

The following documentation is an electronicallysubmitted 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.

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General Information Contact	Default Values	Discount Docur	nent Information									
Procurement Folder:	321829					SO Doc C	de: CRFQ					1
Procurement Type:	Central Master Ag	greement				SOD	ept: 0506					
Vendor ID:	000000114567	2				SO Do	ID: EHP170	8000008				
Legal Name:	OXFORD IMMUN	IOTEC INC				Published D	ate: 5/19/17					
Alias/DBA:						Close D	ate: 6/2/17					
Total Bid:	\$61,740.00					Close T	me: 13:30					
Response Date:	05/22/2017					Sta	tus: Closed					
Response Time:	14:18				Solid	citation Descrip		um #1 - Interferon Release Assay Blo	od C			
					Total of H	eader Attachme	nts: 2					
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Purchasing Division 2019 Washington Street East Post Office Box 50130 Charleston, WV 25305-0130

State of West Virginia Solicitation Response

Proc Folder : 321829 Solicitation Description : Addendum #1 - Interferon Gamma Release Assay Blood Test TB Proc Type : Central Master Agreement					
Date issued	Solicitation Closes	Solicitation Response	Version		
	2017-06-02 13:30:00	SR 0506 ESR05221700000005717	1		

VENDOR	
000000114567	
OXFORD IMMUNOTEC INC	
Solicitation Number: CRFQ 0506	EHP170000008

 Total Bid :
 \$61,740.00
 Response Date:
 2017-05-22
 Response Time:
 14:18:04

Comments:

FOR INFORMATION CONTACT THE BUYER		
April Battle		
(304) 558-0067 april.e.battle@wv.gov		
Signature on File	FEIN #	DATE
All offers subject to all terms and conditions contained in this	aliaitatian	

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
1	Interferon Gamma Release Assay blood test for tuberculosis				\$61,740.00
Comm Code	Manufacturer	Specification		Model #	
85111504					
Extended De	scription : Interferon Gamma Releas	e Assay blood te	est for tubercu	losis	

Comments: See attached redline documentation

INSTRUCTIONS TO VENDORS SUBMITTING BIDS

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

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

3. PREBID MEETING: The item identified below shall apply to this Solicitation. □A pre-bid meeting will not be held prior to bid opening

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

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

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

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

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

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

Questions submitted at least five business days prior to a scheduled pre-bid will be discussed at the pre-bid meeting if possible. Any discussions or answers to questions at the pre-bid meeting are preliminary in nature and are non-binding. Official and binding answers to questions will be published in a written addendum to the Solicitation prior to bid opening.

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

conversations, or questions and answers regarding this Solicitation are preliminary in nature and are nonbinding.

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

Question Submission Deadline: May 18, 2017, at 3:00 PM EST

Submit Questions to: April Battle, Buyer 22 2019 Washington Street, East Charleston, WV 25305 Fax: (304) 558-4115 (Vendors should not use this fax number for bid submission) Email: april.e.battle@wv.gov

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

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

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

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

SEALED BID: Interferon Gamma Release Assy Blood Testing for Tuberculosis BUYER: April Battle, Buyer 22 SOLICITATION NO.: CRFQ 0506 EHP 1700000008 BID OPENING DATE: June 2, 2017 BID OPENING TIME: 1:30 PM EST FAX NUMBER: (304) 558-3970

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. Submission of a response to an Expression or Interest or Request for Proposal is not permitted in wvOASIS.

For Request For Proposal ("RFPn) Responses Only: In the event that Vendor is responding to a request for proposal, the Vendor shall submit one original technical and one original cost proposal plus ________ convenience copies of each to the Purchasing Division at the address shown above. Additionally, the Vendor should identify the bid type as either a technical or cost proposal on the face of each bid envelope submitted in response to a request for proposal as follows:

BID TYPE: (This only applies to CRFP)

□ Technical □ Cost

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

Bid Opening Date and Time: June 2, 2017, at 1:30 PM EST

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

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

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

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

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

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

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

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

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

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

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

18. ELECTRONIC FILE **ACCESS RESTRICTIONS:** Vendor must ensure that its submission in wvOASIS can be accessed 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 SG-1-1 et seq. and the Freedom of Information Act West Virginia Code§§ 29B-1-1 et seq.

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

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

GENERAL TERMS AND CONDITIONS:

1. CONTRACTUAL AGREEMENT: Issuance of 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 of this Contract made by and between the State of West Virginia and the Vendor. Vendor's signature on its bid signifies Vendor's agreement to be bound by and accept the terms and conditions contained in this Contract.

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

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

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

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

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

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

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

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

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

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

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

Term Contract

Initial Contract Term: This Contract becomes effective on ______ award______ and extends for a period of ______ one (1)______ year(s).

Renewal Term: This Contract may be renewed upon the mutual written consent of the Agency, and the Vendor, with approval of the Purchasing Division and the Attorney General's office (Attorney General approval is as to form only). Any request for renewal should be submitted to the Purchasing Division thirty (30) days prior to the expiration date of the initial contract term or appropriate renewal term. A Contract

renewal shall be in accordance with the terms and conditions of the original contract. Renewal of this Contract is limited to ______three (3) ______successive one (1) year periods or multiple renewal periods of less than one year, provided that the multiple renewal periods do not exceed (36) thirty six months in total. Automatic renewal of this Contract is prohibited. Notwithstanding the foregoing, Purchasing Division approval is not required on agency delegated or exempt purchases. Attorney General approval may be required for vendor terms and conditions.

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

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

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

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

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

Other: See attached.

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

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

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

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

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

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

6. 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 below must be provided to the Purchasing Division by the Vendor as specified below.

BID BOND (Construction Only): Pursuant to the requirements contained in W. Va. Code § 5-22-l(c), All Vendors submitting a bid on a construction project shall furnish a valid bid bond in the amount of five percent (5%) of the total amount of the bid protecting the State of West Virginia. The bid bond must be submitted with the bid.

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

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

In lieu of the Bid Bond, Performance Bond, and Labor/Material Payment Bond, the Vendor may provide certified checks, cashier's checks, or irrevocable letters of credit. Any certified check, cashier's check, or irrevocable letter of credit provided in lieu of a bond must be of the same amount and delivered on the same schedule as the bond it replaces. A letter of credit submitted in lieu of a performance and labor/material payment bond will only be allowed for projects under

\$100,000. Personal or business checks are not acceptable. Notwithstanding the foregoing, West Virginia Code \$ 5-22-1 (d) mandates that a vendor provide a performance and labor/material payment bond for construction projects. Accordingly, substitutions for the performance and labor/material payment bonds for construction projects is not permitted.

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

LICENSE(S) / CERTIFICATIONS/PERMITS: In addition to anything required under the Section

entitled Licensing, of the General Terms and Conditions, the apparent successful Vendor shall furnish proof of the following licenses, certifications, and/or permits prior to Contract award, in a form acceptable to the Purchasing Division.

Vendor must be accredited by the Clinical Laboratory Improvements Act/Amendments (CUA).

Vendor must be accredited by the College of American Pathologist (CAP) to perform IGRA blood testing services.

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

8. INSURANCE: The apparent successful Vendor shall furnish proof of the insurance identified by a checkmark below prior to Contract award. Subsequent to contract award, and prior to the insurance expiration date, 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 mandated herein, including but not limited to, policy cancelation, policy reduction, or change in insurers. The insurance coverages identified below must be maintained throughout the life of this contract. The apparent successful Vendor shall also furnish proof of any additional insurance requirements contained in the specifications prior to Contract award regardless of whether or not that insurance requirement is listed 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:

Professional/Malpractice/Errors and Omission Insurance in at least an amount of:

Commercial Crime and Third Party Fidelity Insurance in an amount of:

Cyber Liability Insurance in an amount of:

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

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

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

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

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

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

13. 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.

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

15.PURCHASING CARD ACCEPTANCE: The State of West Virginia currently utilizes a Purchasing Card program, administered under contract by a banking institution, to process payment for goods and services. The Vendor must accept the State of West Virginia's Purchasing Card for payment of all orders under this Contract unless the box below is checked.

DVendor is not required to accept the State of West Virginia's Purchasing Card as payment for all goods and services.

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 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.

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 \$ 148-1-6.1.e.

20. TIME: Time is of the essence with regard to 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: 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.

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 <u>Vendor either party to this Agreement</u> without the express written consent of the <u>Agencyof</u> the other party, the Purchasing Division, the Attorney General's office (as to form only), and any other government agency or office that may be required to approve such assignments. Notwithstanding the foregoing, Purchasing Division approval may or may not be required on certain agency delegated or exempt purchases.

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

31. 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://iwww.state.wv.us/admin/purchase/privacy/default.html.

32. 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§§ SA-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.

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

34. 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.

35. VENDOR CERTIFICATIONS: By signing its bid or entering into this Contract, Vendor certifies (1) that its bid or offer was made without prior understanding, agreement, or connection with any corporation, firm, limited liability company, partnership, person or entity submitting a bid or offer for the same material, supplies, equipment or services; (2) that its bid or offer is in all respects fair and without collusion or fraud;

(3) that this Contract is accepted or entered into without any prior understanding, agreement, or connection to any other entity that could be considered a violation of law; and (4) that it has reviewed this Solicitation in its entirety; understands the requirements, terms and conditions, and other information contained herein.

Vendor's signature on its bid or offer also affirms that neither it nor its representatives have any interest, nor shall acquire any interest, direct or indirect, which would compromise the performance of its services hereunder. Any such interests shall be promptly presented in detail to the Agency. The individual signing this bid or offer on behalf of Vendor certifies that he or she is authorized by the Vendor to execute this bid or offer or any documents related thereto on Vendor's behalf; that he or she is authorized to bind the Vendor in a contractual relationship; and that, to the best of his or her knowledge, the Vendor has properly registered with any State agency that may require registration.

36. VENDOR RELATIONSIDP: 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 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.

37. 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.

Commented [MD1]: Becky

Commented [BW2R1]: Each party should be responsible for their own defense

If the Agency requests access to the Portal to enable Agency to electronically (i) access patient/subject results, and (ii) submit requisitions, Agency acknowledges that such access will allow it and its authorized staff to receive, read and view results that are confidential pursuant to federal and state laws, including but not limited to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as amended. Agency agrees that it will take all necessary and appropriate steps to secure and maintain the security of all user IDs and passwords provided by Vendor to Agency that allow access to the Portal. Agency shall promptly notify Vendor if user IDs or passwords assigned to Agency or Agency personnel are lost, stolen, or otherwise unaccounted for. Agency shall further promptly notify Vendor when an assigned user ID or password should be terminated or reassigned based on personnel changes at Agency. Agency shall indemify and hold Vendor harmless from and against any claims, losses, other consequences or unauthorized access to the Portal made using the Agency user IDs and passwords. Unless damages or other amounts incurred by Vendor resulting from Agency's breach of its obligations related to security of user IDs and passwords under this paragraph. Agency and Vendor agree to comply with all applicable laws, rules, and regulations relating to the use and disclosure of personally identifiable health information provided by or to Agency or Vendor under this Agreement, including the requirements of HIPAA and the HITECH Act.

38. PURCHASING AFF1DAVIT: In accordance with West Virginia Code§ 5A-3-10a, all Vendors are required to sign, notarize, and submit the Purchasing Affidavit stating that neither the Vendor nor a related party owe a debt to the State in excess of \$1,000. The affidavit must be submitted prior to award, but should be submitted with the Vendor's bid. A copy of the Purchasing Affidavit is included herewith.

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

40. 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.

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

 \boxtimes 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.

 \Box 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.reguisitions@wv.gov.

Revised 04/07/2017

42. BACKGROUND CHECK: In accordance with W. Va. Code§ 15-2D-3, the Director of the Division of

Protective Services shall require any service provider whose employees are regularly employed on the grounds or in the buildings of the Capitol complex or who have access to sensitive or critical information to submit to a fingerprint-based state and federal background inquiry through the state repository. The service provider is responsible for any costs associated with the fingerprint-based state and federal background inquiry.

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

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

43. 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 Intentionally Deleted.

a. "State Contract Project" means any erection or construction of, or any addition to, alteration of or other improvement to any building or structure, including, but not limited to, roads or highways, or the installation of any heating or cooling or ventilating plants or other equipment, or the supply of and materials for such projects, pursuant to a contract with the State of West Virginia for which bids were solicited on or after June 6, 2001.

b. "Steel Products" means products rolled, formed, shaped, drawn, extruded, forged, cast, fabricated or otherwise similarly processed, or processed by a combination of two or more or such operations, from steel made by the open heath, basic oxygen, electric furnace, Bessemer or other steel making process. The Purchasing Division Director may, in writing, authorize the use of foreign steel products if:

e. The cost for each contract item used does not exceed one tenth of one percent (.I%) of the total contract cost or two thousand five hundred dollars (\$2,500.00), whichever is greater. For the purposes of this section, the cost is the value of the steel product as delivered to the project; or

d. The Director of the Purchasing Division determines that specified steel materials are not produced in the United States in sufficient quantity or otherwise are not reasonably available to meet contract requirements.

44. 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 <u>Intentionally Deleted</u>.

Commented [BW3]: Not applicable

Commented [BW4]: Not applicable

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 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.

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.

Title) Name, hol maran (Printed Name and Title) borough ma U1252 (51) Nickonsin (Address) 500 (Phone Number) / (Fax Number) Sales pos (a ors immunotec. com (email address)

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

Inc. 2/6/G OXFORD Diagnostic Caboratories (Company) mon

(Authorized Signature) (Representative Name

Sules- Contract admin Desmans

(Printed Name and Title of Authorized Representative)

(Date)

(Phone Number) (Fax Number)

ADDENDUM ACKNOWLEDGEMENT FORM SOLICITATION NO.: CRFQ 0506 EHP1700000008

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)

Addendum No. 1
Addendum No. 2
Addendum No. 3
Addendum No. 4
Addendum No. 5

Addendum No. 6 Addendum No. 7 Addendum No. 8 Addendum No. 9 Addendum No. 10

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

Oxford Immenotes Inc. 1/6/4 Oxford Diegnostic Caboratories Company Authorized Signature
5-22-17

Date

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

REQUEST FOR QUOTATION CRFQ 0506 EHPI70000008 Interferon Gamma Release Assay Blood Testing for Tuberculosis

SPECIFICATIONS

1. PURPOSE AND SCOPE: The West Virginia Department of Health and Human Resources, Bureau for Public Health, Office of Epidemiology and Prevention Services is soliciting bids to establish an open-end contract for Interferon Gamma Release Assay (IGRA) blood testing services to screen for tuberculosis.

The contract awarded as a result of this solicitation may be funded in whole or in part with Federal Funds and thus this solicitation and its resulting awarded contract are subject to the requirements of Attachment 1: Provisions Required for Federally Funded Procurements.

- **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 Interferon Gamma Release Assay (IGRA) blood testing.
 - **2.2 "Pricing Pages"** means the schedule of prices, estimated order quantity, and totals contained in wvOASIS or attached hereto as Exhibit A, and used to evaluate the Solicitationresponses.
 - **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. QUALIFICATIONS:

3.1 Vendor must be accredited by the Clinical Laboratory Improvements Act/Amendments (CLIA).
3.2 Vendor must be accredited by the College of American Pathologist (CAP) to perform IGRA blood testing services.

4. GENERAL REQUIREMENTS:

- **4.1 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.
 - 4.1.1 Interferon Gamma Release Assay (IGRA) blood testing
 - 4.1.1.1 Vendor must perform in vitro blood testing.
 - **4.1.1.2** Vendor must use standard collection tubes that are not specialized.
 - **4.1.1.3** Vendor must provide the health departments (Exhibit B) all blood collection supplies including tubes, packaging material, mailers needed to return the tests.
 - **4.1.1.4** Vendor must report both qualitative interpretation and qualitative assay measurement to determine results interpretations.

Revised 10/27/2014

REQUEST FOR QUOTATION CRFQ 0506 EHP1700000008 Interferon Gamma Release Assay Blood Testing for Tuberculosis

- **4.1.1.5** Vendor must report IGRA blood testing results to the health departments (Exhibit B) "Nit.11in 36-72 hours after receipt of specimens.Vendor reports T-SPOT.*TB* test results within 36 -48 hours of receiving the blood sample, contingent upon the receipt of a viable specimen and a corresponding test order which does not include missing or discrepant information.
- **4.1.1.6** Vendor must provide training (no additional cost) to health departments (Exhibit B) for proper specimen collection, storing, and shipping process.
- 4.1.1.7 Vendor testing must use Food Drug Administration (FDA) approved testing.
- **4.1.1.8** Vendor must provide blood testing that will not cross react with the Bacillus Chalmette-Guerin (BCG) vaccine.
- 4.1.1.9 Vendor testing must not boost responses measured by subsequent tests.
- **4.1.1.10** Vendor must not require use of specialized equipment by health departments for collection.

5. CONTRACTAWARD:

- **5.1 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.
- **5.2 Pricing Pages:** Vendor should complete the Pricing Pages by providing a unit price for the contract service multiply by the quantity requested to arrive at a total cost for each line. Then add the total costs per line for the Grand Total. Vendor should complete the Pricing Pages in their entirety as failure to do so may result in Vendor's bids being disqualified.

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

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

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REQUEST FOR QUOTATION CRFQ 0506 EHP1700000008 Interferon Gamma Release Assay Blood Testing for Tuberculosis

6, ORDERING AND PAYMENT:

- **6.1 Ordering:** Vendor shall accept orders through <u>wvOASIS</u>, 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.
- **6.2 Payment:** Vendor shall accept payment in accordance with the paymentprocedures of the State of West Virginia.

7. DELIVERY AND RETURN:

- 7.1 Delivery Time: Vendor shall deliver test results within 36-72 hours after orders are received. Vendor shall deliver emergency orders within 24 hours after orders are received, for orders place Monday through Friday excluding Holidays. Vendor shall ship all orders in accordance with the above schedule and shall not hold orders until a minimum delivery quantity is met
- **7.2 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.

- **7.3 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 6.freight bill attached to the invoice.
- 7.4 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.
- **7.5 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.

Revised 10/27/2014

8.1.4 Failure to remedy deficient performance upon request.

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

- 8.2.1 Immediate cancellation of the Contract.
- 8.2.2 Immediate cancellation of one or more release orders issued under this Contract.
- 8.2.3 Any other remedies available in law or equity.

9. MISCELLANEOUS:

9.1 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.

9.2 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.

9.3 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.

9.4 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: tic holle 1 Telephone Number: STE 721- 21 Fax Number: Sof Email Address: Salesops Oxfor Immusotec. con

CRFQ 0506 EHP1700000008 Exhibit A – Pricing Page Interferon Gamma Release Assay (IGRA) Blood Testing

DELIVERABLES	COST			
	Unit Cost per test	Qty	Total Cost	
4.1.1 Interferon Gamma Release Assay (IGRA) blood testing	\$51.45	1200	\$ 61,740.00	
GRAND TOTAL COST:		61,00	10.00	

Please provide a Per Unit Cost and Total Cost per Deliverable, and a Grand Total Cost. The contract will be awarded to the Vendor that provides the Deliverables meeting the required specifications for the lowest overall Grand Total Cost.

Vendor Name: OXFORD Immunotec, Inc 216/2 OX	for J Diagnostic Cabovatories
Physical Address: NOO Nickerson Drive, Ste 200 Martborrough, MA 01952	
Remit to Address: 75 Remittance Drive, Dept Chicago, IL 60675	1368
Telephone: 877-598-2522	
Fax: 508-481-4672	
Email: Mdesmarais@Tspot.com	
Authorized Vendor Representative (print name): Michelle De	smorais
Signature: Modul Desmans	Date: 5-22-17

Exhibit B

West Virginia County Health Department List Barbour County Health Depart men t Beckley-Raleigh Health Department Berkeley County Health Department 109 Wabash Avenue 1602 Harper Road 122 Waverly Ct. Philippi, WV 26416-1262 Beckley, WV 25801 Martinsburg, WV 25403-1214 Boone County Health Department Braxton County Health Department Brooke County Health Department P.0. Box209 617.Old Turnpike Road 204 Courthouse Square Madison, WV 25130 Sutton, WV 26601 Wellsburg, WV 26070 Cabell-Huntington Health Department Clay County Health Department Doddridge County Health Department 703 7th Avenue P.0. Box36 60 Pennsylvania Street Huntington, WV 25701 Clay, WV25043-0036 West Union, WV 26456 Fayette County Health Department Grafton-Taylor Health Department Gilmer County Health Depart m ent 202 Church Street 809 Medical Drive, Suite 3 718 West Main Street Grafton, WV 26354 Fayetteville, WV 25840-1208 Glenville, WV 26351 Grant County Health Department Greenbrier County Health Department Hampshire County Health Department P. 0. Box608 9207 Seneca Trail South HC 71, Box9 Petersburg, WV 26847-0608 Ronceverte, WV 24970 Augusta, WV 26704 Hancock County Health Department Hardy County Health Department Harrison -Clarksburg Health P.O. Box 578 411 Spring Avenue, Suite 101 Department New Cumberland, WV26047 Moorefield, WV 26836 330 West Main Street Clarksburg, WV 26301 Jackson County Health Department Jefferson County Health Department Kanawha-Charleston Health 504 South Church Street 1948 Wiltshire Road , Suite 1 Department Ripley, WV25271 Kearneysville, WV 25430 P.0. Box927 Charleston, WV 25323 Lewis County Health Department Lincoln County Health Department Logan County Health Department 125 Court Avenue 8008 Court Avenue 300 Stratton Street, Room 203 Weston, WV 26452 Hamlin, WV 25523 Logan, WV 25601 Ma rion County Health Department Marshal1 County Health Department Mason County Health Department 300 Second Street P O Box 429 216 5th Street Fairmont, WV 26554 Moundsville, WV 26041 Point Pleasant, WV 25550 McDowell County Health Department Mid -Ohio Valley Health Department Mercer County Health Department P. 0. Box218 978 Blue Prince Road 211 Sixth Street Parkersburg, WV 2 6101 Wilcoe, WV 24895 Bluefield, WV 24701

Exhibit B - continued

West Virginia County Health Department List

Mineral County Health Department	Mingo County Health Department	Monongalia County Health Department
Route 3, Box 3045	P. O. Box 1096	453 Van Voorhis Road
Keyser, WV 26726	Williamson, WV 25661	Morgantown, WV 26505
Monroe County Health Department	Morgan County Health Department	Nicholas County Health Department
P. 0. Box 590	187 South Green Street, Suite 2	1 Stevens Road, Suite 201
Union, WV 24983	Berkeley Springs, WV 25411	Summersville, WV 26651
PendletonCountyHealthDepartment	Pocahontas County Health Department	Preston County Health Department
P.O. Box520	900 Tenth Avenue	106 West Main Street, Suite 203
Franklin, WV 26807	Marlinton, WV 24954	Kingwood, WV 26537
Putnam County Health Department	Randolph-Elkins Health Department	Summers County Health Department
P.O. Box 1107	32 Randolph Avenue, Suite 101	151 Pleasant Street
Charleston, WV. 2S324	Elkins, WV 26241	Hinton, WV 25951
Tucker County Health Department 206 Senior Lane Parsons, WV 26287	Upshur-Buckhannon Health Department 15 North Locust Street Buckhannon, WV 26201	Wayne County Health Department P. 0. Box368 Wayne, WV 25-570
Webster County Health Department	Wetzel-Tyler Health Department	Wheeling Ohio Health Department
112 Bell Street, Suite C	425 South Fourth Avenue	1500 Chapline Street
Webster Springs, WV 26288	Paden City, WV 26159	Wheeling, WV 26003

Wyoming County Health Department P. O. Box 1679 Pineville, WV 24874

WV STATE GOVERNMENT

HIPAA BUSTNESS ASSOCIATE ADDENOUIvi

This Health Insurance Portability and Accountability Act of 1996 (hereafter, HIPAA) Business Associate Addendum ("Addendum") is mac; a part of the Agreement ("Agreement") by and between the \$tate of West Virginia r Agency"), and Business Associate ("Associate"), and is effective as of the date of execution of the Addendum.

The Associate performs cortain services on behalf of or for the Agency pursuant to the underlying Agreement that requires the exchange of information including protected health information protected by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the American Recovery and Reinvestment Act of 2009 (Pub. L. No. 111-5) (the "HITECH Act"); any associated regulations and the federal regulations published at 45 CFR parts 160 and 1.64 (sometimes collectively referred to as "HIPAA"). The Agency is a "Covered Entity" as that term is defined in HIP-AA, and the parties to the underlying Agreement are entering into this Addendum to establish the responsibilities of both parties regarding HIPAA-

Whereas it is desirable, in order to further the continued efficient operations of Agency to disclose to its Associate certain information which may contain confidential individually identifiable health information (herea.fter, Protected Health Information or PHI); and

Whereas, it is the desire of both parties that the confidentiality of the PHI disclosed hereundor be maintained and tr ated in accordance with all applicable laws relating to confidentiality, including the Privacy and Security Rufes, the HITECH Act and its associated regul tions, and the parties do agree to at all times treat the PHI and interpret this Addendum consistent witl') that desire.

NOW THEREFORE: the parties agree that in consideration of the mutual promises herein, in the Agreement; and of the exchange of PHI hereunder that:

- 1. Definitions. Terms used, but not otherwise defined, in this Addendum shall have the same meaning as those terms in the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.
 - a. Agency Prpcurement Officer shall mean the appropriate Agency individual listed at: http://www.state.wy.us/admin /purchase/vrc /.ag enc vli .html.
 - b. Agent shall mean those person(s) who are agent(s) of the Business Associate, in accordance with the Federal common law of agency, as referenced in 45 CFR § 160.402(0).
 - Breach shall mean the acquisition, access: use or disclosure of protected healthinformation which comprom ises the security or privacy of such information, except as excluded 1n the cletrnition of Breach in 45 CFR §-164.402.
 - d. Business Associate shall have the meaning given to such term in 45 CFR § 160.103.
 - e. HITECH Act shall mean the Health Information Technology for Economic and Clinical Health Act. Public Law No. 111-05. 111th Congress (2009).

Commented [MD5]: Please note that Oxford is a "Covered Entity" as defined in 45 CFR 160.103 in its clinical laboratory operations. As such, Oxford is directly responsible for its privacy and security practices under the Health Insurance Portability and Accountability Act of 1996, as amended, and the rules promulgated thereunder ("HIPAA") with respect to the protected health information that Oxford receives, generates or discloses. To further expand on this, I attached Oxford Immunotec's HIPAA Response Letter for your review.

- f. Privacy Rule means the Standards for Privacy of Individually Identifiable Health Inf-ormation found at45 CFR Parts 160 and 164.
- g. Protected Health Information or PHI shall have the meaning given to such term in 45 CFR § 160..103, limited to the information created or received by Associate -from or on behalf of Agency.
- Security Rule means the Security Standards for the Protection of Electronic Protected Heafth Information found at 45 CFR Parts 160 and 1'64.
- Subcontractor means a person to whom a business associate delegates a function, activity, or service, other than in the capacity of a member of the workforce of such business associate.

2. Permitted Uses and Disclosures.

- a PHI Described. This means PHI created, received, maintained or transmitted on behalf of the Agency by the Associate. This PHI is governed by this Addendum and is limited to the minimum necessary, to complete the tasks or to provide the services associated with the terms of the original Agreement, and is described in Appendi)(A
- b. Purposes .. Except as otherwise limited in this Addendum, Associate may use or disclose the PHI on behalf of, or to provide services to. Agency for thepurposes neces\$ary to complete the tasks, or provide the services, associated with, and required by the terms of the original Agreement, or as required by law_if such use or disclosure of the PHI would not violate the Privacy or Security Rules or applicable state law if done by Agency or Associate, or violate the minimum necessary and related Privacy and Security policies and procedures of the Agency. The Associate is directly liable under HIPAA for impermissible uses and disclosures of the PHI it hancles on behalf of Agency.
- Further Uses and Dis.cfosures. Except as otherwise limited in this Addendum, the Associate m y disctose PHI to third parties for the purpose of its own proper management and administration, or as required by law, provided that (i) the disclosure is required by law, or (ii) the Associate has obtained from the third party reasonable assurances that the PHI will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the third party by the Associate; and; (iii) an agreement to notify the Associate and Agency of ar.y instances of which it (the third party) is aWare-.in which the confidentiality of the information has been breached. To the extent practical, the information should be in a limited data set or the minum necessary information pursuant to 45 CFR § 164.502, or take other measures as necessary to satisfy the Agency's obligations under 45 CFR § 164.502.

3. Obligations of Associate.

- a. Stated Purposes Only. The PHI may not be used by the Associate for any purpose other than as stated in this Addendum or as required or permitted by law.
- b. Umfted Dtsclosure. The PHI is confidential and will not be disclosed by the Associate other than as stated in this Addendum or aS required or permitted by law. Associate is prohibited from directly or 1ndirectly receiving any remuneration in exchange for an individual's PHI unless Agency gives written approval and the individual provides a vand authorization. Associate will refrain from marketing activities that would violate HIPAA, including specifically Section 13406 of the HITECH Act Associate will report to Agency any use or disclosure of the PHI, including any Security Incident not provided for by this Agreement of which it becomes aware.
- c. Safeguards. The Associate will use appropriate safeguards, and comply with Subpart C of 45 CFR Part 164 with respect to electronic protected health information, to prevent use or disclosure of the PHI, except as provided forin this Addendum. This shall include, but not be limited to:
 - i. Limitation Qf the groups pf its workforce and agents, to whom the PHI is disclosed to those reasonably required to accomplish the purposes stated in this Addendum, and the use and disclosure of the minimum PHI necessary or a Limited Data Set;
 - ii. Appropriate notification and training of its workforce and agents in order to protect the PHI from unauthorized use and disclosure;
 - ill. Maintenance of a comprehensive , reasonable and appropriate written PHI privacy and security program that includes administrative, technical and physical safeguards appropriate to the size, nature, scope and complexity of the Associate's operations, in compliance with the Security Rule;
 - iv. In accordance with 45 CFR §§ 164.502(e)(1)(ii)and 164.308(b)(2), if applicable, ensure that *any* subcontractors that create, receive, maintain, or transmit pr'otected health information on behalf of the business associate agree to the same restrictions, conditions, and requirements that apply to the business associate with respect to such information.
- d. Compliance With Law, the Associate Will not use or disclose the PHI in a manner in violation of existing law and specifically not in violation of laws relating to confidentiality of PHI, including but not limited to, the Privacy and Security Rules.
- e. Mitig tion. Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Associate of a use or disclosure of the PHI by Associate in violation of the requirements of this Addendum, and report its mitigation activity back to the Agency.

- Access to PHI. Associate shall make the PHI maintained by Associate or its agents or subcontractors in Designated Record Sets available to Agency for inspection and copying, and in electronic format, if requested; within ten (10) days of a request by Agency ta enable Agency tofulfill its obligations under the Privacy Rule, including, but not limited to, 45 CER § 164-524 and consistent with Section 13405 of the HITECH Act.
- i. Amendment of PHI. Within ten (10) days of receipt of a request from Agency for an amendment of the PHI or a record about an individual contained rn a Designated Record Set, Associate or its agents or subcontractors shall make such PHI available to Agency for amendment and incorporate any such amendment to enable Agency to fulfill its obligations under the Privaay Rule, including, but not limited to. 45 CFR § 164.526.
- iii. Accounting Rights. Within ten (10) days of notice of a request for an accotJnting of disclosures Of the PHI, Associate and its agents or subcontractors shall makij available to Agency the documentation required to provide an accounting of disclosures to enable Agency to fulfill its obligations under the Privacy Rule, including, but not limited to, 45 CFR §164.528 and consistent with Section 13405 of the HITECH Act. Associate agr s to document disclosures of the PHI and information related to such disclosures as would be required for Agency to respond to a requestby ah individual for an accounting of disclosures of PHI in accordance with 45 CFR § 164.528. This should iticlude a process that allows for an accounting to be collected and maintained by Associate and its agents or subcontractors for at least six (6) years from the date of disclosure, or longer if required by state Jaw. At a minimum such documentation shallinclude:
 - the date of disclosure;
 - the name of the entity or person who received the PHI.and if known, the address of the entity or person;
 - a brief description of the PHI disclosed; and
 - <u>a brief statement of purposes of the discloswe that</u> reasonably informs the individual of the basis for the disclosure, or a copy of the individual's authorization. Or-a -copy of the written request for disclosure.
- iv. Request for Restriction. Under the direction of the Agency, abide by any individual's request to restrict the disclosure of PHI. consistent with the requirements of Section 13405 of the HITECH Act and 45 CFR § 164.522, when the Agency determines to do so (except as required by law) and if the disclosure is to a health plan for payment or health care operations and it pertains to a health care item or service for Which the health care provider was paid in full "out of pocket."
- v. Immediate Discontinuanc .e. of Use or Disclosure . The Associate will immediately discontinue_use_or_disclosure_of Agency_PHI portaining to any individual when so requested by Agency_Tilis includes, but is not limited to, cases in which an individual has withdrawn or modified anauthorization to use or disclose PHI.

- g. Retention of PHI. Notwithstanding section 4.a. of this Addendum, Associate and its subcontractors or agents shall retain all PHI pursuant to state and federal law and shall continue to maintain the PHJ required under Section 3.f. of this Addendum for a period of six (6) years after termination of the Agreement, or longer if required under state law.
- h. Agent's, Subcontractor's Compliance. The Associate shall notify the Agency of all subcontracts and agreements relating to the Agreement, where the subcontractor or agent receives PHI as described in section 2.a. of this Addendum. Such notification shall occur within 30 (thirty) calendar days of the execution of the subcontract and shall be delivered to the Agency Procurement Officer. The Associate will ensure that any of its subcontractors, to whom it provides: any of the PHI it receives hereunder, or to whom it provides any PHI which the Associate creates or receives on behalf of the Agency, ag-ree to the restrictions and conditions which apply to the Associate hereunder. The Agency May request copies Of downstream subcontracts and agreements to determine whether all restrictions, terms and conditions have been flowed down. Failure to ensure that downstream contracts, subcontracts and agreements contain the required restrictions, terms and conditions may result in termination of the Agreement.
- j. Federal and Agency Access. The Associate shall make its internal practices, books, and records relating to the us and disclostire of PHI, as well as the PHI, received from, or -created or received by the Associate on behalf of the Agency available to the U.S. Secretary of Health and Human Services consistent with 45' CFR § 164.504. The Associate shall also make tnese records available to Agency, or Agency's contractor; for periodic audit of Associate's compliance With the Privacy and Security Ru les. Upon Agency's request, the Associate shall provide proof of compliance with HIPAA and HITECH data privacy/protection guidelines, certification of a secure network and other assurance relative to compliance with the Privacy and Security Rules. This section shall also apply to Associate's subcontractors, if any.
- Ic. Security. The Associate shall take all steps necessary to ensure the continuous security of all PHI and data systems containing PHI. In addition. compliance with 74 FR 19006 Guidance Specifying the Technologies and Methodologies That Render PHI Unusable, Unreadable, or Indecipherable to Unauthorized Individuals for Purposes of the Breach Notification.Requirements under Section 13402 of Title XIII is required. to the extent practicable. If Associate chooses not to adopt such methodologies as defined in 74 FR 19006 to secure the PHI governed by this Addendum, it must subrnH.such written rationale, including its Security Risk Analysis, to the Agency Procurement Officer for review prior to the execution of the Addendum. This review may take up to ten (10) days.
- I. Notification of Breach. During the term of this Addendum, the Associate shall notify the Agency ar.d, unless otherwise directed by the Agency in writing, the WV Office of Technology immediately by e-mail or web form upon the discovery of any Breach of unsecl.Ired PHI; or within 2.4 hours by e-mail or web form of any suspectEld Security Incident, intrusion or unauthorized use or disc losure of PHI in violation of this Agreement and this Addendum, or potential loss of confidential data affecting this Agreement. Notification shall be provided to the Agency Procurement Officer at www.state.wy.us/admin/purchase/vrc/agencyli.htm and,

unless otherwise directed by the Agency in writing, the Office of Technology at incident@wv-gov_or.https://apps.wv.gov/ot/ir/Detault.aspx-

The Associate shall immediately investigate. such Security Incident, Breach, or unauthorized use or disclosure of PHI or confidential data. Within 72 hours of the discovery, the Associate shall notify the Agency Procurement Office, and, unless otherwise directed by the Agency in writing, the Office of Technology of: (a) Date of discovery; (b) What data elements were involved and the extent of the data involved in the Breach; (c) A description of the unauthorized persons known or reasonably believed to have improperly used or disclosed PHI OF confidential data; (d) A description of where the PHI or confidential data is believed to have been rmproperty transmitted, sent, or utrized; (e) A description of the probable causes of the improper use or disclosure; and (f) Whether any federal or state laws requiring individual notifications of Breaches are triggered.

Agency will coordinate with Associate to determine additional specific actions that will be required of the Associate, for mitigation of the Bre ach, which may include notification to the individual or other authorities.

All associated costs shall be borne by the Associate. This may include, but not be limited to costs associated with notifying affected individuals.

If the Associate enters into a subcontract relating to the Agreement where the subcontractor or agent receives PHI as described in section 2.a. of this Addendum, all such subcontracts or downstream agreements shall contain the same incident notification requirements as contained herein, with reporting directly to the Agency Procurement Officer. Failure to include such requirement

in any subcontract or agreement *may* result iii the Agency's termination of the Agreement.

m. Assistance In Litigation or Administrative Proceedings. The Associate shall make itself and any subcontractors, workforce or agents assisting Associate in the performance of its obligations under this Agreement, available to the Agency at no cost to the Agency to testify as witnesses, or otherwise, in the everit of litigation or administrative proceedings being commenced against the Agency, its officers or employees based upon claimed violations of HIPAA, the HIPM regulations or other laws relating to security and privacy, which involves inaction or actions, by the Associate, except where Associate or its subcontractor, workforce or agent is anamed as an adverse party.

4. Addendum Administration.

- a, Te.rm. This Addendum shall terminate on termination of the underlying Agreement or on thedate the Agency terminates for cause as authorized in paragraph (c) of this Section, whichever is sooner.
- b. Duties at TermInatl9n. Upon any termination of the underlying Agreement, the Associate shalf return or destroy, at the Ag.ency's option, all PHI received from, or created or received by the Associate on behalf of the Agency that the A oclate still maintains in any form and retain no copies of such PHI or, if such return or destruction is not feasible, the Associate shall extend the protections of this Addendum to the PHI and limit further uses and disclosures to the purposes that make the return or destruction of the PHI infeasible This shall also apply to all agents and subcontractors of Associate. The duty of the Associate and its agents

and subcontractors to assist the Agency with any HIPAA required accounting of disclosures survives the termination of the underlying Agreement.

- c. Termination for Cause. Associate authorizes termination of this Agreement by Agency; *if* Agency determines Associate has violated a material *term* of the Agreement. Agency may, at its sole discretion, allow Associate a reasonable period of time to cure the material breach before termination.
- d. Judtctal or Admiristrat.lve Proceedings The Agency may terminate this Agreement if the Associate is found guilty of a criminal violation of HfPAA The Agency may terminate this. Agreement if a finding or stipulation that the Associate has violated any standard or requirement of HIPANHITECH, or other security or privacy laws is *made* in any administrative or civil proceeding in which the Associate is a party or has been joined. Associate shall be subject to prosecution by the Department of Justice for violations of HIPAA/HITECH and shall be responsible for any administrative associated with prosecution.

e. Surviva,I The respective rights and obligations of Associate under this

Addendum shall survive the tennination of the underlying Agreement.

5. General Provisions/Ownership of PHL

- **Retention of Ownership.** Ownership of the PHI resides with the Agency and is to be returned on demand or destroyed at the Agency's option, at any time, and subject to the restrictions found within section 4.b. above.
- Secondary PHI. Any data or PHI generated from the PHI disclosed hereunder which. would permit identification of an individual must be held confidential and is also the property of Agency.
- c. Electronic Transmission. Except as permitted by law or this Addend m. the PHI or any data generated from the PHI which would permit identification of an individual must not be transmitted to another party by electronic or other means for additional uses or disclosures not authorized by this Addendum or to another contractor, or allied agency, or affiliate without prior written approval of Agency.
- d. No Sales. Reports or data containing the PHI may not be sold without Agency's or the affected individual's written consent.
- e, No Third Party Beneficiaries. Noth ing express or implied in this Addendum is intende<:t to confer, nor shall anything herein confer, upon any person other than Agency, Associate and their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever,
- f...Interpretation. The provisions of this Addendum shall prevail over any provisions in the Agreement that may conflict or appear inconsistent with any provisions in this Addendum. The interpretation of this Addendum shall be made under the laws of the state ofWest Virginia.
- g-Amendment. The parties agtee that to the extent necessary to comply with applicable law they will agree to further amend this Addendum.

h. Additional Terms and Conditions. Additional discretionary terms may be included

in the release order or change order process.

I

AGREED:

Name of Agency:.	
	_

Name of Associate:_____

Sgn a lure: ._____

Signature:._____

Title:_____

Dale: _____

Date:_____

Ti le:_____

Form - I/WBM-012004 Amended 08 .26.2013

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Appendix A

Intentionally Omitted

(To be completed by the Agency's Procurement Officer prior to the execution of the Addendum, and shall b-e made a part of the Addendum. PHI not identified prior to xecution of the Addendum may only be added by amending Appendrx A and the Addendum, via Change .Order.)

Name of Associate; ____

Name of Agency:._wvD H H R ,

Describe the PHI (do not include any actual PHI). If not applicable, please indicate the Same.

Alty and all personally identifiable information including but not limited to patient name, address, date of birth, Social Security Number, torephone number, and insuranceinformation.

Any and all protected health information including but not limited to patient diagnosis, lab test, radiological exams, physical health exams, and/or treatment procedures.

ATTACHMENT 1

Provisions Required for Federally Funded Procurements

- 1. Federal Funds: This purchase is being funded in whole or in part with Federal Funds and is subject to the requirements established in 2 CFR § 200. Pursuant to 2 CFR § 200.317 the provisions of 2 CFR § 200.322 and 200.326 are expressly included in this solicitation below and incorporated into any contract resulting from this solicitation by reference.
- 2. 2 CFR §200.322 Procurement of recovered materials: A non-Federal entity that is a state agency or agency of a political subdivision of a state and its contractors must comply with section 6002 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act. The requirements of Section 6002 include procuring only items designated in guidelines of the Environmental Protection Agency (EPA) at 40 CFR part 247 that contain the highest percentage of recovered materials practicable, consistent with maintaining a satisfactory level of competition, where the purchase price of the item exceeds \$10,000 or the value of the quantity acquired during the preceding fiscal year exceeded \$10,000; procuring solid waste management services in a manner that maximizes energy and resource recovery; and establishing an affirmative procurement program for procurement of recovered materials identified in the EPA guidelines.
- **3. §200.326 Contract provisions:** Pursuant to the requirements contained in 2 CFR §§ 200.317 and 200.326, the following provisions are included any contract resulting from this solicitation, to the extent that the provisions are applicable.

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

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

§ 148-1-5. Remedies.

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

5.2. Contract Cancellation.

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

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

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

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

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

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

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

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

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

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

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

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

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

5.3. Non-Responsible. If the Director believes that a vendor may be non-responsible, the Director may request that a vendor or spending unit provide evidence that the vendor either does or does not have the capability to fully perform the contract requirements, and the integrity and reliability necessary to assure good faith performance. If the Director determines that the vendor is non-responsible, the Director shall reject that vendor's bid and shall not award the contract to that vendor. A determination of non-responsibility must be evaluated on a case-by-case basis and can only be made after the vendor inquestion 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.

54a The Director may suspend, for a period not to exceed one (1) year, the right of a vendor to bid on procurements issued by the Purchasing Division or any state spending unit under its authority if:

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

instances in any 12 monthperiod.

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

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

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

54b. Vendor suspension for the reasons listed in section 5.4 above shall occur as follows:

5.4.b.1. Upon a determination by the Director that a suspension is warranted, the Director will serve a notice of suspension to the vendor.

5.4.b.2. A notice of suspension must inform the vendor:

5.4.b.2.A. Of the grounds for the suspension;

5.4.b.2.B. Of the duration of the suspension;

5.4.b.2.C. Of the right to request a hearing contesting the suspension;

5.4.b.2.D. That a request for a hearing must be served on the Director no later than five (5) working days of the vendor's receipt of the notice of suspension;

5.4.b.2.E. That the vendor's failure to request a hearing no later than five

(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.b.2.F. 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.b.3 A vendor's failure to serve a request for hearing on the Director no later than five (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.b.4 A vendor who files a timely request for hearing but nevertheless fails to provide an explanation of why t e 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.b.5. Within five (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 b.6. The hearing will be recorded and an official record prepared. Within ten (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.

54c. A vendor may appeal a decision of the Director to the Secretary of Administration. The appeal must be in writing and served on the Secretary no later than five (5) working days of receipt of the Director's decision.

54d The Secretary, or his or her designee, will schedule an appeal hearing and serve on the vendor, a notice of hearing that includes the date, time and place of the hearing. The appeal hearing will be recorded and an official record prepared. Within ten (10) working days of the conclusion .of the appeal hearing, the Secretary will issue and serve on the vendor a written decision either confirming or reversing the suspension.

54e. Any notice or service related to suspension actions or proceeding\$ must be provided by certified mail, return receipt requested.

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

55a Debarment proceedings shall be conducted in accordance with West Virginia Code§ 5A-3-33e and these rules. A vendor that has received notice of the proposed debarment by certified mail, return receipt requested, must respond to the proposed debarment within 30 working days after receipt of notice or the debarment will be instituted without further notice. A vendor is deemed to have received notice, notwithstanding the vendor's failure to accept the certified mail, if the letter is addressed to the vendor at its last known address. After considering the matter and reaching a decision, the Director shall notify the vendor of his or her decision by certified mail, return receipt requested.

55b. 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 nolbe permitted to participate in the state's procurement process during debarment proceedings.

55c. 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.

55d. Pursuant to West Virginia Code section 5A-3-33e(e), the length of the debarment period will be specified in the debarment decision and will be for a period of time that the Director finds necessary and proper to protect the public from an irresponsible vendor.

55e. List of Debarred Vendors. The Director shall maintain and publicly postalist of debarred vendors on the Purchasing Division's website.

5.6. Damages.

56a A vendor who fails to perform as required under a contract shall be liable for actual damages and costs incurred by the state.

56b<u>56a</u> 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

Commented [MD6]: becky Commented [BW7R6]: Remove by the Spending Unit for the merchandise until the amount of actual damages incurred has been determined.

566<u>56</u> The Spending Unit shall seek to collect damages by following the procedures established by the Office of the Attorney General for the collection of delinquent obligations.

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

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

5.2. Contract Cancellation.

52a. Cancellation. The Director may cancel a purchase or contract immediately under any one of the following conditions including, but not limited to:

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

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

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

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

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

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

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

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

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

41 CFR § 60-1,3 defines "Federally assisted construction contract" as any agreement or modification thereof between any applicant and a person for construction work which is paid for in whole or in part with funds obtained from the Government or borrowed on the credit of the Government pursuant to any Federal program involving a grant, contract, loan, insurance, or guarantee, or undertaken pursuant to any Federal program involving such grant, contract, loan, insurance, or guarantee, or any application or modification thereof approved by the Government for a grant, contract, loan, insurance, or guarantee

under which the applicant itself participates in the construction work.

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

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

The Vendor is deeply committed to a policy of equal opportunity employment for all employees, applicants, contractors and customers. The Vendor does not discriminate on the basis of age, race, religion, gender, national origin, color, disability, marital status, veteran status, sexual orientation, genetic information, sexual identity, sex including pregnancy, gender identity, receipt of free medical care, or any other category protected by federal, state or local law, and we will not tolerate employees engaging in any behavior that is not in keeping with the Company's equal opportunity The Vendor is committed to making sure its products and services are available to all policy. persons and that its policies and procedures relating to customer accounts are applied without regard to race, religion, gender, or national origin. In addition, the Vendor will endeavor to make reasonable accommodation for known physical or mental limitations in order to enable otherwise gualified individuals to perform the essential functions of their respective positions. In accordance with the requirements of described above, and except as otherwise provided in the applicable regulations, the following language is hereby incorporated into any contract resulting from this solicitation involving federally assisted construction which is not exempt from the requirements of the equal opportunity clause:

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

During the performance of this contract, the contractor agrees as follows:

- (1) The contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin. The contractor will take affirmative action to ensure that applicants are employed, and that employees are treated during employment without regard to their race, color, religion, sex, or national origin, such action shall include, but not be limited to the following: Employment, upgrading, demotion, or transfer; recruitment or recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship. The contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices to be provided setting forth the provisions of this nondiscrimination clause.
- (2) The contractor will, in all solicitations or advertisements for employees placed by or on behalf of the contractor, state that all qualified applicants will receive considerations for employment without regard to race, color, religion, sex, or national origin.
- (3) The contractor will send to each labor union or representative of workers with which he has a collective bargaining agreement or other contract or understanding, a notice to be provided advising the said labor union or workers' representatives of the contractor's commitments under this section, and shall post copies of the notice in conspicuous places available to employees and applicants for employment.

Commented [MD8]: becky

Commented [BW9R8]: Per HR can agree to this language

- (4) The contractor will comply with all provisions of Executive Order 11246 of September 24, 1965, and of the rules, regulations, and relevant orders of the Secretary of Labor.
- (5) The contractor will furnish all information and reports required by Executive Order 11246 of September 24, 1965, and by rules, regulations, and orders of the Secretary of Labor, or pursuant thereto, and will permit access for his books, records, and accounts by the administering agency and the Secretary of Labor for purposes of investigation to ascertain compliance with such rules, regulations, and orders.
- (6) In the event of the contractor's noncompliance with the nondiscrimination clauses of this contract or with any of the said rules, regulations, or orders, this contract may be canceled, terminated, or suspended in whole or in part and the contractor may be declared ineligible for further Government contracts or federally assisted construction contracts in accordance with procedures authorized in Executive Order 11246 of September 24, 1965, and such other sanctions may be imposed and remedies invoked as provided in Executive Order 11246 of September 24, 1965, or by rule, regulation, or order of the Secretary of Labor, or as otherwise provided by law.
- (7) The contractor will include the portion of the sentence immediately preceding paragraph (1) and the provisions of paragraphs (1) through (7) in every subcontract or purchase order unless exempted by rules, regulations, or orders of the Secretary of Labor issued pursuant to section 204 of Executive Order 11246 of September 24, 1965, so that such provisions will be binding upon each subcontractor or vendor. The contractor will take such action with respect to any subcontract or purchase order as the administering agency may direct as a means of enforcing such provisions, including sanctions for noncompliance: *Provided, however*. That in the event a contractor becomes involved in, or is threatened with, litigation with a subcontractor or vendor as a result of such direction by the administering agency the contractor may request the United States to enter into such litigation to protect the interests of the United States.

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

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

The applicant further agrees that it will refrain from entering into any contract or contract modification subject to Executive Order 11246 of September 24, 1965, with a contractor debarred from, or who has not demonstrated eligibility for, Government contracts and federally assisted construction contracts pursuant to the Executive order and will carry out such sanctions and penaltics for violation of the equal opportunity clause as may be imposed upon contractors and subcontractors by the administering agency or the Secretary of Labor pursuant to Part 11, Subpart D of the Executive order. In addition, the applicant agrees that if it fails or refuses to comply with these undertakings, the administering agency may take any or all of the following actions: Cancel, terminate, or suspend in whole or in part this grant (contract, loan, insurance, guarantee); refrain from extending any further assistance to the applicant under the program with respect to which the failure or refund occurred until satisfactory assurance of future compliance has been received from such applicant; and refer the ease to the Department of Justice for appropriate legal proceedings.

(D) Davis-Bacon Act, as amended (40 U.S.C.3141-3148).-Any construction contract resulting from this solicitation hereby requires compliance with the Davis-Bacon Act {40 U.S.C.3141 3144, and 3146 3148) as supplemented by Department of Labor regulations (29 CFR Part 5, "Labor Standards Provisions Applicable to Contracts Covering Federally Financed and Assisted Construction"). In accordance with the statute, contractors are required to pay wages to laborers and mechanics at a rate not less than the prevailing wages specified in a wage determination made by the Secretary of Labor. In addition, contractors are required to pay wages not less than once a week Intentionally Omitted.

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

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

(F) Rightsto Inventions Made Under a Contract or Agreement. If the Federal award meets the definition of "funding agreement' 'i1nder37 CFR§ 401.2 (a) and the recipient or sub-recipient 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 sub-recipient 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.

Commented [MD10]: Becky

Commented [BW11R10]: Not applicable

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

(H) **Debarment and Suspension (Executive Orders 12549 and 12689)** - Any contract resulting from this solicitation will not be awarded to parties listed on the government wide Excluded Parties. List System in the System for Award Management (SAM), in accordance with the 0MB guidelines af 2 CFR 180 that implement Executive Orders 12549 (3 CFR Part 1986 Comp., p. 189) and 12689 (3 CFR Part 1989 Comp., p. 235), "Debarment and Suspension."

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

STATE OF WEST VIRGINIA Purchasing Division

PURCHASING AFFIDAVIT

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

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

DEFINITIONS:

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

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

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

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

WITNESS THE FOLLOWING SIGNATURE:

Authorized Signature:	Vendor's Name		
State of			
County of,to-wit: Taken, subscribed, and sworn to before methis_day of 20	Date:		
Taken, subscribed, and sworn to before methis_day of 20	State of		
My Commission expires20	County of,to-wit:		
	Taken, subscribed, and sworn to before methis_day	/ of	20
AFFIXSEALHERE NOTARY PUBLIC	My Commission expires	20	
	AFFIXSEALHERE	NOTARY PUBLIC	

Purchasing Affidavit (Revised 0BI01/2015j

State of West Virginia VENDOR PREFERENCE CERTIFICATE

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

1. Application ismade for 2.5% vendor preference for the reason checked:

□Bidderis anindividualresident vendor and has resided continuously in West Virginia for four (4) years immediately preceding the date of this certification; or,

 \Box Bidderis apartnership, association or corporation resident vendor and has maintained its had us or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification;

Bidderis aresident vendor partnership, association, or corporation with at least eightypercent of ownership interest of bidder held by another entity that meets the applicable four year residency requirement; **or**,

 \Box Bidderisa nonresident vendor which has an affiliate or subsidiary which employs a minimum of one hundred stateresidents and which has maintained its head quarters or principal place of business within West Virginia continuously for the four (4) years immediately preceding the date of this certification; **or**,

2. Application is made for 2.5% vendor preference for the reason checked:

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

3. Application is made for 2.5% vendor preference for the reason checked:

Bidderisa nonresident vendor that employs a minimum of one hundred stateresidents, or a nonresident vendor which has an affiliate or subsidiary which maintains its headquarters or principal place of business within West Virginia and employs a minimum of one hundred stateresidents, and for purposes of producing or distributing the commodities or completing the project which is the subject of the bidder's bid and continuously over the entire term of the project, on average at least seventy-five percent of the bidder's employees or the bidder's affiliate's or subsidiary's employees are residents of West Virginia who have resided in the state continuously for the two immediately preceding years and the vendor's bid; **or**,

- 4. Application is made for 5% vendor preference for the reason checked:
- \Box Bidder meets either the requirement of both subdivisions (1) and (2) or subdivision (1) and (3) as stated above; or,
- 5. Application is made for 3.5% vendor preference who is a veteran for the reason checked:

Bidder is an individual resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard and has resided in West Virginia continuously for the four years immediately preceding the date on which the bid is submitted; **or**,

- 6. Application is made for 3.5% vendor preference who is a veteran for the reason checked: Didderisaresident vendor who is a veteran of the United States armed forces, the reserves or the National Guard, if, for purposes of producing or distributing the commodities or completing the project which is the subject of the vendor's bid and continuously over the entire term of the project, on average at least seventy-five percent of the vendor's employees are residents of West Virginia who have resided in the state continuously for the two immediately preceding years.
- 7. Application is made for preference as a non-resident small, women- and minority-owned business, in accordance with West VirginiaCode §SA-3-59 and West VirginiaCode of State Rules.

 \Box Bidder has been or expects to be approved prior to contract award by the Purchasing Division and minority-owned business. as a certified small, women-owned business.

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

By submission of this certificate, Bidder agrees to disclose any reasonably requested information to the Purchasing Division and authorizes the Department of Revenue to disclose **u**heDirectorofPurchasing appropriate information verifying that Bidder has paid the required business truces, provided that such information does not contain the amounts of truces paid or any other information deemed by the TrueCommissioner to be confidential.

Bidder hereby certifies that this certificate is true and accurate in all respects; and that if a contract is issued to Bidder and if anything contained within this certificate changes during the term of the contract, Bidder will notify the Purchasing Division in writing immediately.

Bidder:		
Date:		
Signed:		
Title		

*Check any combination of preference consideration(s) indicated above, which you are entitled to receive.



May 22, 2017 Oxford Immunotec, Inc. d/b/a Oxford Diagnostic Laboratories® Tel: 877-598-2522

To: April Battle West Virginia Bureau for Public Health 350 Capitol Street, Room 702 Charleston, WV 25301

This is in response to the request for evidence that Oxford Diagnostic Laboratories[®] possesses the adequate resources, capability, experience and technical capabilities to respond to solicitation request for T-SPOT[®].*TB* testing.

The T-SPOT®.*TB* test is a unique, single-visit blood test, also known as an interferongamma release assay (IGRA) for TB infection. The T-SPOT.*TB* test is the only blood test that has demonstrated in a pivotal clinical study both sensitivity and specificity exceeding 95% and reliability in all at-risk groups. The T-SPOT.*TB* test does not cross react with the bacille Calmette-Guerin (BCG) vaccine and there is no association between T-SPOT.*TB* test results and immunocompromised status.

According to the CDC Guidelines, IGRAs (e.g. the T-SPOT.*TB* test) may be used in place of a TST in most situations and are preferred for BCG vaccinated individuals and for those persons who are unlikely to return for the reading of the test results.

Oxford Diagnostic Laboratories is College of American Pathologists accredited (number 8044548) and has obtained the necessary Clinical Laboratory Improvement Amendments, or CLIA, registrations (number 44D2035207) and a license from the State of Tennessee Department of Health (documentation enclosed.)

The T-SPOT.*TB* test is the only commercially available, FDA approved interferon-gamma release assay (IGRA) that utilizes the ELISPOT technology.

The T-SPOT.*TB* test offers key advantages in test performance and simplicity and, as such, has been granted the unique CPT[®] code of 86481 by the American Medical Association.



May 22, 2017 Oxford Immunotec, Inc. d/b/a Oxford Diagnostic Laboratories® Tel: 877-598-2522

To: April Battle West Virginia Bureau for Public Health 350 Capitol Street, Room 702 Charleston, WV 25301

Key personnel will be available to the West Virginia Bureau for Public Health as resources throughout their partnership with Oxford Diagnostic Laboratories. Refer to the abridged contact list below for your points of contact.

Title	Field of Expertise	Name	Direct Dial	Email Address
	Appointed Local			
	Representative	Michelle	508-731-	
Sales & Contract Admin.	& Contract Manager	Desmarais	2714	mdesmarais@tspot.com
			502-727-	
Territory Manager	Sales Facing Inquiries	Justin Bauer	6094	jbauer@tspot.com
		Anne	508-731-	
Accounts Receivable Mgr.	Invoice Inquiries	Schmersal	2713	aschmersal@tspot.com

Our Client Support Team is staffed Monday-Friday of each week and available to you by phone or email between the hours of 8:00AM CT – 6:00PM CT.

Client Support / Toll Free: 877-598-2522 / Email: requests@tspot.com



May 22, 2017 Oxford Immunotec, Inc. d/b/a Oxford Diagnostic Laboratories® Tel: 877-598-2522

To: April Battle West Virginia Bureau for Public Health 350 Capitol Street, Room 702 Charleston, WV 25301

T-SPOT.*TB*[®] tests can be ordered through, and T-SPOT.*TB* results can be accessed from SNAP[™], Oxford Diagnostic Laboratories' Client Portal.

Please refer to the attached End User Agreement for additional information.



End User Agreement

Customer Access Agreement

I have requested access to the ODL Client Portal in order to electronically (i) access patient/subject results, and (ii) submit test requisitions. I acknowledge that electronic access to the ODL Client Portal will enable me (and my authorized staff) to receive, read and view test results that are confidential pursuant to federal and state laws, including but not limited to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). ODL is willing to provide such access based upon my representations and agreements as set forth below.

In connection with my request for access, I represent and warrant that I am authorized to receive test results and submit test requisitions on behalf of my employer and that my employer has approved my request for access to the ODL Client Portal. I acknowledge and agree that my user ID and password provided by ODL are unique to me and that my user ID and password will be used only by me to access the ODL Portal.

I agree that I shall take all necessary and appropriate steps to secure and maintain the security of my user ID and password provided to me by ODL that enables access to the ODL Client Portal. I further agree that I will be solely responsible for all damages or exposure resulting from or relating to any unauthorized access to the ODL Client Portal made while using my specific user ID and password. I will promptly advise ODL of any lost or stolen user ID or password so that ODL can deny access to unauthorized persons. I shall further advise ODL if I am no longer employed by or affiliated with my employer so that ODL can remove my access to the portal.



v.2015

Re: HIPAA Matters

Dear Sir or Madam:

Please allow this letter to respond to your recent request regarding a potential business associate agreement ("BAA") with Oxford Immunotec, Inc. dba Oxford Diagnostic Laboratories ("Oxford").

As you may know, the Health Insurance Portability and Accountability Act of 1996, as amended, and the rules promulgated thereunder ("HIPAA") requires a Covered Entity to enter into a BAA with another entity if such other entity is as a "Business Associate" of the Covered Entity. The HIPAA Privacy Rule lists the functions or activities, as well as particular services that make a person or entity a Business Associate of a Covered Entity. Business Associate functions and activities include claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and repricing. 45 CFR 160.103. Business Associate services include legal, actuarial, accounting, consulting, data aggregation management, administrative, accreditation, and financial services. *Id.* Notably, as a provider of medical diagnostic testing services, Oxford is not acting on your entity's behalf with respect to any of the foregoing types of functions, activities, or services.

Rather, Oxford is subject to HIPAA directly as a Covered Entity in its medical diagnostic testing service operations. Helpfully, in a HIPAA guidance document available on the Department of Health and Human Services ("HHS") website, HHS expressly recognizes that disclosures by a Covered Entity to a laboratory for the treatment of an individual do not require a business associate agreement.¹

Please be assured that Oxford is committed to maintaining the privacy of protected health information received and generated by Oxford in connection with the diagnostic testing services it provides and complying fully with Oxford's obligations as a Covered Entity under HIPAA. Oxford has implemented and adheres to robust HIPAA privacy policies and procedures.

We trust that this letter fully resolves your request for a BAA with Oxford. If you have any further questions, please don't hesitate to contact Oxford's Privacy Officer, Elizabeth Keiley, at (508) 281-5388.

¹ <u>http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/businessassociates.pdf;</u> Page 4.





The College of American Pathologists certifies that the laboratory named below

Oxford Diagnostic Laboratories Memphis, Tennessee Charles R. Handorf, MD,PhD

CAP Number: 8044548 AU-ID: 1650272 CLIA Number: 44D2035207

has met all applicable standards for accreditation and is hereby accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to September 27, 2018 to maintain accreditation.

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

IL un Mo FRAP

Chair, Commission on Laboratory Accreditation

President, College of American Pathologists



If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE) GENERAL IMMUNOLOGY (220) EFFECTIVE DATE 12/07/2015 LAB CERTIFICATION (CODE)

EFFECTIVE DATE



FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER. PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.



CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)

			2016							
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 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).										
PRODU		seme	111(3)	•	CONTAC	т				
	r J. Gallagher Risk Management S	Servi	ces.	Inc.	NAME: PHONE			FAX		
470 A	tlantic Avenue		,	-	(A/C. No	, Ext):		(A/C, No):		
Bosto	n MA 02210				È-MÁIL ADDRES	SS:				
										NAIC #
					INSURE	RA:Federal	Insurance (Company		20281
INSUR	ED				INSURE	RB:				
	d Immunotec, Inc.				INSURE	RC:				
	lickerson Road orough, MA 01752				INSURE	RD:				
liviant	0100g11, MA 01752				INSURE	RE:				
					INSURE	RF:				
COV	ERAGES CER	TIFIC		NUMBER: 920358272				REVISION NUMBER:		
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CEF	ICATED. NOTWITHSTANDING ANY RE RTIFICATE MAY BE ISSUED OR MAY CLUSIONS AND CONDITIONS OF SUCH	PERT POLI	AIN, CIES.	THE INSURANCE AFFORD	ED BY '	THE POLICIE	S DESCRIBED	D HEREIN IS SUBJECT TO		
INSR LTR	TYPE OF INSURANCE	ADDL INSD		POLICY NUMBER		POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMIT	s	
	COMMERCIAL GENERAL LIABILITY	Y	Y	74988580		12/17/2016	12/17/2017	EACH OCCURRENCE	\$1,000	,000
	CLAIMS-MADE X OCCUR							DAMAGE TO RENTED PREMISES (Ea occurrence)	\$1,000	,
									\$10,00	
								MED EXP (Any one person)		
								PERSONAL & ADV INJURY	\$1,000	
								GENERAL AGGREGATE	\$2,000	,
-								PRODUCTS - COMP/OP AGG	\$1,000	,000
	OTHER:							COMBINED SINGLE LIMIT	\$	
				73550869		12/17/2016	12/17/2017	(Ea accident)	\$1,000	,000
	ANY AUTO							BODILY INJURY (Per person)	\$	
	ALL OWNED SCHEDULED AUTOS							BODILY INJURY (Per accident)	\$	
	HIRED AUTOS X AUTOS							PROPERTY DAMAGE (Per accident)	\$	
									\$	
A 2	UMBRELLA LIAB X OCCUR			79864807		12/17/2016	12/17/2017	EACH OCCURRENCE	\$1,000	,000
	EXCESS LIAB CLAIMS-MADE							AGGREGATE	\$1,000	.000
	DED RETENTION \$								\$,
AV	ORKERS COMPENSATION			71751303		12/17/2016	12/17/2017	X PER OTH-	φ	
	ND EMPLOYERS' LIABILITY NY PROPRIETOR/PARTNER/EXECUTIVE							X PER OTH- STATUTE ER	\$1.000	000
C	FFICER/MEMBER EXCLUDED?	N / A						E.L. EACH ACCIDENT	• ,	,
Ìİf	Mandatory in NH) yes, describe under							E.L. DISEASE - EA EMPLOYEE		
	ÉSCRIPTION OF OPERATIONS below							E.L. DISEASE - POLICY LIMIT	\$1,000	,000
DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)										
State of West Virginia, Department of Administration, Purchasing Division is included as an Additional Insureds as required by written contract between the Named Insured and the Additional Insureds on the general liability policy. Coverage is subject to the policy terms and conditions. Coverage afforded by the general liability policy shall be primary and non-contributory for the Certificate Holder listed below with respect to work performed by (insert Insured). Coverage is subject to the policy terms and conditions and the requirements of the written contract between the Named Insured and the Additional See Attached										
CER	CERTIFICATE HOLDER CANCELLATION									
West Virginia Bureau for Public Health 2019 Washington Street East Purchasing Division Charleston WV 25305-0130			SHO THE ACC	ULD ANY OF ⁻ EXPIRATION ORDANCE WI	N DATE THE TH THE POLIC	ESCRIBED POLICIES BE C. EREOF, NOTICE WILL F Y PROVISIONS.				
USA			AUTHORIZED REPRESENTATIVE							
		Patrick & Veale								

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AGENCY CUSTOMER ID: MER ID: _____ LOC #: _____



ADDITIONAL REMARKS SCHEDULE

Page 1 of 1

AGENCY Arthur J. Gallagher Risk Management Service	NAMEDINSURED Oxford Immunotec, Inc. 700 Nickerson Road	
POLICY NUMBER	Marlborough, MA 01752	
CARRIER	NAIC CODE	
		EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: CERTIFICATE OF LIABILITY INSURANCE

Insured. A waiver of subrogation is afforded under the General Liability policy in favor of the certificate holder as required by written contract and where allowable by law.

STATE OF WEST VIRGINIA Purchasing Division PURCHASING AFFIDAVIT

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

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

DEFINITIONS:

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

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

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

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

WITNESS THE FOLLOWING SIGNATURE:

Vendor's Name: Oxford Imminiter I	nc. d/b/a Oxford Diggnostic Cabovatories
Authorized Signature: Michael Dermane	Date: <u>S-11-17</u>
State of Massachusetts	
County of Middlesex, to-wit:	
Taken, subscribed, and sworn to before me this $\underline{\Pi^+}$ day of	of <u>May</u> , 20 <u>17</u> .
My Commission expires June 17	, 20 <u>}}.</u>
AFFIX SEAL HERE	NOTARY PUBLIC Melisso By
MELISSA O'BRYANT	Purchasing Affidavit Revised 08/01/2015)

