



The following documentation is an electronically-submitted vendor response to an advertised solicitation from the *West Virginia Purchasing Bulletin* within the Vendor Self-Service portal at wvOASIS.gov. As part of the State of West Virginia's procurement process, and to maintain the transparency of the bid-opening process, this documentation submitted online is publicly posted by the West Virginia Purchasing Division at WVPurchasing.gov with any other vendor responses to this solicitation submitted to the Purchasing Division in hard copy format.

Header @ 4

List View

- General Information
- Contact
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- Document Information
- Clarification Request

Procurement Folder: 1122177

Procurement Type: Central Master Agreement

Vendor ID:

Legal Name: EKF DIAGNOSTICS INC

Alias/DBA:

Total Bid: \$87,723.00

Response Date:

Response Time:

Responded By User ID:

First Name:

Last Name:

Email:

Phone:

SO Doc Code: CRFQ

SO Dept: 0506

SO Doc ID: WIC2300000002

Published Date: 11/9/22

Close Date: 12/1/22

Close Time: 13:30

Status: Closed

Solicitation Description:

Total of Header Attachments: 4

Total of All Attachments: 4

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
1	HemoCue Hb301 HemoGlogin Analyzers or Equal	100.00000	EA	0.000000	0.00

Comm Code	Manufacturer	Specification	Model #
41115815			

Commodity Line Comments: First 100 of item# 900-001, DiaSpect TM instruments @ \$0.00
This includes the Connectivity Cord Item # 900-901 @ \$0.00 & EKf Link license Item # 0760-0102 @ \$0.00
All instruments purchased thereafter \$355.00/ea

Extended Description:

3.1.1 HemoCue Hb301 HemoGlogin Analyzers or Equal

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
2	Microcuvettes for use with Analyzers	100000.00	EA	0.840000	84000.00

Comm Code	Manufacturer	Specification	Model #
41121813			

Commodity Line Comments: Item #900-100 Reagent Free microcuvettes 100ct configuration

Extended Description:

3.1.2 Microcuvettes for use with Analyzers

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
3	Carrying Case for use with Analyzers and Cuvette vial	100.00000	EA	37.230000	3723.00

Comm Code	Manufacturer	Specification	Model #
41115816			

Commodity Line Comments: Item #900-600

Extended Description:

3.1.3 Carrying Case for use with Analyzers and Cuvette vial

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
4	Vendor Training, Support, and Ongoing Assistance	0.00000	EA	0.000000	0.00

Comm Code	Manufacturer	Specification	Model #
86000000			

Commodity Line Comments:

Extended Description:

3.1.4 Vendor Training, Support, and Ongoing Assistance



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

State of West Virginia
 Centralized Request for Quote
 Laboratory

Proc Folder: 1122177			Reason for Modification:
Doc Description: HEMOGLOBIN ANALYZERS AND MICROCUVETTES			
Proc Type: Central Master Agreement			
Date Issued	Solicitation Closes	Solicitation No	Version
2022-11-09	2022-12-01 13:30	CRFQ 0506 WIC2300000002	1

BID RECEIVING LOCATION

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

VENDOR

Vendor Customer Code: *VC0000003734*

Vendor Name: *EKF Diagnostics*

Address: *1261 N. Main St*

Street:

City: *Boerne*

State: *TX* Country: *USA* Zip: *78006*

Principal Contact: *Mindy Rodriguez*

Vendor Contact Phone: *830 249 0772* Extension: *142*

FOR INFORMATION CONTACT THE BUYER
 Crystal G Hustead
 (304) 558-2402
 crystal.g.hustead@wv.gov

Vendor Signature X *Chyl Breaks* FEIN# *45-3356870* DATE *17 Nov 2022*

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

ADDITIONAL INFORMATION

THE STATE OF WEST VIRGINIA PURCHASING DIVISION FOR THE AGENCY, WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, BUREAU FOR PUBLIC HEALTH (BPH), OFFICE OF NUTRITION SERVICES (ONS) - WOMEN, INFANTS, AND CHILDREN (WIC) PROGRAM, IS SOLICITING BIDS TO ESTABLISH AN OPEN-END CONTRACT FOR HEMOCUE HB301 ANALYZERS, OR EQUAL, AND HEMOCUE MICROCUVETTES, OR EQUAL PER THE ATTACHED DOCUMENTS.

QUESTIONS REGARDING THE SOLICITATION MUST BE SUBMITTED IN WRITING TO CRYSTAL.G.HUSTEAD@WV.GOV PRIOR TO THE QUESTION PERIOD DEADLINE CONTAINED IN THE INSTRUCTIONS TO VENDORS SUBMITTING BIDS

INVOICE TO		SHIP TO	
HEALTH AND HUMAN RESOURCES BPH - NUTRITION SERVICES 350 CAPITOL ST, RM 519 CHARLESTON WV US		OFFICE OF HEALTH FACILITIES 160 JACOBSON DRIVE DOCK 11 POCA WV US	

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
1	HemoCue Hb301 HemoGlogin Analyzers or Equal	100.00000	EA	0.00	0.00

Comm Code	Manufacturer	Specification	Model #
41115815	EKF Diagnostics	Equal	900-001

Extended Description:

3.1.1 HemoCue Hb301 HemoGlogin Analyzers or Equal

INVOICE TO		SHIP TO	
HEALTH AND HUMAN RESOURCES BPH - NUTRITION SERVICES 350 CAPITOL ST, RM 519 CHARLESTON WV US		OFFICE OF HEALTH FACILITIES 160 JACOBSON DRIVE DOCK 11 POCA WV US	

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
2	Microcuvettes for use with Analyzers	100000.00000	EA	1.84	84,000.00

Comm Code	Manufacturer	Specification	Model #
41121813	EKF Diagnostics	Equal	900-100

Extended Description:

3.1.2 Microcuvettes for use with Analyzers

INVOICE TO		SHIP TO	
HEALTH AND HUMAN RESOURCES BPH - NUTRITION SERVICES 350 CAPITOL ST, RM 519 CHARLESTON WV US		OFFICE OF HEALTH FACILITIES 160 JACOBSON DRIVE DOCK 11 POCA WV US	

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
3	Carrying Case for use with Analyzers and Cuvette vial	100.00000	EA	37.23	3,723.00

Comm Code	Manufacturer	Specification	Model #
41115816	EKF Diagnostics	Equal	900-600

Extended Description:

3.1.3 Carrying Case for use with Analyzers and Cuvette vial

INVOICE TO		SHIP TO	
HEALTH AND HUMAN RESOURCES BPH - NUTRITION SERVICES 350 CAPITOL ST, RM 519 CHARLESTON WV US		OFFICE OF HEALTH FACILITIES 160 JACOBSON DRIVE DOCK 11 POCA WV US	

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
4	Vendor Training, Support, and Ongoing Assistance	0.00000	EA	0.00	0.00

Comm Code	Manufacturer	Specification	Model #
86000000			

Extended Description:

3.1.4 Vendor Training, Support, and Ongoing Assistance

SCHEDULE OF EVENTS

Line	Event	Event Date
1	VENDOR QUESTION DEADLINE	2022-11-17

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 **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 individual is permitted to represent more than one vendor at the pre-bid meeting. Any individual that does attempt to represent two or more vendors will be required to select one vendor to which the individual's attendance will be attributed. The vendors not selected will be deemed to have not attended the pre-bid meeting unless another individual attended on their behalf.

An attendance sheet provided at the pre-bid meeting shall serve as the official document verifying 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 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 emails should have the solicitation number in the subject line.

Question Submission Deadline: November 17, 2022 at 10:00 AM ET

Submit Questions to: Crystal Husted
2019 Washington Street, East
Charleston, WV 25305
Fax: (304) 558-3970
Email: crystal.g.husted@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 on or before the date and time of the bid opening listed in section 7 below. Vendors can submit bids electronically through wvOASIS, in paper form delivered to the Purchasing Division at the address listed below either in person or by courier, or in facsimile form by faxing to the Purchasing Division at the number listed below. Notwithstanding the foregoing, the Purchasing Division may prohibit the submission of bids electronically through wvOASIS at its sole discretion. Such a prohibition will be contained and communicated in the wvOASIS system resulting in the Vendor's inability to submit bids through wvOASIS. The Purchasing Division will not accept bids, modification of bids, or addendum acknowledgment forms via email. Bids submitted in paper or facsimile form must contain a signature. Bids submitted in wvOASIS are deemed to be electronically signed.

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.

For Request for Proposal ("RFP") Responses Only: Submission of a response to a Request for Proposal is not permitted in wvOASIS. In the event that Vendor is responding to a request for proposal, the Vendor shall submit one original technical and one original cost proposal prior to the bid opening date and time identified in Section 7 below, plus n/a convenience copies of each to the Purchasing Division at the address shown below. Additionally, the Vendor should clearly identify and segregate the cost proposal from the technical proposal in a separately sealed envelope.

Revised 09/12/2022

Bid Delivery Address and Fax Number:
Department of Administration, Purchasing Division
2019 Washington Street East
Charleston, WV 25305-0130
Fax: 304-558-3970

A bid submitted in paper or facsimile form should contain the information listed below on the face of the submission envelope or fax cover sheet. Otherwise, the bid may be rejected by the Purchasing Division.

VENDOR NAME:
BUYER: Crystal Husted
SOLICITATION NO.: CRFQ WIC2300000002
BID OPENING DATE: December 1, 2022
BID OPENING TIME: 1:30 PM ET
FAX NUMBER: 304-558-3970

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: December 1, 2022 at 1:30 PM ET

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. ALTERNATE MODEL OR BRAND: Unless the box below is checked, 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.

This Solicitation is based upon a standardized commodity established under W. Va. Code § 5A-3-61. Vendors are expected to bid the standardized commodity identified. Failure to bid the standardized commodity will result in your firm's bid being rejected.

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 be requested in purchases of motor vehicles or construction and maintenance equipment and machinery used in highway and other infrastructure projects. Any request for preference must be submitted in writing with the bid, must specifically identify the preference requested with reference to the applicable subsection of West Virginia Code § 5A-3-37, and must include with the bid any information necessary to evaluate and confirm the applicability of the requested preference. A request form to help facilitate the request can be found at: www.state.wv.us/admin/purchase/vrc/Venpref.pdf.

15A. RECIPROCAL PREFERENCE: The State of West Virginia applies a reciprocal preference to all solicitations for commodities and printing in accordance with W. Va. Code § 5A-3-37(b). In effect, non-resident vendors receiving a preference in their home states, will see that same preference granted to West Virginia resident vendors bidding against them in West Virginia. Any request for reciprocal preference must include with the bid any information necessary to evaluate and confirm the applicability of the preference. A request form to help facilitate the request can be found at: www.state.wv.us/admin/purchase/vrc/Venpref.pdf.

16. SMALL, WOMEN-OWNED, OR MINORITY-OWNED BUSINESSES: For any solicitations publicly advertised for bid, in accordance with West Virginia Code §5A-3-37 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 and viewed by the Purchasing Division staff immediately upon bid opening. The Purchasing Division will consider any file that cannot be immediately accessed and 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 to make a file viewable if those documents are required with the bid. A Vendor may be required to provide document passwords or remove access restrictions to allow the Purchasing Division to print or electronically save documents provided that those documents are viewable by the Purchasing Division prior to obtaining the password or removing the access restriction.

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.

22. WITH THE BID REQUIREMENTS: In instances where these specifications require documentation or other information with the bid, and a vendor fails to provide it with the bid, the Director of the Purchasing Division reserves the right to request those items after bid opening and prior to contract award pursuant to the authority to waive minor irregularities in bids or specifications under W. Va. CSR § 148-1-4.6. This authority does not apply to instances where state law mandates receipt with the bid.

23. EMAIL NOTIFICATION OF AWARD: The Purchasing Division will attempt to provide bidders with e-mail notification of contract award when a solicitation that the bidder participated in has been awarded. For notification purposes, bidders must provide the Purchasing Division with a valid email address in the bid response. Bidders may also monitor wvOASIS or the Purchasing Division’s website to determine when a contract has been awarded.

24. ISRAEL BOYCOTT CERTIFICATION: Vendor’s act of submitting a bid in response to this solicitation shall be deemed a certification from bidder to the State that bidder is not currently engaged in, and will not for the duration of the contract, engage in a boycott of Israel. This certification is required by W. Va. Code § 5A-3-63.

GENERAL TERMS AND CONDITIONS:

1. CONTRACTUAL AGREEMENT: Issuance of an Award Document signed by the Purchasing Division Director, or his designee, and approved as to form by the Attorney General's office constitutes acceptance by the State of this Contract made by and between the State of West Virginia and the Vendor. Vendor's signature on its bid, or on the Contract if the Contract is not the result of a bid solicitation, 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: The Initial Contract Term will be for a period of one (1) year. The Initial Contract Term becomes effective on the effective start date listed on the first page of this Contract, identified as the State of West Virginia contract cover page containing the signatures of the Purchasing Division, Attorney General, and Encumbrance clerk (or another page identified as _____), and the Initial Contract Term ends on the effective end date also shown on the first page of this Contract.

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 delivered to the Agency and then 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. Unless otherwise specified below, 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 the total number of months available in all renewal years combined. Automatic renewal of this Contract is prohibited. Renewals must be approved by the Vendor, Agency, Purchasing Division and Attorney General's office (Attorney General approval is as to form only)

Alternate Renewal Term – This contract may be renewed for _____ successive _____ year periods or shorter periods provided that they do not exceed the total number of months contained in all available renewals. Automatic renewal of this Contract is prohibited. Renewals must be approved by the Vendor, Agency, Purchasing Division and Attorney General's office (Attorney General approval is as to form only)

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 of the work covered by the preceding sentence, the vendor agrees that:

the contract will continue for _____ years;

the contract may be renewed for _____ successive _____ year periods or shorter periods provided that they do not exceed the total number of months contained in all available renewals. Automatic renewal of this Contract is prohibited. Renewals must be approved by the Vendor, Agency, Purchasing Division and Attorney General's Office (Attorney General approval is as to form only).

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.

Construction/Project Oversight: This Contract becomes effective on the effective start date listed on the first page of this Contract, identified as the State of West Virginia contract cover page containing the signatures of the Purchasing Division, Attorney General, and Encumbrance clerk (or another page identified as _____), and continues until the project for which the vendor is providing oversight is complete.

Other: Contract Term specified in _____

4. AUTHORITY TO PROCEED: Vendor is authorized to begin performance of this contract on the date of encumbrance listed on the front page of the Award Document unless either the box for "Fixed Period Contract" or "Fixed Period Contract with Renewals" has been checked in Section 3 above. If either "Fixed Period Contract" or "Fixed Period Contract with Renewals" has been checked, Vendor must not begin work until it receives a separate notice to proceed from the State. The notice to proceed will then be incorporated into the Contract via change order to memorialize the official date that work commenced.

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/Award Document 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.

Construction: This Contract is for construction activity more fully defined in the specifications.

6. 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.

7. REQUIRED DOCUMENTS: All of the items checked in this section must be provided to the Purchasing Division by the Vendor as specified:

LICENSE(S) / CERTIFICATIONS / PERMITS: In addition to anything required under the Section of the General Terms and Conditions entitled Licensing, the apparent successful Vendor shall furnish proof of the following licenses, certifications, and/or permits upon request and in a form acceptable to the State. The request may be prior to or after contract award at the State's sole discretion.

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

8. INSURANCE: The apparent successful Vendor shall furnish proof of the insurance identified by a checkmark below prior to Contract award. The insurance coverages identified below must be maintained throughout the life of this contract. Thirty (30) days prior to the expiration of the insurance policies, Vendor shall provide the Agency with proof that the insurance mandated herein has been continued. Vendor must also provide Agency with immediate notice of any changes in its insurance policies, including but not limited to, policy cancelation, policy reduction, or change in insurers. The apparent successful Vendor shall also furnish proof of any additional insurance requirements contained in the specifications prior to Contract award regardless of whether that insurance requirement is listed in this section.

Vendor must maintain:

Commercial General Liability Insurance in at least an amount of: \$1,000,000.00 per occurrence.

Automobile Liability Insurance in at least an amount of: \$1,000,000.00 per occurrence.

Professional/Malpractice/Errors and Omission Insurance in at least an amount of: _____ per occurrence. Notwithstanding the forgoing, Vendor's are not required to list the State as an additional insured for this type of policy.

Commercial Crime and Third Party Fidelity Insurance in an amount of: _____ per occurrence.

Cyber Liability Insurance in an amount of: _____ per occurrence.

Builders Risk Insurance in an amount equal to 100% of the amount of the

Contract. [] **Pollution Insurance** in an amount of: _____ per

occurrence.

Aircraft Liability in an amount of: _____ per occurrence.

9. WORKERS' COMPENSATION INSURANCE: 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. VENUE: All legal actions for damages brought by Vendor against the State shall be brought in the West Virginia Claims Commission. Other causes of action must be brought in the West Virginia court authorized by statute to exercise jurisdiction over it.

11. LIQUIDATED DAMAGES: 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. Vendor shall pay liquidated damages in the amount specified below or as described in the specifications:

_____ for _____.

Liquidated Damages Contained in the Specifications.

Liquidated Damages Are Not Included in this Contract.

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. 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. Notwithstanding the foregoing, Vendor must extend any publicly advertised sale price to the State and invoice at the lower of the contract price or the publicly advertised sale price.

14. PAYMENT IN ARREARS: Payments for goods/services will be made in arrears only upon receipt of a proper invoice, detailing the goods/services provided or receipt of the goods/services, whichever is later. Notwithstanding the foregoing, payments for software maintenance, licenses, or subscriptions may be paid annually in advance.

15. PAYMENT METHODS: Vendor must accept payment by electronic funds transfer and P-Card. (The State of West Virginia's Purchasing Card program, administered under contract by a banking institution, processes payment for goods and services through state designated credit cards.)

16. 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.

17. ADDITIONAL FEES: Vendor is not permitted to charge additional fees or assess additional charges that were not either expressly provided for in the solicitation published by the State of West Virginia, included in the Contract, or included in the unit price or lump sum bid amount that Vendor is required by the solicitation to provide. Including such fees or charges as notes to the solicitation may result in rejection of vendor's bid. Requesting such fees or charges be paid after the contract has been awarded may result in cancellation of the contract.

18. 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. If that occurs, the State may notify the Vendor that an alternative source of funding has been obtained and thereby avoid the automatic termination. Non-appropriation or non-funding shall not be considered an event of default.

19. 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 § 148-1-5.2.b.

20. TIME: Time is of the essence regarding all matters of time and performance in this Contract.

21. 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.

22. COMPLIANCE WITH LAWS: 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.

SUBCONTRACTOR COMPLIANCE: Vendor shall notify all subcontractors providing commodities or services related to this Contract that as subcontractors, they too are required to comply with all applicable laws, regulations, and ordinances. Notification under this provision must occur prior to the performance of any work under the contract by the subcontractor.

23. 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.

24. 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.

25. 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.

26. 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.

27. 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.

28. 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.

29. 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.

30. 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>.

31. 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.

Revised 09/12/2022

32. 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. Obligations related to political subdivisions may include, but are not limited to, business licensing, business and occupation taxes, inspection compliance, permitting, etc. 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.

SUBCONTRACTOR COMPLIANCE: Vendor shall notify all subcontractors providing commodities or services related to this Contract that as subcontractors, they too are required to be licensed, in good standing, and up-to-date on all state and local obligations as described in this section. Obligations related to political subdivisions may include, but are not limited to, business licensing, business and occupation taxes, inspection compliance, permitting, etc. Notification under this provision must occur prior to the performance of any work under the contract by the subcontractor.

33. 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.

34. VENDOR NON-CONFLICT: Neither Vendor nor its representatives are permitted to have any interest, nor shall they 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.

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. NO DEBT CERTIFICATION: In accordance with West Virginia Code §§ 5A-3-10a and 5-22-1(i), the State is prohibited from awarding a contract to any bidder that owes a debt to the State or a political subdivision of the State. By submitting a bid, or entering into a contract with the State, Vendor is affirming that (1) for construction contracts, the Vendor is not in default on any monetary obligation owed to the state or a political subdivision of the state, and (2) for all other contracts, neither the Vendor nor any related party owe a debt as defined above, and neither the Vendor nor any related party are in employer default as defined in the statute cited above unless the debt or employer default is permitted under the statute.

38. 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.

39. 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.division@wv.gov.

40. BACKGROUND CHECK: In accordance with W. Va. Code § 15-2D-3, 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.

41. 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.
- c. The Purchasing Division Director may, in writing, authorize the use of foreign steel products if:
 1. 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
 2. 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.

42. 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.

43. INTERESTED PARTY SUPPLEMENTAL DISCLOSURE: W. Va. Code § 6D-1-2 requires that for contracts with an actual or estimated value of at least \$1 million, the Vendor must submit to the Agency a disclosure of interested parties prior to beginning work under this Contract. Additionally, the Vendor must submit a supplemental disclosure of interested parties reflecting any new or differing interested parties to the contract, which were not included in the original pre-work interested party disclosure, within 30 days following the completion or termination of the contract. A copy of that form is included with this solicitation or can be obtained from the WV Ethics Commission. This requirement does not apply to publicly traded companies listed on a national or international stock exchange. A more detailed definition of interested parties can be obtained from the form referenced above.

44. PROHIBITION AGAINST USED OR REFURBISHED: Unless expressly permitted in the solicitation published by the State, Vendor must provide new, unused commodities, and is prohibited from supplying used or refurbished commodities, in fulfilling its responsibilities under this Contract.

45. VOID CONTRACT CLAUSES: This Contract is subject to the provisions of West Virginia Code § 5A-3-62, which automatically voids certain contract clauses that violate State law.

46. ISRAEL BOYCOTT: Bidder understands and agrees that, pursuant to W. Va. Code § 5A-3-63, it is prohibited from engaging in a boycott of Israel during the term of this contract.

DESIGNATED CONTACT: Vendor appoints the individual identified in this Section as the Contract Administrator and the initial point of contact for matters relating to this Contract.

(Printed Name and Title) Mindy Rodriguez Inside Sales Supervisor
(Address) 1261 N. Main St Boerne TX 78006
(Phone Number) / (Fax Number) 830 249 0772^{x142} 830 331 2091
(email address) mindyrodriquez@ekfdiagnostics.com

CERTIFICATION AND SIGNATURE: By signing below, or submitting documentation through wvOASIS, I certify that: I have reviewed this Solicitation/Contract 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/Contract 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 this bid or offer was made without prior understanding, agreement, or connection with any entity submitting a bid or offer for the same material, supplies, equipment or services; that this bid or offer is in all respects fair and without collusion or fraud; 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; 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.

By signing below, I further certify that I understand this Contract is subject to the provisions of West Virginia Code § 5A-3-62, which automatically voids certain contract clauses that violate State law; and that pursuant to W. Va. Code 5A-3-63, the entity entering into this contract is prohibited from engaging in a boycott against Israel.

EKF Diagnostics
(Company) _____
Cheryl Brooks
(Signature of Authorized Representative) _____
Cheryl Brooks
(Printed Name and Title of Authorized Representative) (Date) _____
830 249 0772 830 331 2091
(Phone Number) (Fax Number) _____
cherylbrooks@ekfdiagnostics.com
(Email Address) _____

ADDENDUM ACKNOWLEDGEMENT FORM
SOLICITATION NO.: CRFQ WIC2300000002

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)

- | | |
|---|--|
| <input type="checkbox"/> Addendum No. 1 | <input type="checkbox"/> Addendum No. 6 |
| <input type="checkbox"/> Addendum No. 2 | <input type="checkbox"/> Addendum No. 7 |
| <input type="checkbox"/> Addendum No. 3 | <input type="checkbox"/> Addendum No. 8 |
| <input type="checkbox"/> Addendum No. 4 | <input type="checkbox"/> Addendum No. 9 |
| <input type="checkbox"/> Addendum No. 5 | <input type="checkbox"/> 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.

CKF Diagnostics

Company

Chap Brack
Authorized Signature

11/29/2022
Date

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

REQUEST FOR QUOTATION
CRFQ WIC2300000002
HemoCue Hb301 Analyzer (or equal) and HemoCue Microcuvettes (or equal)

SPECIFICATIONS

1. **PURPOSE AND SCOPE:** 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) – Women, Infants, and Children (WIC) Program to establish an open-end contract for HemoCue Hb301 Analyzers, or equal, and HemoCue Microcuvettes, or equal.

NOTE: This request is covered in part or in whole by federal funds. All bidders will be required to acknowledge and adhere to the Federal Funds Addendum Attachment.

NOTE: The WVDHHR has developed an EEO Utilization Report and it is available at: <http://www.wvdhhr.org/pdfs/H1.5%20Utilization%20Report%20and%20EEO%20policy.pdf>

2. **DEFINITIONS:** The terms listed below shall have the meanings assigned to them below. Additional definitions can be found in section 2 of the General Terms and Conditions.

- 2.1 “**Contract Item**” or “**Contract Items**” means the list of items identified in Section 3.1 below and on the Pricing Pages.
- 2.2 “**Pricing Pages**” means the schedule of prices, estimated order quantity, and totals contained in wvOASIS, and used to evaluate the Solicitation responses.
- 2.3 “**Solicitation**” means the official notice of an opportunity to supply the State with goods or services that is published by the Purchasing Division.

3. **GENERAL REQUIREMENTS:**

- 3.1 **Contract Items and Mandatory Requirements:** Vendor shall provide Agency with the Contract Items listed below on an open-end and continuing basis. Contract Items must meet or exceed the mandatory requirements as shown below.

3.1.1 **Contract Item #1 – HemoCue Hb301 Hemoglobin Analyzers, or equal**

3.1.1.1 Analyzers must have a minimum warranty period of two years.

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

**REQUEST FOR QUOTATION
CRFQ WIC230000002**

HemoCue Hb301 Analyzer (or equal) and HemoCue Microcuvettes (or equal)

- 3.1.1.3** Each analyzer unit shall come complete with: the ability to store a minimum of 500 patient results, cable(s) or adapter(s), and an operating manual and/or quick reference guide.
- 3.1.1.4** Analyzers must connect to a personal computer via a USB and/or 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 may be asked to provide an in-person demonstration to the ONS staff, at the Vendor’s expense, showing that the alternate product is fully functional within the WIC Crossroads SAM system.
- 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, which may be found on this website: <http://icsh.org/>, and will need no further calibration post-delivery.
- 3.1.1.6** Analyzers must have a linearity of a minimum of 0.0 g/dL and a maximum of 23.0 g/dL in a general clinic setting. Anything over 23.0 g/dL must be confirmed using a suitable laboratory method.
- 3.1.1.7** Analyzers must have a Total Precision CV of 1.3% or 1.5%.
- 3.1.1.8** Analyzers must have an internal self-test that verifies the performance of the optronic unit and a minimum of 4 points of linearity range when it is turned on and a minimum of every 2 hours subsequently to ensure it is working properly.
- 3.1.1.9** Analyzer must be capable of sampling capillary, venous, or arterial whole blood.
- 3.1.1.10** Analyzer must be capable of operation with an AC adaptor or applicable size and number of batteries required for functionality.
- 3.1.1.11** Analyzers must be capable of producing results in g/dL within a minimum of 2 seconds and a maximum of 20 seconds.

REQUEST FOR QUOTATION
CRFQ WIC2300000002
HemoCue Hb301 Analyzer (or equal) and HemoCue Microcuvettes (or equal)

- 3.1.2.5** Vendor must be able to supply the estimated annual usage of 100,000 microcuvettes, whether it is less or more. As per specification 3.1.2.2, vials must be packaged between 50 and 100 each.
- 3.1.2.6** The Vendor must be able to provide a quantity of 100 vials within a sixty-day period.
- 3.1.2.7** 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: Carrying Case, or equal, for use with Contract Items bid under 3.1.1 and 3.1.2**

 - 3.1.3.1** A hard shell carrying case, or equal, capable of carrying at least 1 analyzer (Contract Item #1 under 3.1.1) and one vial of microcuvettes (Contract Item #2 under 3.1.2), must be offered.
- 3.1.4 Contract Item #4: Vendor Training, Support, and Ongoing Assistance over the life of the contract**

 - 3.1.4.1** 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.
 - 3.1.4.2** Vendor shall be responsible for all mileage and travel costs, including travel time, associated with the performance of this Contract. Any anticipated mileage or travel costs may be included in the flat fee or hourly rate listed on the Vendor's bid, but such costs will not be paid by the Agency separately.
 - 3.1.4.3** Vendor must provide annual on-site instrument in-process verification to ensure the equipment is still in good working order.
 - 3.1.4.4** Vendor must provide online training and annual certification for all State Staff.

REQUEST FOR QUOTATION
CRFQ WIC230000002
HemoCue Hb301 Analyzer (or equal) and HemoCue Microcuvettes (or equal)

- 3.1.1.12** Analyzers must weigh a minimum of one (1) pound and a maximum of five (5) pounds.
 - 3.1.1.13** Analyzers must include tools such as: operator's manual, suggested evaluations, and validation of operating procedure templates for the hemoglobin systems.
- 3.1.2 Contract Item #2: Microcuvettes for use with the HemoCue Hb301 Analyzer, or compatible with the Hemoglobin Analyzer bid under Contract Item 3.1.1**
- 3.1.2.1** Microcuvettes must be compatible with the HemoCue HB301 Hemoglobin Analyzers, or equal.
 - 3.1.2.1.1** Successful Vendors bidding an "equal to" product may be asked to 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 HB301 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 provide documentation showing that any brand microcuvettes will work with the HemoCue HB301 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 packaged in vials of a minimum of 50 and a maximum of 100.
 - 3.1.2.3** Microcuvettes must have an expiration date in the future of a minimum of eighteen (18) months for unopened vials and six (6) months for opened vials.
 - 3.1.2.4** Microcuvettes must be capable of being stored in temperatures between a minimum of 50 degrees Fahrenheit and a maximum of 110 degrees Fahrenheit.

REQUEST FOR QUOTATION
CRFQ WIC2300000002
HemoCue Hb301 Analyzer (or equal) and HemoCue Microcuvettes (or equal)

- 3.1.4.5** Upon receipt of the Analyzers bid under 3.1.1, the Vendor must provide site visits within 90 days to support the implementation and reinforce training. Vendor will also provide on-going online training to staff at no charge per ONS requests.
- 3.1.4.6** At a minimum, the Vendor must provide telephone and/or email technical support available during the WIC Clinic Hours of 9:00 AM – 4:00 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 total cost as shown on the Pricing Pages.
- 4.2 Pricing Pages:** Vendor should complete the Commodity Lines by entering the Unit Price and then multiplying it by the Estimated Quantity in order to find the Extended Price for each of the Contract Items. Add the totals in the Extended Price Column together to find the Grand Total. Vendor should complete the Commodity Lines in their entirety as failure to do so may result in Vendor's bids being disqualified.

The Commodity Lines 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 Commodity Lines 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.

REQUEST FOR QUOTATION
CRFQ WIC230000002
HemoCue Hb301 Analyzer (or equal) and HemoCue Microcuvettes (or equal)

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 ninety (90) working days after orders are received. Vendor shall deliver all applicable contract items to the WIC Storage Area at the WVDHHR Materials Management, 160 Jacobson Drive, Dock 11, Poca, WV 25159. 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.

REQUEST FOR QUOTATION
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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.

**REQUEST FOR QUOTATION
CRFQ WIC2300000002**

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- 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: Mindy Rodriguez
Telephone Number: 830 349 0792 x142
Fax Number: 830 331 2091
Email Address: mindyrodriquez@ekfdiagnostics.com

FEDERAL FUNDS ADDENDUM

2 C.F.R. §§ 200.317 – 200.327

Purpose: This addendum is intended to modify the solicitation in an attempt to make the contract compliant with the requirements of 2 C.F.R. §§ 200.317 through 200.327 relating to the expenditure of certain federal funds. This solicitation will allow the State to obtain one or more contracts that satisfy standard state procurement, state federal funds procurement, and county/local federal funds procurement requirements.

Instructions: Vendors who are willing to extend their contract to procurements with federal funds and the requirements that go along with doing so, should sign the attached document identified as: “REQUIRED CONTRACT PROVISIONS FOR NON-FEDERAL ENTITY CONTRACTS UNDER FEDERAL AWARDS (2 C.F.R. § 200.317)”

Should the awarded vendor be unwilling to extend the contract to federal funds procurement, the State reserves the right to award additional contracts to vendors that can and are willing to meet federal funds procurement requirements.

Changes to Specifications: Vendors should consider this solicitation as containing two separate solicitations, one for state level procurement and one for county/local procurement.

State Level: In the first solicitation, bid responses will be evaluated with applicable preferences identified in sections 15, 15A, and 16 of the “Instructions to Vendors Submitting Bids” to establish a contract for both standard state procurements and state federal funds procurements.

County Level: In the second solicitation, bid responses will be evaluated with applicable preferences identified in Sections 15, 15A, and 16 of the “Instructions to Vendors Submitting Bids” omitted to establish a contract for County/Local federal funds procurement.

Award: If the two evaluations result in the same vendor being identified as the winning bidder, the two solicitations will be combined into a single contract award. If the evaluations result in a different bidder being identified as the winning bidder, multiple contracts may be awarded. The State reserves the right to award to multiple different entities should it be required to satisfy standard state procurement, state federal funds procurement, and county/local federal funds procurement requirements.

State Government Use Caution: State agencies planning to utilize this contract for procurements subject to the above identified federal regulations should first consult with the federal agency providing the applicable funding to ensure the contract is compliant.

County/Local Government Use Caution: County and Local government entities planning to utilize this contract for procurements subject to the above identified federal regulation should first consult with the federal agency providing the applicable funding to ensure the contract is compliant. For purposes of County/Local government use, the solicitation resulting in this contract was conducted in accordance with the procurement laws, rules, and procedures governing the West Virginia Department of Administration, Purchasing Division, except that vendor preference has been omitted for County/Local use purposes and the contract terms contained in the document entitled “REQUIRED CONTRACT PROVISIONS FOR NON-FEDERAL ENTITY CONTRACTS UNDER FEDERAL AWARDS (2 C.F.R. § 200.317)” have been added.

FEDERAL FUNDS ADDENDUM

**REQUIRED CONTRACT PROVISIONS FOR NON-FEDERAL ENTITY
CONTRACTS UNDER FEDERAL AWARDS (2 C.F.R. § 200.317):**

The State of West Virginia Department of Administration, Purchasing Division, and the Vendor awarded this Contract intend that this Contract be compliant with the requirements of the Procurement Standards contained in the Uniform Administrative Requirements, Cost Principles, and Audit Requirements found in 2 C.F.R. § 200.317, et seq. for procurements conducted by a Non-Federal Entity. Accordingly, the Parties agree that the following provisions are included in the Contract.

1. MINORITY BUSINESSES, WOMEN'S BUSINESS ENTERPRISES, AND LABOR SURPLUS AREA FIRMS:

(2 C.F.R. § 200.321)

- a. The State confirms that it has taken all necessary affirmative steps to assure that minority businesses, women's business enterprises, and labor surplus area firms are used when possible. Those affirmative steps include:

- (1) Placing qualified small and minority businesses and women's business enterprises on solicitation lists;
- (2) Assuring that small and minority businesses, and women's business enterprises are solicited whenever they are potential sources;
- (3) Dividing total requirements, when economically feasible, into smaller tasks or quantities to permit maximum participation by small and minority businesses, and women's business enterprises;
- (4) Establishing delivery schedules, where the requirement permits, which encourage participation by small and minority businesses, and women's business enterprises;
- (5) Using the services and assistance, as appropriate, of such organizations as the Small Business Administration and the Minority Business Development Agency of the Department of Commerce; and
- (6) Requiring the prime contractor, if subcontracts are to be let, to take the affirmative steps listed in paragraphs (1) through (5) above.

- b. Vendor confirms that if it utilizes subcontractors, it will take the same affirmative steps to assure that minority businesses, women's business enterprises, and labor surplus area firms are used when possible.

2. DOMESTIC PREFERENCES:

(2 C.F.R. § 200.322)

- a. The State confirms that as appropriate and to the extent consistent with law, it has, to the greatest extent practicable under a Federal award, provided a preference for the purchase, acquisition, or use of goods, products, or materials produced in the United

States (including but not limited to iron, aluminum, steel, cement, and other manufactured products).

b. Vendor confirms that will include the requirements of this Section 2. Domestic Preference in all subawards including all contracts and purchase orders for work or products under this award.

c. Definitions: For purposes of this section:

(1) "Produced in the United States" means, for iron and steel products, that all manufacturing processes, from the initial melting stage through the application of coatings, occurred in the United States.

(2) "Manufactured products" means items and construction materials composed in whole or in part of non-ferrous metals such as aluminum; plastics and polymer-based products such as polyvinyl chloride pipe; aggregates such as concrete; glass, including optical fiber; and lumber.

3. BREACH OF CONTRACT REMEDIES AND PENALTIES:

(2 C.F.R. § 200.327 and Appendix II)

(a) The provisions of West Virginia Code of State Rules § 148-1-5 provide for breach of contract remedies, and penalties. A copy of that rule is attached hereto as Exhibit A and expressly incorporated herein by reference.

4. TERMINATION FOR CAUSE AND CONVENIENCE:

(2 C.F.R. § 200.327 and Appendix II)

(a) The provisions of West Virginia Code of State Rules § 148-1-5 govern Contract termination. A copy of that rule is attached hereto as Exhibit A and expressly incorporated herein by reference.

5. EQUAL EMPLOYMENT OPPORTUNITY:

(2 C.F.R. § 200.327 and Appendix II)

Except as otherwise provided under 41 CFR Part 60, and if this contract meets the definition of "federally assisted construction contract" in 41 CFR Part 60-1.3, this contract includes 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."

6. DAVIS-BACON WAGE RATES:
(2 C.F.R. § 200.327 and Appendix II)

Vendor agrees that if this Contract includes construction, all construction work in excess of \$2,000 will be completed and paid for in 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 must:

- (a) 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.
- (b) pay wages not less than once a week.

A copy of the current prevailing wage determination issued by the Department of Labor is attached hereto as Exhibit B. The decision to award a contract or subcontract is conditioned upon the acceptance of the wage determination. The State will report all suspected or reported violations to the Federal awarding agency.

7. ANTI-KICKBACK ACT:
(2 C.F.R. § 200.327 and Appendix II)

Vendor agrees that it will comply 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”). Accordingly, Vendor, Subcontractors, and anyone performing under this contract 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. The State must report all suspected or reported violations to the Federal awarding agency.

8. CONTRACT WORK HOURS AND SAFETY STANDARDS ACT
(2 C.F.R. § 200.327 and Appendix II)

Where applicable, and only for contracts awarded by the State in excess of \$100,000 that involve the employment of mechanics or laborers, Vendor agrees to comply 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, Vendor 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.

9. RIGHTS TO INVENTIONS MADE UNDER A CONTRACT OR AGREEMENT.
(2 C.F.R. § 200.327 and Appendix II)

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.

10. CLEAN AIR ACT
(2 C.F.R. § 200.327 and Appendix II)

Vendor agrees that if this contract exceeds \$150,000, Vendor is to comply 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). Violations must be reported to the Federal awarding agency and the Regional Office of the Environmental Protection Agency (EPA).

11. DEBARMENT AND SUSPENSION
(2 C.F.R. § 200.327 and Appendix II)

The State will not award to any vendor that is listed on the governmentwide exclusions 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.” SAM Exclusions contains the names of parties debarred, suspended, or otherwise excluded by agencies, as well as parties declared ineligible under statutory or regulatory authority other than Executive Order 12549.

12. BYRD ANTI-LOBBYING AMENDMENT
(2 C.F.R. § 200.327 and Appendix II)

Vendors that apply or bid for an award exceeding \$100,000 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.

13. PROCUREMENT OF RECOVERED MATERIALS

(2 C.F.R. § 200.327 and Appendix II; 2 C.F.R. § 200.323)

Vendor agrees that it and the State 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.

14. PROHIBITION ON CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT.

(2 C.F.R. § 200.327 and Appendix II; 2 CFR § 200.216)

Vendor and State agree that both are prohibited from obligating or expending funds under this Contract to:

- (1) Procure or obtain;
- (2) Extend or renew a contract to procure or obtain; or
- (3) Enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in Public Law 115–232, section 889, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).
 - (i) For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).
 - (ii) Telecommunications or video surveillance services provided by such entities or using such equipment.
 - (iii) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

In implementing the prohibition under Public Law 115-232, section 889, subsection (f), paragraph (1), heads of executive agencies administering loan, grant, or subsidy programs shall prioritize available funding and technical support to assist affected businesses, institutions and organizations as is reasonably necessary for those affected entities to transition from covered communications equipment and services, to procure replacement equipment and services, and to ensure that communications service to users and customers is sustained.

State of West Virginia
Purchasing Division

By: _____

Printed Name: _____

Title: _____

Date: _____

Vendor Name: EKF Diagnostics

By: Mindy Rodriguez

Printed Name: Mindy Rodriguez

Title: Inside Sales Supervisor

Date: 11/29/2022

**EXHIBIT A To:
REQUIRED CONTRACT PROVISIONS FOR NON-FEDERAL ENTITY
CONTRACTS UNDER FEDERAL AWARDS (2 C.F.R. § 200.317):**

W. Va. CSR § 148-1-5

West Virginia Code of State Rules
Title 148. Department of Administration
Legislative Rule (Ser. 1)
Series 1. Purchasing

W. Va. Code St. R. § 148-1-5
§ 148-1-5. Remedies.
Currentness

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.

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

5.2.1.a. The vendor agrees to the cancellation;

5.2.1.b. 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;

5.2.1.c. Failure to honor any contractual term or condition or to honor standard commercial practices;

5.2.1.d. The existence of an organizational conflict of interest is identified;

5.2.1.e. Funds are not appropriated or an appropriation is discontinued by the legislature for the acquisition;

5.2.1.f. Violation of any federal, state, or local law, regulation, or ordinance, and

5.2.1.g. The contract was awarded in error.

5.2.2. 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.

5.2.3. 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.

5.2.4. 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:

5.2.4.a. 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

5.2.4.b. 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.

5.4.1. The Director may suspend, for a period not to exceed 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:

5.4.1.a. The vendor has submitted a bid and then requested that its bid be withdrawn after bids have been publicly opened.

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

5.4.1.c. 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.

5.4.1.d. The vendor's actions have given rise to one or more of the grounds for debarment listed in W. Va. Code § 5A-3-33d.

5.4.2. Vendor suspension for the reasons listed in section 5.4 above shall occur as follows:

5.4.2.a. Upon a determination by the Director that a suspension is warranted, the Director will serve a notice of suspension to the vendor.

5.4.2.b. A notice of suspension must inform the vendor:

5.4.2.b.1. Of the grounds for the suspension;

5.4.2.b.2. Of the duration of the suspension;

5.4.2.b.3. Of the right to request a hearing contesting the suspension;

5.4.2.b.4. That a request for a hearing must be served on the Director no later than 5 working days of the vendor's receipt of the notice of suspension;

5.4.2.b.5. That the vendor's failure to request a hearing no later than 5 working days of

the receipt of the notice of suspension will be deemed a waiver of the right to a hearing and result in the automatic enforcement of the suspension without further notice or an opportunity to respond; and

5.4.2.b.6. That a request for a hearing must include an explanation of why the vendor believes the Director's asserted grounds for suspension do not apply and why the vendor should not be suspended.

5.4.2.c. A vendor's failure to serve a request for hearing on the Director no later than 5 working days of the vendor's receipt of the notice of suspension will be deemed a waiver of the right to a hearing and may result in the automatic enforcement of the suspension without further notice or an opportunity to respond.

5.4.2.d. A vendor who files a timely request for hearing but nevertheless fails to provide an explanation of why the asserted grounds for suspension are inapplicable or should not result in a suspension, may result in a denial of the vendor's hearing request.

5.4.2.e. Within 5 working days of receiving the vendor's request for a hearing, the Director will serve on the vendor a notice of hearing that includes the date, time and place of the hearing.

5.4.2.f. The hearing will be recorded and an official record prepared. Within 10 working days of the conclusion of the hearing, the Director will issue and serve on the vendor, a written decision either confirming or reversing the suspension.

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

5.4.4. 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 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.

5.4.5. 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 W. Va. Code § 5A-3-33d or if the vendor has been declared ineligible to participate in procurement related activities under federal laws and regulation.

5.5.1. Debarment proceedings shall be conducted in accordance with W. Va. 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.

5.5.2. 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.

5.5.3. 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.

5.5.4. Pursuant to W.Va. Code § 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.

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

5.5.6. Related Party Debarment. The Director may pursue debarment of a related party at the same time that debarment of the original vendor is proceeding or at any time thereafter that the Director determines a related party debarment is warranted. Any entity that fails to provide the Director with full, complete, and accurate information requested by the Director to determine related party

status will be presumed to be a related party subject to debarment.

5.6. Damages.

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

5.6.2. 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.

5.6.3. 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.

Credits

History: Filed 4-1-19, eff. 4-1-19; Filed 4-16-21, eff. 5-1-21.

Current through register dated May 7, 2021. Some sections may be more current. See credits for details.

W. Va. C.S.R. § 148-1-5, WV ADC § 148-1-5

End of Document

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**EXHIBIT B To:
REQUIRED CONTRACT PROVISIONS FOR NON-FEDERAL ENTITY
CONTRACTS UNDER FEDERAL AWARDS (2 C.F.R. § 200.317):**

Prevailing Wage Determination

- Not Applicable Because Contract Not for Construction
- Federal Prevailing Wage Determination on Next Page



CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
09/08/2022

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

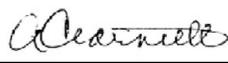
PRODUCER Willis Towers Watson Midwest, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	CONTACT Willis Towers Watson Certificate Center NAME: PHONE (A/C, No, Ext): 1-877-945-7378 FAX (A/C, No): 1-888-467-2378 E-MAIL ADDRESS: certificates@willis.com	
	INSURER(S) AFFORDING COVERAGE	
INSURED EKF Diagnostics, Inc. DBA Stanbio Laboratory, L.P. 1261 North Main Street Boerne, TX 78006	INSURER A: Great Northern Insurance Company NAIC # 20303	
	INSURER B: Federal Insurance Company 20281	
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** W25917069 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS
A	<input checked="" type="checkbox"/> COMMERCIAL GENERAL LIABILITY <input type="checkbox"/> CLAIMS-MADE <input checked="" type="checkbox"/> OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: <input type="checkbox"/> POLICY <input type="checkbox"/> JEC1 <input checked="" type="checkbox"/> LOC OTHER:			3578-60-26 GAB	06/30/2022	06/30/2023	EACH OCCURRENCE \$ 1,000,000 DAMAGE TO RENTED PREMISES (Ea occurrence) \$ 1,000,000 MED EXP (Any one person) \$ 10,000 PERSONAL & ADV INJURY \$ 1,000,000 GENERAL AGGREGATE \$ 2,000,000 PRODUCTS - COMP/OP AGG \$
B	AUTOMOBILE LIABILITY <input type="checkbox"/> ANY AUTO <input type="checkbox"/> OWNED AUTOS ONLY <input type="checkbox"/> SCHEDULED AUTOS <input checked="" type="checkbox"/> HIRED AUTOS ONLY <input checked="" type="checkbox"/> NON-OWNED AUTOS ONLY			(22) 7356-75-97	06/30/2022	06/30/2023	COMBINED SINGLE LIMIT (Ea accident) \$ BODILY INJURY (Per person) \$ 1,000,000 BODILY INJURY (Per accident) \$ PROPERTY DAMAGE (Per accident) \$
B	<input checked="" type="checkbox"/> UMBRELLA LIAB <input checked="" type="checkbox"/> OCCUR <input type="checkbox"/> EXCESS LIAB <input type="checkbox"/> CLAIMS-MADE DED RETENTION \$			7981-24-69	06/30/2022	06/30/2023	EACH OCCURRENCE \$ 5,000,000 AGGREGATE \$ 5,000,000
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	Y/N	N/A				<input type="checkbox"/> PER STATUTE <input type="checkbox"/> OTH-ER E.L. EACH ACCIDENT \$ E.L. DISEASE - EA EMPLOYEE \$ E.L. DISEASE - POLICY LIMIT \$

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Parent Entity

CERTIFICATE HOLDER EKF Diagnostics, Inc. Avon House, 19 Stanwell Road Penarth, Cardiff CF64 2EZ, UK	CANCELLATION SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.
	AUTHORIZED REPRESENTATIVE 



DiaSpect Tm

User Manual

DiaSpect Tm User Manual

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DiaSpect Tm User Manual

1. Intended Use

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

- Caution: Federal law restricts this device for sale by or on the order of a physician or other licensed practitioner (Rx only).
- CLIA Complexity for whole blood: Waived

Laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test, or the test will no longer be considered CLIA waived.

2. Principles of the Procedure

Based on a photometric principle, the DiaSpect Tm system utilizes a broad-spectrum, multi-chromatic sensor with compensation for turbidity and scattering which measures the absorbance of whole blood over a wide spectral range. The light path length through the cuvette cavity, in combination with the DiaSpect Tm analyzer, determines the exactness of the hemoglobin measurement. The hemoglobin concentration is calculated from the measured absorbance at multiple wavelengths.

The cuvettes do not contain any reagent. The system is calibrated against the hemoglobincyanide (HiCN) method, the international reference method for the determination of hemoglobin concentration in blood as described in NCCLS/CLSI H15-A3 and ICSH standard 1995.^{1,2}

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

DiaSpect Tm User Manual

3. The DiaSpect Tm system

3.1 DiaSpect Tm analyzer

Upon delivery, open the carton on a stable surface, remove the instrument and the accessories, and check that all the components are included and undamaged.

A comprehensive list (with item numbers) of all parts for the DiaSpect Tm system can be found in sections 15 and 16.

The DiaSpect Tm analyzer can be stored at 0 to 50 °C (32 to 122 °F). Temperatures of -30 to 70 °C (-22 to 158 °F) are temporarily permitted during transport (24 hours max.).

The operating temperature of the instrument is 10 to 42 °C (50 to 107 °F). Allow the analyzer to reach ambient temperature before use.



1



2



3

1. *DiaSpect Tm analyzer*

2. *User Manual*

3. *Power supply, adapter plug and USB cable*

3.2 DiaSpect Tm Cuvettes

Cuvettes are ready for use upon removal from the package. A sample volume of 10 µL is required to ensure proper filling of the DiaSpect Tm Cuvette. The cuvette serves as sample collector and measuring cuvette at the same time. The blood sample is drawn into the cavity by capillary force.

DiaSpect Tm User Manual

Refer to the product label and package insert of the DiaSpect Tm Cuvettes for information on storage and expiry. Unused cuvettes should be stored in their original bag.



DiaSpect Tm Cuvettes Cuvettes in foil bag

4. Control Material

DiaSpect Controls HBT are available to facilitate compliance with local, state and/or federal regulations or accreditation requirements.

The DiaSpect Control HBT is produced in three concentrations that correspond to three known levels of human hemoglobin. Refer to the product label and package insert of the DiaSpect Control HBT for further information on storage and expiry.



Package configurations of DiaSpect Control HBT

DiaSpect Control HBT1	3 x DiaSpect Control HBT-Low
DiaSpect Control HBT2	3 x DiaSpect Control HBT-Medium
DiaSpect Control HBT3	3 x DiaSpect Control HBT-High
DiaSpect Control HBT4	1 x DiaSpect Control HBT-Low 1 x DiaSpect Control HBT-Medium 1 x DiaSpect Control HBT-High

Contents: 1.9 mL per vial, 3 vials per package

DiaSpect Tm User Manual

5. Important Safety Instructions and Notes on Radio Interference

DiaSpect Tm analyzer

- Avoid strong mechanical shocks to the analyzer.
- Do not expose the analyzer to liquids.
- After storage or transport, allow the analyzer to acclimate to its operating temperature of 10 to 42 °C (50 to 107 °F) to prevent condensation damage.
- Do not place the DiaSpect Tm analyzer in direct sunlight or near a heat source.
- Do not place the DiaSpect Tm analyzer in, or next to, wet areas such as sinks or wash basins.
- Do not insert anything other than the USB cable into the socket in the back of the analyzer.

Power Supply

- Only use the power supply provided with the instrument. Do not expose the power supply to liquids.
- Do not place the power supply near heat sources or expose it to direct sunlight.
- Do not use the power supply if its cable has a visible kink in it or becomes damaged.

Blood

Always handle blood as potentially infectious. Use gloves and avoid direct skin or mucous membrane contact with donated blood, blood specimens, blood from transfer pipettes, DIFF-SAFE® blood dispensers, blood from filled cuvettes or blood on the cuvette holder / DiaSpect Tm analyzer. Dispose of contaminated items in proper hazardous waste containers.

DiaSpect Tm User Manual

FCC statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Notes on radio interference

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful. Interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer.

Caution

Changes or modifications not expressly approved by the manufacturer could void the user’s authority to operate the equipment.

RF exposure info

The equipment complies with FCC RF exposure limits set forth for an uncontrolled environment.

Radio equipment	Frequency Bands	Radio Frequency Power
Bluetooth® Low Energy	2.402 - 2.480 GHz	<1 mW

DiaSpect Tm User Manual

6. Installation and Operation

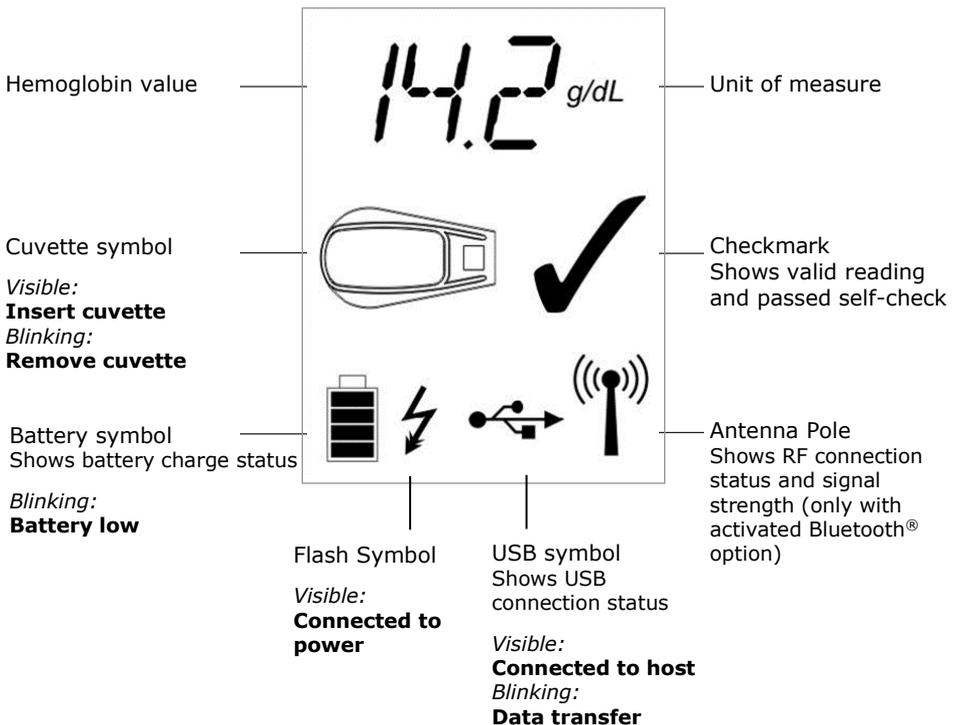
Only healthcare professionals may use the DiaSpect Tm analyzer.

Please read this entire manual before using the analyzer for the first time. Follow the instructions carefully when performing the test as not doing so may result in inaccurate test results.

The DiaSpect Tm analyzer comes ready for use. No installation procedure is necessary. The display is always ON. The analyzer does not have an ON/OFF switch. When not in use, the analyzer remains in a low power mode.

The DiaSpect Tm analyzer may be used as a handheld device.

Understanding the DiaSpect Tm Display



DiaSpect Tm User Manual

6.1 Charging

The DiaSpect Tm analyzer has a built-in rechargeable battery. The battery can be recharged by connecting to a power supply or to a computer via a USB cable. A USB cable and a power supply for charging the battery are supplied.

Charging by power supply:

1. Connect the USB cable to the analyzer.
2. Check that the adapter plug is connected to the power supply.
3. Connect the USB cable to the power supply and plug the power supply into a power outlet.



Charging by power supply

Charging by computer:

1. Connect the USB cable to the analyzer.
2. Connect the USB cable to the USB port of a computer.



Charging by computer

- The battery symbol in the display shows the current charging state.
- The flash symbol indicates that the instrument is connected to power. Leaving the instrument connected to a power source when the battery is fully charged will neither overcharge the battery nor decrease its lifespan.

DiaSpect Tm User Manual

- A fully charged battery lasts up to 40 days / 10,000 tests of continuous use. The battery must be charged when the last status bar is shown, at the latest when E07 is indicated on the display, see Troubleshooting Guide (section 9).
- Fully charge the battery after 9 months, whether or not the instrument has been in use.

6.2 Data Transfer

The DiaSpect Tm analyzer comes with USB 2.0 and an optional Bluetooth® function.

For additional information on data transfer, please contact the manufacturer.

6.3 Cleaning and Disinfection

1. Pull the backside of the cuvette holder slightly towards you and lift up.
2. Using a swab, clean the cuvette holder with cold water or a mild detergent, followed by disinfectant. Dry thoroughly.
3. Re-insert the dry cuvette holder by pressing down until you feel a “click”.
4. Clean device with cold water or mild detergent, followed by disinfectant.



To disinfect the instrument, use conventional solvent-free surface disinfectants or PDI Super Sani-Cloth® Germicidal Disposable Wipes and follow labeling directions.

Do not spray the instrument when cleaning, as this will damage the instrument!

Only use wipes lightly dampened in water/detergent/disinfectant for cleaning and disinfection.

DiaSpect Tm User Manual

6.4 Quality Control

The DiaSpect Tm system is factory calibrated and requires no further calibration.

The DiaSpect Tm analyzer will perform an automatic self-check after each measurement. Passing the self-check verifies the measurement performance and is indicated by a check-mark. An error code is displayed if the self-check fails and the analyzer will cease measuring, so there is no risk of an incorrect result being displayed.

DiaSpect Controls HBT are available to facilitate compliance with local, state and/or federal regulations or accreditation requirements.

Run the controls as described in section 7.3. Control values must fall within the ranges stated on the vial labels. If controls are not in range, repeat with a new cuvette. If values are still out of range, contact Technical Support at 1-800-531-5535.

6.5 Disposal

Used Cuvettes

Dispose of used cuvettes in a container for potentially infectious waste. Consult local environmental authorities for adequate disposal.

DiaSpect Tm Analyzer

The lithium-ion battery in the DiaSpect Tm analyzer has to be disposed of separately. For disposal of the battery, analyzer and power supply, follow the relevant regional or local waste disposal regulations. If you require the manufacturer to dispose of the instrument and its components, please return them to EKF Diagnostics (see section 6.6). Confirmation of appropriate disinfection of the instrument should be included in the shipment.

DiaSpect Control HBT

For disposal of the control material refer to the respective instructions for use.

DiaSpect Tm User Manual

6.6 Service and Maintenance

The DiaSpect Tm analyzer does not require maintenance. For cleaning, see 6.3.

If damaged, the cuvette holder, USB cable, adaptor plug and the power supply can be replaced by the user.

Should the DiaSpect Tm analyzer fail to function as intended, try to solve the issue by using the Troubleshooting Guide, (Section 9). If this is not possible, return the DiaSpect Tm analyzer to EKF Diagnostics or your local distributor.

Never open the analyzer or the power supply.

Any repairs which may be necessary must be carried out by the manufacturer or by authorized personnel only.

Failure to follow the specific instructions for use may result in warranty services offered by the manufacturer being restricted.

For Technical Support, please contact:

EKF Diagnostics, Inc.
1261 North Main Street
Boerne, TX 78006
USA

Phone: 1-800-531-5535
Email: techsupport@ekfdiagnostics.com
www.ekfusa.com

DiaSpect Tm User Manual

7. Specimen Collection and Preparation for Analysis

Capillary blood or venous whole blood containing K2-EDTA or lithium heparin anticoagulant may be used.

7.1. Capillary Sampling

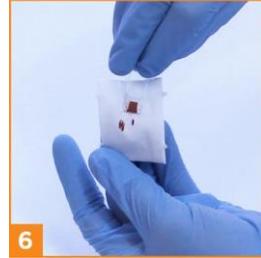
With gloved hands, take a DiaSpect Tm Cuvette out of the foil bag and close the bag. Make sure the hand is warm and relaxed. Use the middle or ring finger for sampling. Avoid fingers with rings on.

1. Disinfect and dry the puncture site.
2. Gently massage the finger towards the tip to increase blood flow. Avoid going past the first knuckle.
3. Make the incision on the upward-facing side of the fingertip, so that the blood drop sits on top of the finger, to facilitate filling of the cuvette.



4. Apply light pressure towards the fingertip (but not past the first knuckle) until a blood drop appears. Wipe away the first 3 drops and make sure there is a free blood flow before filling the cuvette with the fourth drop.
5. Be sure to have a sufficient sized blood drop to fill the cuvette. Fill the cuvette completely by touching the corner of the cuvette to the blood drop. Do not refill the cuvette. If a cuvette cannot be filled in one continuous process, or if the cuvette contains air bubbles, discard the cuvette and use a new one, repeating steps 4 and 5.
6. Gently wipe off the excess blood on the outside of the cuvette with a gauze pad. Be sure to gently wipe both sides. Do not wipe too close to the open end as this can draw blood out of the cuvette.

DiaSpect Tm User Manual



Repeat Testing

Be careful to apply the procedure described in step 1-6 correctly when collecting capillary blood for hemoglobin measurements.

The most common causes for erroneous results are choice of an unsuitable size or type of lancet, incorrect capillary sampling technique, restricted capillary blood flow, or the presence of tissue fluid in the sample after pressing the fingertip too hard. These factors commonly affect the result.

Confirmation of an unexpected or unacceptable result can exclude sampling mistakes as the cause. As the DiaSpect method is very fast, this confirmatory test can probably be done using the same incision. Further drops following the 4th drop may be used for testing as long as there is still a free flow of blood.

If the blood flow has decreased or stopped, another incision should be made for the confirming sample. Repeat the procedure described in steps 1-6 and record all results from repeated sampling, including relevant information about the reason for retesting.

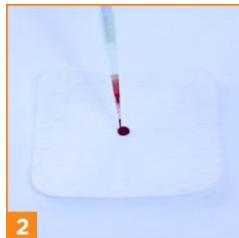
DiaSpect Tm User Manual

7.2 Venous Sampling

If a venous sample cannot be run immediately, it may be refrigerated up to 72 hours. If the blood is refrigerated, then the blood should be allowed to reach room temperature before testing. K2-EDTA or lithium heparin tubes may be used.

With gloved hands, take a DiaSpect Tm Cuvette out of the foil bag and close the bag.

1. Make sure the sample is at room temperature before testing. Mix the tube by gentle inversion at least 8 times.
2. Place a drop of blood on to a hydrophobic surface (e.g. Parafilm) using a commercially available transfer pipette or DIFF-SAFE® Blood Dispenser.
3. Fill the cuvette completely by touching the corner of the cuvette to the blood drop. Do not refill the cuvette. If a cuvette cannot be filled in one continuous process, or if the cuvette contains air bubbles, discard the cuvette and use a new one, repeating steps 2 and 3.
4. Gently wipe off the excess blood on the outside of the cuvette with a gauze pad. Be sure to gently wipe both sides. Do not wipe too close to the open end as this can draw blood out of the cuvette.



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7.3 Control Sampling

1. The DiaSpect Tm system can be verified by use of DiaSpect Control HBT. If stored refrigerated, allow the control solution to reach room temperature first.

With gloved hands, take a DiaSpect Tm Cuvette out of the foil bag and close the bag.

Mix the control solution by gentle inversion 5 times immediately before sampling. Open the vial and discard the first drop.

2. Dispense a second drop of the control solution on to a hydrophobic surface (e.g. Parafilm).

Fill the cuvette completely by touching the corner of the cuvette to the drop. Do not refill the cuvette. If a cuvette cannot be filled in one continuous process, or if the cuvette contains air bubbles, discard the cuvette and use a new one with a new drop of control solution.

3. Gently wipe off the excess control solution on the outside of the cuvette with a gauze pad. Be sure to gently wipe both sides. Do not wipe too close to the open end as this can draw control solution out of the cuvette.



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8. Measuring

1. Insert the filled cuvette in the cuvette holder.
2. Press down gently until you feel a “click” and hold in position until the result appears on the screen. **Pull the cuvette out of the DiaSpect Tm quickly.**
3. Dispose of the used cuvette in a container for potentially infectious waste. Record the test result as soon as the checkmark is shown.
4. The result will remain on the display until replaced by the next measurement. To erase the latest result, press down on the empty cuvette holder.



Use only completely filled cuvettes for measuring. A filled cuvette should be analyzed within 1 minute after filling. A filled cuvette should be kept in a horizontal position until measurement.

If the DiaSpect Tm analyzer has been out of use for a couple of hours, an error code may appear after the first measurement. Remove the filled cuvette, make a “blank” measurement by pressing down the empty cuvette holder and then reinsert the filled cuvette for measurement.

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9. Troubleshooting Guide

Symptom	Possible Cause	Correction
Unexpectedly high / low result	Improper sample	Repeat the sampling. Make sure that the sampling is done correctly. See 7.1 to 7.3 for more information.
Error E01	Calibration lost	Contact Technical Support at 1-800-531-5535.
Error E02	Sensor read error	Repeat measurement with the same cuvette. If error persists, contact Technical Support at 1-800-531-5535.
Error E03	Self-check failed	E03 may be displayed if a filled cuvette is left in the cuvette holder, or was removed too slowly. In order to reset the self-check function, press down on the empty cuvette holder. The screen should display "---" and a "√". If error persists, contact Technical Support at 1-800-531-5535.
Error E04	Light source too dark	Remove cuvette from cuvette holder. Press cuvette holder several times until the screen reads "---" and a "√" appears. If error persists, contact Technical Support at 1-800-531-5535.
Error E05	Light source too bright	Remove cuvette from cuvette holder. Press cuvette holder several times until the screen reads "---" and a "√" appears. If error persists, contact Technical Support at 1-800-531-5535.
Error E07	Battery too low to perform measurements	Recharge the battery.
Display blank, measuring not possible	Battery completely discharged	To recharge the battery, connect with a power outlet or computer and charge for a minimum of 4 hours. If recharging fails, contact Technical Support at 1-800-531-5535.

DiaSpect Tm User Manual

10. Expected Values^{3 - 8}

The unit of measure for the hemoglobin value is g/dL. The following hemoglobin values are considered normal:

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

* Reference ranges are based on medically accepted published reference ranges (Dacie and Lewis, Practical Haematology, Twelfth Edition, Elsevier Limited 2017). These ranges are for general guidance only. Each laboratory should establish its own normal range.

11. Performance Characteristics

a) Within Run and Total Precision

Repeatability and overall reproducibility of three samples was tested over 20 days.

Sample	Concentration	Within-Run (SD, %CV)	Total (SD, %CV)
Low	7.99 g/dL	(0.085, 1.06%)	(0.11, 1.38%)
Medium	12.58 g/dL	(0.11, 0.88%)	(0.14, 1.09%)
High	15.82 g/dL	(0.15, 0.92%)	(0.22, 1.41%)

b) Accuracy, Point-of-Care

The results of the comparison studies between the DiaSpect Tm and the predicate device performed at the point-of-care are summarized in the following table. The study was performed across four external sites.

Sample Type	N	Min	Max	Slope	Correlation Coefficient (r)
EDTA	344	4.1 g/dL	24.5 g/dL	0.9858	0.986
Li-heparin	120	10.4 g/dL	20.0 g/dL	0.9834	0.987
Capillary	363	8.5 g/dL	20.1 g/dL	0.9903	0.963

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DiaSpect Tm has not been evaluated for capillary samples with hemoglobin values below 8.5 g/dL as such samples are very rarely seen in the primary care setting. It is recommended that patients showing a capillary hemoglobin of less than 8.5 g/dL are referred to a confirmatory laboratory test.

c) Accuracy, Blood Donation Centers

A method comparison of 150 capillary and 147 venous samples was conducted at two blood bank settings, giving the following results:

Sample Type	N	DiaSpect Tm Minimum	DiaSpect Tm Maximum	Hb301 Minimum	Hb301 Maximum
K2-EDTA	147	10.4 g/dL	22.0 g/dL	11.1 g/dL	20.7 g/dL
Capillary	150	10.5 g/dL	20.6 g/dL	10.7 g/dL	20.7 g/dL

DiaSpect Tm vs HemoCue Hb 301 (linear regression)

Matrix	N	Slope (95% CI)	Intercept (95% CI)	r
Capillary	150	0.9541 (0.9134~0.9948)	0.2619 (-0.3496~0.8733)	0.967
Venous	147	1.1465 (1.1068~1.1863)	-2.5299 (-3.4183~-2.1122)	0.978

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

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

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

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

Using the HemoCue Hb301 as the reference method, the agreements for blood donor eligibility are as follows:

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

Agreement (Score 95% CI)

Accept = 127/134 = 94.8% (89.6~97.4%)

Reject = 14/16 = 87.5% (64.0~96.5%)

Overall = 141/150 = 94.0% (89.0~96.8%)

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

Agreement (Score 95% CI)

Accept = 120/133 = 90.2% (84.0~94.2%)

Reject = 13/14 = 92.9% (68.5~98.7%)

Overall = 133/147 = 90.5% (84.6~94.2%)

The discordance observed was investigated by comparison to a laboratory reference method. In a separate study, 100 capillary and 100 venous samples were tested with the DiaSpect Tm, the HemoCue Hb 301 and the Sysmex XP-300. The DiaSpect Tm was found to be substantially equivalent to the Sysmex XP-300 (calibrated to the hemiglobincyanide method, HiCN), while the HemoCue Hb 301 consistently provided results that were higher by approximately 0.6 g/dL. These results are summarized below.

The bias of the DiaSpect Tm at donor eligibility cutoffs was calculated from the regression curves using the Sysmex XP-300 as the reference method.

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

The positive bias of the Hb 301 at donor eligibility cutoffs was calculated using the Sysmex XP-300 as the reference method. The positive bias of the Hb 301 is consistent with its higher acceptance rate of donors near the eligibility cutoff, and is supported by the literature.^{9,10}

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

DiaSpect Tm User Manual

12. Technical Specifications

Operating temperature	10 to 42 °C (50 to 107 °F)
Operating humidity	0 to 100%, non-condensing
Storage temperature	0 to 50 °C (32 to 122 °F) -30 to 70 °C (-22 to 158 °F) during transport, 24 hour max.
Sample volume	10 µL
Measurement range	1.2–25.5 g/dL
Wavelength	Multiple wavelengths ranges, 450 nm to 750 nm
Measuring time	1 second
Battery	3.6 V integrated lithium-ion rechargeable batteries
Safety	Tested in accordance with IEC 61010
Instrument input rating	5 V, 100 mA (PC) / 350 mA (power supply)
Power supply input rating	125mA, 100–240 V AC, 50–60 Hz
Data interface	USB 2.0, Bluetooth® Smart (optional)
Protection class	IP 21
Supply current	Max. 100 mA from USB host Max 350 mA from USB power supply
Duration of use	A fully charged battery lasts up to 40 days / 10,000 tests
Analyzer dimensions	L = 6 in, W = 3.5 in, H = 1.6 in
Analyzer weight	0.4 lb
Dimensions of transport box	L = 9 in, W = 6.5 in, H = 2.8 in
Weight of analyzer and transport box	1.3 lb

DiaSpect Tm User Manual

13. Limitations

Specificity & Disease States

The following substances and disease states do not affect the test results.

Potential Interferent	Test Concentration	Potential Interferent	Test Concentration
Bilirubin	20.0 mg/dL	Ferrous Fumarate	30 mg/dL
Cholesterol	500 mg/dL	Iron Dextran	284 mg/dL
Creatinine	5 mg/dL	Folic Acid	1000 ng/dL
Protein	12 mg/dL	Vitamin B12	2500 ng/dL
Triglyceride	1000 mg/dL	Lithium Carbonate	23 mg/dL
Urea	258 mg/dL	Immunoglobulin	500 mg/dL
Uric Acid	24 mg/dL	Methyldopa	1.7 mg/dL
Acetaminophen	2 mg/dL	Salicylic Acid	100 mg/dL
Ascorbic Acid	6 mg/dL	5x EDTA	Tube filled to 1/5 volume
Dopamine	0.1 mg/dL	Hypochromia	Disease state
Ibuprofen	55 mg/dL	High WBC Count	Disease state
Tetracycline	1.5 mg/dL	Polycythemia	Disease state
Ferrous Sulfate	22 mg/dL	Sickle Cell	Disease state
Ammonium Ferric Citrate	30 mg/dL		

For further limitations of the procedure, see the DiaSpect Tm Cuvettes package insert.

DiaSpect Tm User Manual

14. References

1. NCCLS/CLSI document H15-A3, Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard-Third Edition
2. Recommendations for reference method for haemoglobinometry in human blood (ICSH standard 1995) and specifications for international haemiglobincyanide standard (4th edition)
3. Dacie and Lewis, Practical Haematology, 12th edition, 2017
4. Fandek N, Moreau D, Newell K C, Ofner A, eds. Clinical Laboratory Tests - Values and Implications. 2nd ed. Springhouse: Springhouse Corporation, 1995: 328pp.
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. Sümngig A, et.al. The impact of noninvasive, capillary, and venous hemoglobin screening on donor deferrals and the hemoglobin content of red blood cells concentrates: a prospective study. Transfusion. 2015 Dec;55(12):2847-54.
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Other:

DiaSpect Tm Cuvettes package insert

DiaSpect Control HBT package Insert

The following consumables, spare parts and accessories may be used with the DiaSpect Tm analyzer REF 7049-0013-0264 / Cat. 900-001.

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15. Consumables

DiaSpect Tm Cuvettes (1x100 pcs)	REF 7049-3013-0584 / Cat.900-100
DiaSpect Tm Cuvettes (5x100pcs)	REF 7049-3013-0369 / Cat.900-500
DiaSpect Control HBT1	REF 7049-6211 / Cat.900-501
DiaSpect Control HBT2	REF 7049-6212 / Cat.900-502
DiaSpect Control HBT3	REF 7049-6213 / Cat.900-503
DiaSpect Control HBT4	REF 7049-6214 / Cat.900-504

16. Spare parts and accessories

Cuvette Holder	REF 7049-1011-0145
USB Cable	REF 7049-7021-0161
Power supply with US adapter	REF 7049-7013-0187
Carrying case for DiaSpect Tm (plastic)	REF 7049-8011-0179

DiaSpect Tm User Manual

17. Symbols Used

IP21	Protection of electrical equipment against foreign objects, water and access
	Serial number
	In-vitro-Diagnostic Medical Device
	Reference Number
	Dispose of the instrument in compliance with local regulations for the disposal of electronic equipment. Do not put in domestic waste!
	Consult Instructions for Use
	Caution
	Manufacturer
	Direct current
	Antenna Pole, Shows RF connection status and signal strength (only with activated Bluetooth® option)
	Temperature limitation

DiaSpect Tm User Manual

USA Contact

EKF Diagnostics, Inc.
1261 North Main Street
Boerne, TX 78006
USA
Phone 1-800-531-5535
Email: techsupport@ekfdiagnostics.com
www.ekfusa.com

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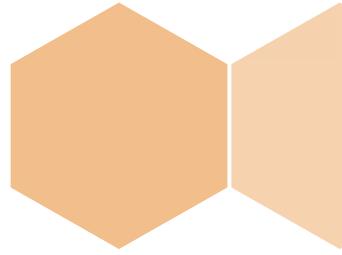


EKF-diagnostic GmbH
Ebendorfer Chaussee 3
39179 Barleben
Germany

Manual revision: 3.02
Released: 01/2021

DiaSpect Tm Notes

DiaSpect Tm Notes



EKF-diagnostic GmbH,
Ebendorfer Chaussee 3,
39179 Barleben Germany

Phone: +49 39203 511 0
Fax: +49 39203 511 171

USA Contact

EKF Diagnostics
1261 North Main Street
Boerne, TX 78006
USA

Phone 1-800-531-5535
Email: techsupport@ekfdiagnostics.com
www.ekfusa.com

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DiaSpect Tm



DiaSpect Tm

Immediate hemoglobin results
from a hand-held analyzer

- Results in less than two seconds
- Reagent-free cuvettes
- Internal battery for 40 days
or 10,000 tests continuous use
- 2 ½ years cuvette shelf life

Fast, easy to use and reliable in all climate conditions

<p>Fast and accurate</p>	<ul style="list-style-type: none"> • Results in less than two seconds • Measuring range: 1.2 - 25.5 g/dL • Precision (within run): CV ≤ 1% • Factory calibrated against HiCN reference method according to ICSH • Photometric method with broad spectrum and compensation for turbidity and scattering • No additional calibration required
<p>Easy to use</p>	<ul style="list-style-type: none"> • 'Always on' technology. The analyzer is always ready for use • Automatic self-check between every measurement • Long cuvette shelf life: 2 ½ years from date of production • Cuvettes unaffected by humidity or temperature and can be used until expiration date after opening the bag
<p>Practical and portable</p>	<ul style="list-style-type: none"> • Sample volume: 10 µL • Capillary or venous blood (EDTA and lithium heparin tubes can be used) • Maintenance free • Operating ambient temperature: 10 to 35°C (50 to 95°F) • Storage temperature: 0 to 50°C (32 to 122°F) • Transport temperature: -30 to 70°C (-22 to 158°F) up to a maximum of 24 hours. • Integrated rechargeable lithium-ion battery (40 days or 10,000 tests of continuous use) • Compact: 150 (d) x 90 (w) x 40mm (h) / 5.9 (d) x 3.5 (w) x 1.5 (h) inches • Lightweight: 180 g / 0.4 lb • Connect to PC via USB 2.0



1 Collect blood sample



2 Insert the filled cuvette and press down gently



3 Results appear in less than two seconds

U.S.A. Sales

EKF Diagnostics
1261 North Main Street
Boerne, TX 78006

☎ 1 800 531 5535
✉ sales2@ekfdiagnostics.com
www.ekfusa.com

Manufacturer
EKF-diagnostic GmbH
Ebendorfer Chaussee 3
39179 Barleben
Germany

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