratory's Hemo Character Tools.



Training and Education Program

Product installation, certification, and refresher training sessions are included at no cost to you and your clinics.

Unmatched Support

Stanbio Laboratory's Public Health Specialists are dedicated to meeting your needs. Give us a call and we'll ensure that you receive the attention you deserve.

Specialized Packaging

Your **Hemo**Point® **H2** comes packaged with unique items that will make testing educational and fun for your participants.

Hemo's Tool Kit Includes:

- Educational Poster
  - Parent's explanation on one side
  - Instructions for use on the other
- Participant Anemia Educational Brochure
- Children's Activity Book
- Hemo Character Stickers
- Clinician Scrubs

Hemo...At the Point of Care

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WV-10
Approved / Revised
08/01/15

State of West Virginia
VENDOR PREFERENCE CERTIFICATE

Certification and application is hereby made for Preference in accordance with ***West Virginia Code***, §5A-3-37. (Does not apply to construction contracts). ***West Virginia Code***, §5A-3-37, provides an opportunity for qualifying vendors to request (at the time of bid) preference for their residency status. Such preference is an evaluation method only and will be applied only to the cost bid in accordance with the ***West Virginia Code***. This certificate for application is to be used to request such preference. The Purchasing Division will make the determination of the Vendor Preference, if applicable.

1. **Application is made for 2.5% vendor preference for the reason checked:**
☐ Bidder is an individual resident vendor and has resided continuously in West Virginia for four (4) years immediately preceding the date of this certification; **or,**
☐ Bidder is a partnership, association or corporation resident vendor and has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; or 80% of the ownership interest of Bidder is held by another individual, partnership, association or corporation resident vendor who has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; **or,**
☐ Bidder is a nonresident vendor which has an affiliate or subsidiary which employs a minimum of one hundred state residents and which has maintained its headquarters or principal place of business within West Virginia continuously for the four (4) years immediately preceding the date of this certification; **or,**

2. **Application is made for 2.5% vendor preference for the reason checked:**
☐ Bidder is a resident vendor who certifies that, during the life of the contract, on average at least 75% of the employees working on the project being bid are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; **or,**

3. **Application is made for 2.5% vendor preference for the reason checked:**
☐ Bidder is a nonresident vendor employing a minimum of one hundred state residents or is a nonresident vendor with an affiliate or subsidiary which maintains its headquarters or principal place of business within West Virginia employing a minimum of one hundred state residents who certifies that, during the life of the contract, on average at least 75% of the employees or Bidder's affiliate's or subsidiary's employees are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; **or,**

4. **Application is made for 5% vendor preference for the reason checked:**
☐ Bidder meets either the requirement of both subdivisions (1) and (2) or subdivision (1) and (3) as stated above; **or,**

5. **Application is made for 3.5% vendor preference who is a veteran for the reason checked:**
☐ Bidder is an individual resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard and has resided in West Virginia continuously for the four years immediately preceding the date on which the bid is submitted; **or,**

6. **Application is made for 3.5% vendor preference who is a veteran for the reason checked:**
☐ Bidder is a resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard, if, for purposes of producing or distributing the commodities or completing the project which is the subject of the vendor's bid and continuously over the entire term of the project, on average at least seventy-five percent of the vendor's employees are residents of West Virginia who have resided in the state continuously for the two immediately preceding years.

7. **Application is made for preference as a non-resident small, women- and minority-owned business, in accordance with *West Virginia Code* §5A-3-59 and *West Virginia Code of State Rules*.**
☐ Bidder has been or expects to be approved prior to contract award by the Purchasing Division as a certified small, women- and minority-owned business.

Bidder understands if the Secretary of Revenue determines that a Bidder receiving preference has failed to continue to meet the requirements for such preference, the Secretary may order the Director of Purchasing to: (a) reject the bid; or (b) assess a penalty against such Bidder in an amount not to exceed 5% of the bid amount and that such penalty will be paid to the contracting agency or deducted from any unpaid balance on the contract or purchase order.

By submission of this certificate, Bidder agrees to disclose any reasonably requested information to the Purchasing Division and authorizes the Department of Revenue to disclose to the Director of Purchasing appropriate information verifying that Bidder has paid the required business taxes, provided that such information does not contain the amounts of taxes paid nor any other information deemed by the Tax Commissioner to be confidential.

Under penalty of law for false swearing (West Virginia Code, §61-5-3), Bidder hereby certifies that this certificate is true and accurate in all respects; and that if a contract is issued to Bidder and if anything contained within this certificate changes during the term of the contract, Bidder will notify the Purchasing Division in writing immediately.

Bidder: N/A **Signed:** [signature]

Date: _____ **Title:** Director of Sales

STATE OF WEST VIRGINIA RFQ NO. WIC1600000001
Purchasing Division

PURCHASING AFFIDAVIT

MANDATE: Under W. Va. Code §5A-3-10a, no contract or renewal of any contract may be awarded by the state or any of its political subdivisions to any vendor or prospective vendor when the vendor or prospective vendor or a related party to the vendor or prospective vendor is a debtor and: (1) the debt owed is an amount greater than one thousand dollars in the aggregate; or (2) the debtor is in employer default.

EXCEPTION: The prohibition listed above does not apply where a vendor has contested any tax administered pursuant to chapter eleven of the W. Va. Code, workers' compensation premium, permit fee or environmental fee or assessment and the matter has not become final or where the vendor has entered into a payment plan or agreement and the vendor is not in default of any of the provisions of such plan or agreement.

DEFINITIONS:

"Debt" means any assessment, premium, penalty, fine, tax or other amount of money owed to the state or any of its political subdivisions because of a judgment, fine, permit violation, license assessment, defaulted workers' compensation premium, penalty or other assessment presently delinquent or due and required to be paid to the state or any of its political subdivisions, including any interest or additional penalties accrued thereon.

"Employer default" means having an outstanding balance or liability to the old fund or to the uninsured employers' fund or being in policy default, as defined in W. Va. Code § 23-2c-2, failure to maintain mandatory workers' compensation coverage, or failure to fully meet its obligations as a workers' compensation self-insured employer. An employer is not in employer default if it has entered into a repayment agreement with the Insurance Commissioner and remains in compliance with the obligations under the repayment agreement.

"Related party" means a party, whether an individual, corporation, partnership, association, limited liability company or any other form or business association or other entity whatsoever, related to any vendor by blood, marriage, ownership or contract through which the party has a relationship of ownership or other interest with the vendor so that the party will actually or by effect receive or control a portion of the benefit, profit or other consideration from performance of a vendor contract with the party receiving an amount that meets or exceed five percent of the total contract amount.

AFFIRMATION: By signing this form, the vendor's authorized signer affirms and acknowledges under penalty of law for false swearing (*W. Va. Code* §61-5-3) that neither vendor nor any related party owe a debt as defined above and that neither vendor nor any related party are in employer default as defined above, unless the debt or employer default is permitted under the exception above.

WITNESS THE FOLLOWING SIGNATURE:

Vendor's Name: EKF Diagnostics

Authorized Signature: [signature] Date: 1-19-16

State of TEXAS

County of KENDALL, to-wit:

Taken, subscribed, and sworn to before me this 19 day of JANUARY, 2016.

My Commission expires NOV. 19, 2016.

AFFIX SEAL HERE

CHERYL HARRISON
Notary Public
STATE OF TEXAS
My Comm. Exp. Nov. 19, 2016

NOTARY PUBLIC [signature]