



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

Request for Quotation

RFQ NUMBER
 LBS12065

PAGE
 1

ADDRESS CORRESPONDENCE TO ATTENTION OF:
 ROBERTA WAGNER
 304-558-0067

RFQ COPY

TYPE NAME/ADDRESS HERE

VENDOR
 Trinity Biotech Distribution
 2823 Girts Road
 Jamestown, NY 14701

SHIP TO

HEALTH AND HUMAN RESOURCES
 BPH - LABORATORY SERVICES
 167-ELEVENTH AVENUE
 SOUTH CHARLESTON, WV
 25303 304-558-3530

DATE PRINTED	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
01/20/2012				

BID OPENING DATE: 02/23/2012 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT. NO.	ITEM NUMBER	UNIT PRICE	AMOUNT
OPEN-END BLANKET CONTRACT						
0001	30,000	EA	193-12	REPORTABLE SPECIMENS TRINITY BIOTECH PART#30-01-0051	\$2.90 ea	\$87,000.00
0002	500	EA	193-12	REPORTABLE SPECIMENS TRINITY BIOTECH PART#30-01-0051	\$1.00 ea	\$500.000
OPEN END CONTRACT						
<p>THE SUCESSFUL VENDOR AGREES TO ENTER WITH THE AGENCY, THE WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN SERVICES, INTO AND OPEN END CONTRACT TO PROVIDE NEWBORN SCREENING SECTION OF THE OFFICE OF LABORATORY SERVICES (OLS), 167 11TH. AVENUE, SOUTH CHARLESTON, WV 25303, FOR REAGENTS TO PERFORM HEMOGLOBINAPATHY SCREENING FOR DETECTION OF HEMOGLOBINS (HBS) A, F, S, C, E, D, O AND BART'S FROM NEONATAL DRIED BLOOD SPOT SPECIMENS. THIS COST PER REPORTABLE SPECIMEN SERVICE IS TO BE TRINITY BIOTECH</p>						

RECEIVED
 2012 FEB 17 AM 10:09
 WV PURCHASING DIVISION

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE <i>James E. Siegman</i>	TELEPHONE 540-273-5054	DATE 2/14/2012
TITLE Clinical Sales Rep.	FEIN 161614982	ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

GENERAL TERMS & CONDITIONS REQUEST FOR QUOTATION (RFQ) AND REQUEST FOR PROPOSAL (RFP)

1. Awards will be made in the best interest of the State of West Virginia.
 2. The State may accept or reject in part, or in whole, any bid.
 3. Prior to any award, the apparent successful vendor must be properly registered with the Purchasing Division and have paid the required \$125 fee.
 4. All services performed or goods delivered under State Purchase Order/Contracts are to be continued for the term of the Purchase Order/Contracts, contingent upon funds being appropriated by the Legislature or otherwise being made available. In the event funds are not appropriated or otherwise available for these services or goods this Purchase Order/Contract becomes void and of no effect after June 30.
 5. Payment may only be made after the delivery and acceptance of goods or services.
 6. Interest may be paid for late payment in accordance with the *West Virginia Code*.
 7. Vendor preference will be granted upon written request in accordance with the *West Virginia Code*.
 8. The State of West Virginia is exempt from federal and state taxes and will not pay or reimburse such taxes.
 9. The Director of Purchasing may cancel any Purchase Order/Contract upon 30 days written notice to the seller.
 10. The laws of the State of West Virginia and the *Legislative Rules* of the Purchasing Division shall govern the purchasing process.
 11. Any reference to automatic renewal is hereby deleted. The Contract may be renewed only upon mutual written agreement of the parties.
 12. **BANKRUPTCY:** In the event the vendor/contractor files for bankruptcy protection, the State may deem this contract null and void, and terminate such contract without further order.
 13. **HIPAA BUSINESS ASSOCIATE ADDENDUM:** The West Virginia State Government HIPAA Business Associate Addendum (BAA), approved by the Attorney General, is available online at www.state.wv.us/admin/purchase/vrc/hipaa.html and is hereby made part of the agreement provided that the Agency meets the definition of a Cover Entity (45 CFR §160.103) and will be disclosing Protected Health Information (45 CFR §160.103) to the vendor.
 14. **CONFIDENTIALITY:** The vendor agrees that he or she will not disclose to anyone, directly or indirectly, any such personally identifiable information or other confidential information gained from the agency, unless the individual who is the subject of the information consents to the disclosure in writing or the disclosure is made pursuant to the agency's policies, procedures, and rules. Vendor further agrees to comply with the Confidentiality Policies and Information Security Accountability Requirements, set forth in <http://www.state.wv.us/admin/purchase/privacy/noticeConfidentiality.pdf>.
 15. **LICENSING:** Vendors 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, and the West Virginia Insurance Commission. The vendor must provide all necessary releases to obtain information to enable the director or spending unit to verify that the vendor is licensed and in good standing with the above entities.
 16. **ANTITRUST:** In submitting a bid to any agency for the State of West Virginia, the bidder offers and agrees that if the bid is accepted the bidder will 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 the bidder.
- I certify that this bid is made without prior understanding, agreement, or connection with any corporation, firm, limited liability company, partnership, or person or entity submitting a bid for the same material, supplies, equipment or services and is in all respects fair and without collusion or fraud. I further certify that I am authorized to sign the certification on behalf of the bidder or this bid.

INSTRUCTIONS TO BIDDERS

1. Use the quotation forms provided by the Purchasing Division. Complete all sections of the quotation form.
2. Items offered must be in compliance with the specifications. Any deviation from the specifications must be clearly indicated by the bidder. Alternates offered by the bidder as **EQUAL** to the specifications must be clearly defined. A bidder offering an alternate should attach complete specifications and literature to the bid. The Purchasing Division may waive minor deviations to specifications.
3. Unit prices shall prevail in case of discrepancy. All quotations are considered F.O.B. destination unless alternate shipping terms are clearly identified in the quotation.
4. All quotations must be delivered by the bidder to the office listed below prior to the date and time of the bid opening. Failure of the bidder to deliver the quotations on time will result in bid disqualifications: Department of Administration, Purchasing Division, 2019 Washington Street East, P.O. Box 50130, Charleston, WV 25305-0130
5. Communication during the solicitation, bid, evaluation or award periods, except through the Purchasing Division, is strictly prohibited (W.Va. C.S.R. §148-1-6.6).



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<p>PART #03-01-0051 OR EQUAL BASED ON THE ATTACHED SPECIFICATIONS AND REQUIREMENTS.</p> <p>VENDOR MUST PROVIDE AN AUTOMATED PROCESSING SYSTEM AT NO ADDITIONAL CHARGE FOR USE WITH THE REQUESTED REAGENTS. THIS SYSTEM INCLUDES A COMPUTER, MONITOR, PRINTER, ETC., WHICH WILL BE RETAINED AND MAINTAINED BY THE VENDOR BUT MUST HAVE CAPABILITY OF INTERFACING WITH THE LIMS (LABORATORY INFORMATION MANAGEMENT SYSTEM).</p> <p>EXHIBIT 3</p> <p>LIFE OF CONTRACT: THIS CONTRACT BECOMES EFFECTIVE ON AWARD AND EXTENDS FOR A PERIOD OF ONE (1) YEAR OR UNTIL SUCH "REASONABLE TIME" THEREAFTER AS IS NECESSARY TO OBTAIN A NEW CONTRACT OR RENEW THE ORIGINAL CONTRACT. THE "REASONABLE TIME" PERIOD SHALL NOT EXCEED TWELVE (12) MONTHS. DURING THIS "REASONABLE TIME" THE VENDOR MAY TERMINATE THIS CONTRACT FOR ANY REASON UPON GIVING THE DIRECTOR OF PURCHASING 30 DAYS WRITTEN NOTICE.</p> <p>UNLESS SPECIFIC PROVISIONS ARE STIPULATED ELSEWHERE IN THIS CONTRACT DOCUMENT BY THE STATE OF WEST VIRGINIA, ITS AGENCIES, OR POLITICAL SUBDIVISIONS, THE TERMS, CONDITIONS AND PRICING SET FORTH HEREIN ARE FIRM FOR THE LIFE OF THE CONTRACT.</p> <p>RENEWAL: THIS CONTRACT MAY BE RENEWED UPON THE MUTUAL WRITTEN CONSENT OF THE SPENDING UNIT AND VENDOR, SUBMITTED TO THE DIRECTOR OF PURCHASING THIRTY (30) DAYS PRIOR TO THE EXPIRATION DATE. SUCH RENEWAL SHALL BE IN ACCORDANCE WITH THE TERMS AND CONDITIONS OF THE ORIGINAL CONTRACT AND SHALL BE LIMITED TO TWO (2) ONE (1) YEAR PERIODS.</p>						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE <i>James E. Siegman</i>	TELEPHONE 540-273-5054	DATE 02/14/2012
TITLE Clinical Sales Rep.	FEIN 161614982	ADDRESS CHANGES TO BE NOTED ABOVE

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<p>CANCELLATION: THE DIRECTOR OF PURCHASING RESERVES THE RIGHT TO CANCEL THIS CONTRACT IMMEDIATELY UPON WRITTEN NOTICE TO THE VENDOR IF THE COMMODITIES AND/OR SERVICES SUPPLIED ARE OF AN INFERIOR QUALITY OR DO NOT CONFORM TO THE SPECIFICATIONS OF THE BID AND CONTRACT HEREIN.</p> <p>OPEN MARKET CLAUSE: THE DIRECTOR OF PURCHASING MAY AUTHORIZE A SPENDING UNIT TO PURCHASE ON THE OPEN MARKET, WITHOUT THE FILING OF A REQUISITION OR COST ESTIMATE, ITEMS SPECIFIED ON THIS CONTRACT FOR IMMEDIATE DELIVERY IN EMERGENCIES DUE TO UNFORESEEN CAUSES (INCLUDING BUT NOT LIMITED TO DELAYS IN TRANSPORTATION OR AN UNANTICIPATED INCREASE IN THE VOLUME OF WORK.)</p> <p>QUANTITIES: QUANTITIES LISTED IN THE REQUISITION ARE APPROXIMATIONS ONLY, BASED ON ESTIMATES SUPPLIED BY THE STATE SPENDING UNIT. 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.</p> <p>ORDERING PROCEDURE: SPENDING UNIT(S) SHALL ISSUE A WRITTEN STATE CONTRACT ORDER (FORM NUMBER WV-39) TO THE VENDOR FOR COMMODITIES COVERED BY THIS CONTRACT. THE ORIGINAL COPY OF THE WV-39 SHALL BE MAILED TO THE VENDOR AS AUTHORIZATION FOR SHIPMENT, A SECOND COPY MAILED TO THE PURCHASING DIVISION, AND A THIRD COPY RETAINED BY THE SPENDING UNIT.</p> <p>BANKRUPTCY: IN THE EVENT THE VENDOR/CONTRACTOR FILES FOR BANKRUPTCY PROTECTION, THIS CONTRACT IS AUTOMATICALLY NULL AND VOID, AND IS TERMINATED WITHOUT FURTHER ORDER.</p>						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

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<p>THE TERMS AND CONDITIONS CONTAINED IN THIS CONTRACT SHALL SUPERSEDE ANY AND ALL SUBSEQUENT TERMS AND CONDITIONS WHICH MAY APPEAR ON ANY ATTACHED PRINTED DOCUMENTS SUCH AS PRICE LISTS, ORDER FORMS, SALES AGREEMENTS OR MAINTENANCE AGREEMENTS, INCLUDING ANY ELECTRONIC MEDIUM SUCH AS CD-ROM.</p> <p>REV. 04/11/2001 EXHIBIT 4</p> <p>LOCAL GOVERNMENT BODIES: UNLESS THE VENDOR INDICATES IN THE BID HIS REFUSAL TO EXTEND THE PRICES, TERMS, AND CONDITIONS OF THE BID TO COUNTY, SCHOOL, MUNICIPAL AND OTHER LOCAL GOVERNMENT BODIES, THE BID SHALL EXTEND TO POLITICAL SUBDIVISIONS OF THE STATE OF WEST VIRGINIA. IF THE VENDOR DOES NOT WISH TO EXTEND THE PRICES, TERMS, AND CONDITIONS OF THE BID TO ALL POLITICAL SUBDIVISIONS OF THE STATE, THE VENDOR MUST CLEARLY INDICATE SUCH REFUSAL IN HIS BID. SUCH REFUSAL SHALL NOT PREJUDICE THE AWARD OF THIS CONTRACT IN ANY MANNER.</p> <p>REV. 3/88</p> <p>INQUIRIES: WRITTEN QUESTIONS SHALL BE ACCEPTED THROUGH CLOSE OF BUSINESS ON 2/7/2012. QUESTIONS MAY BE SENT VIA USPS, FAX, COURIER OR E-MAIL. IN ORDER TO ASSURE NO VENDOR RECEIVES AN UNFAIR ADVANTAGE, NO SUBSTANTIVE QUESTIONS WILL BE ANSWERED ORALLY. IF POSSIBLE, E-MAIL QUESTIONS ARE PREFERRED. ADDRESS INQUIRIES TO: ROBERTA WAGNER DEPARTMENT OF ADMINISTRATION PURCHASING DIVISION 2019 WASHINGTON ST., EAST</p>						
						* Trinity will extend pricing to political subdivisions provided test volumes are similar.

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CHARLESTON, WV 25311 FAX: 304-558-4115 E-MAIL: ROBERTA.A.WAGNER@WV.GOV THE MODEL/BRAND/SPECIFICATIONS NAMED HEREIN ESTABLISH THE ACCEPTABLE LEVEL OF QUALITY ONLY AND ARE NOT INTENDED TO REFLECT A PREFERENCE OR FAVOR ANY PARTICULAR BRAND OR VENDOR. VENDORS WHO ARE BIDDING ALTERNATES SHOULD SO STATE AND INCLUDE PERTINENT LITERATURE AND SPECIFICATIONS. FAILURE TO PROVIDE INFORMATION FOR ANY ALTERNATES MAY BE GROUNDS FOR REJECTION OF THE BID. THE STATE RESERVES THE RIGHT TO WAIVE MINOR IRREGULARITIES IN BIDS OR SPECIFICATIONS IN ACCORDANCE WITH SECTION 148-1-4(F) OF THE WEST VIRGINIA LEGISLATIVE RULES AND REGULATIONS. PURCHASING CARD ACCEPTANCE: THE STATE OF WEST VIRGINIA CURRENTLY UTILIZES A VISA PURCHASING CARD PROGRAM WHICH IS ISSUED THROUGH A BANK. THE SUCCESSFUL VENDOR MUST ACCEPT THE STATE OF WEST VIRGINIA VISA PURCHASING CARD FOR PAYMENT OF ALL ORDERS PLACED BY ANY STATE AGENCY AS A CONDITION OF AWARD. REV 07/16/2007 VENDOR PREFERENCE CERTIFICATE THIS TEAM EXHIBIT HAS BEEN REPLACED BY THE ONLINE VERSION WHICH IS AVAILABLE HERE:						

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<p>HTTP://WWW.STATE.WV.US/ADMIN/PURCHASE/VRC/VENPREF.PDF</p> <p>NOTICE</p> <p>A SIGNED BID MUST BE SUBMITTED TO:</p> <p>DEPARTMENT OF ADMINISTRATION PURCHASING DIVISION BUILDING 15 2019 WASHINGTON STREET, EAST CHARLESTON, WV 25305-0130</p> <p>PLEASE NOTE: A CONVENIENCE COPY WOULD BE APPRECIATED.</p> <p>THE BID SHOULD CONTAIN THIS INFORMATION ON THE FACE OF THE ENVELOPE OR THE BID MAY NOT BE CONSIDERED:</p> <p>SEALED BID</p> <p>BUYER:-----RW/FILE 22-----</p> <p>RFQ. NO.:-----LBS12065-----</p> <p>BID OPENING DATE:-----2/23/2012-----</p> <p>BID OPENING TIME:-----1:30 PM-----</p> <p>PLEASE PROVIDE A FAX NUMBER IN CASE IT IS NECESSARY TO CONTACT YOU REGARDING YOUR BID:</p> <p>-----716-487-1419-----</p>						

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CONTACT PERSON (PLEASE PRINT CLEARLY): ----- James E. Siegmann -----						
ANY INDIVIDUAL SIGNING THIS BID IS CERTIFYING THAT: (1) HE OR SHE IS AUTHORIZED BY THE BIDDER TO EXECUTE THE BID OR ANY DOCUMENTS RELATED THERETO ON BEHALF OF THE BIDDER, (2) THAT HE OR SHE IS AUTHORIZED TO BIND THE BIDDER IN A CONTRACTUAL RELATIONSHIP, AND (3) THAT THE BIDDER HAS PROPERLY REGISTERED WITH ANY STATE AGENCIES THAT MAY REQUIRE REGISTRATION.						
***** THIS IS THE END OF RFQ LBS12065 ***** TOTAL:						\$87,500.00

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Volume

The estimated volume is 30,000 specimens per year for the initial screening of hemoglobinopathies. Of this amount, approximately 500 specimens will need the confirmatory assay performed for hemoglobinopathies that resulted as abnormal in the initial screening. Quantities listed are approximations only, based on estimates supplied by the spending unit. It is understood and agreed that the contract shall cover the quantities actually ordered for delivery during the term of the contract, whether it be it more or less.

Cost per reportable specimen must be Trinity Biotech Part # 03-01-0051, or equal. The cost per specimen for the reagent rental of the system must include reagents, calibrators, columns, consumables, installation, training and regularly scheduled maintenance. Vendors bidding other testing methods that provide the same end result, must clearly state their testing methods.

Selected vendor must provide an automated processing system at no additional charge for use with the requested reagents. This system includes a computer, monitor, printer, software program and manuals which will be retained and maintained by the vendor. It must have capability of interfacing with the Laboratory Information Management System (LIMS).

Reagent Specifications & Requirements

1. The reagents and test protocol must be FDA cleared for use in neonatal screening.
2. The reagents must have a shelf life of 90 days or more beyond date of receipt.
3. Reagents and columns must NOT be lot specific.
4. The column must allow for 500 injections.
5. The column and reagents must be the same for the screen and confirmatory high resolution assay.
6. The column must be composed of PolyCAT A weak cation exchange material, or equal.

7. When submitting quote, vendor must provide the cost per reportable specimen.
8. Vendor must provide interpretation of any chromatograph at no charge.

Hemoglobinopathy Screening System Specifications & Requirements

System must include the following minimum components and specifications at no cost to the Office of Laboratory Services:

1. Method must be designed for analysis of neonatal dried blood spot specimens.
2. Instrument must be FDA cleared for quantification of A, F and presumptive identification of hemoglobin variants.
3. Instrument must be able to perform a screening and a confirmatory assay.
4. Instrument must be able to perform automatic reflex test from screen to confirmation high resolution assay.
5. Instrument must be capable of automated sample preparation for bloodspot specimens.
6. Instrument must use relative retention times for the identification of hemoglobin variants.
7. Instrument must use a detection of 413nm.
8. The quantification of A + F must not require calibration.
9. The list of hemoglobins that must be detectable, labeled and quantitated includes F, A, S, C, D, O, E and Barts.
10. Vendor must supply computer, monitor, printer, software, cables, and communication ports and any other components necessary for operation. Must meet the following minimum specifications

- Must have Fast Ethernet 100 BT or greater connectivity
- Must be capable of interfacing with WVDHHR network domain to allow automatic data transfer to a designated folder to merge data into the Neometrics laboratory information management system (LIMS)
- Must have Windows XP

11. Vendor must allow all WVDHHR network security and management configurations required by established policy to maintain network security and restriction access as necessary.

12. Must have electronic chromatogram storage and retrieval.

14 Must provide a printed data record.

Installation and Training Requirements

1. Delivery and installation of equipment must be within 90 days of the approved purchase order.
2. Vendor must provide a company representative for installation and training. Subcontracting of these services shall not be acceptable.
 - a. Vendor must show proof of Worker's compensation and general liability insurance. The minimum amount of insurance coverage required is \$1,000,000.00.
3. Training of OLS personnel either off site or on site must be provided within four weeks after installation of the equipment at the expense of the vendor.

Maintenance Specifications

1. Vendor will be responsible for all shipping charges incurred by shipping of the equipment to and from the laboratory.

2. Equipment will remain the property of the vendor.
3. The vendor will maintain all equipment in proper working condition or replace malfunctioning equipment at no cost to the state unless the state is guilty of negligence in the operation of said equipment. If repairs can not be made by telephone instructions to lab personnel, a service tech will be sent to the lab within 48 hours of notification by the state to the vendor.
4. Replacement parts and equipment are to be shipped overnight to the lab at no additional cost.
5. Any upgrades made by the vendor will be at no additional cost to the state.
6. Vendor must provide technical support during the hours of 8:00 a.m. - 5:00 p.m. EST 7 days a week.

Contract period: Upon award and continue for a period of one year.

At the end of one (1) year, an option is reserved to renew the agreement in accordance with the terms and conditions of the original contract and shall be limited to two (2) one (1) year renewals or OLS is to return instrumentation to vendor in boxes provided by vendor.

Shipping terms are to be F.O.B. Destination unless otherwise stated in vendor's quote.

Vendor must submit an original itemized invoice for each order. Payment will be made in arrears after receipt of each completed order.

RFQ Cost Sheet

Bidders shall provide a cost for the following:

Cost per Reportable Specimen: Trinity Biotech Part #30-01-0051, or equal:

\$ <u>2.90</u> each quick screen	\$ <u>87,000.00</u>
Cost per specimen (approximately 30,000 reportable specimens per year)	Total

This is the initial screening test of all specimens received in the Newborn Screening Section analyzed for hemoglobinopathies.

\$ <u>1.00</u> each reflex high resolution	\$ <u>500.00</u>
Cost per specimen (approximately 500 reportable specimens per year)	Total

This is the confirmatory assay of specimens analyzed for hemoglobinopathies that resulted as abnormal in the initial screening.

GRAND TOTAL: \$ 87,500.00

The award will be made to vendor with the lowest overall grand total cost of all tests which meets all the requested specifications and requirements.

James E. Siegman
Vendor Signature

02/14/2012
Date

ATTACHMENT
P.O.# LBS12065

This agreement constitutes the entire agreement between the parties, and there are no other terms and conditions applicable to the licenses granted hereunder.

Agreed

Jaime E. Siegma 02/14/2012
Signature Date

Clinical Sales Representative

Title

Trinity Biotech Distribution

Company Name

Signature Date

Title

Agency/Division

AGREEMENT ADDENDUM

IV-96
ev. 10/07

In the event of conflict between this addendum and the agreement, this addendum shall control:

DISPUTES - Any references in the agreement to arbitration or to the jurisdiction of any court are hereby deleted. Disputes arising out of the agreement shall be presented to the West Virginia Court of Claims.

HOLD HARMLESS - Any clause requiring the Agency to indemnify or hold harmless any party is hereby deleted in its entirety.

GOVERNING LAW - The agreement shall be governed by the laws of the State of West Virginia. This provision replaces any references to any other State's governing law.

TAXES - Provisions in the agreement requiring the Agency to pay taxes are deleted. As a State entity, the Agency is exempt from Federal, State, and local taxes and will not pay taxes for any Vendor including individuals, nor will the Agency file any tax returns or reports on behalf of Vendor or any other party.

PAYMENT - Any references to prepayment are deleted. Payment will be in arrears.

INTEREST - Should the agreement include a provision for interest on late payments, the Agency agrees to pay the maximum legal rate under West Virginia law. All other references to interest or late charges are deleted.

RECOUPMENT - Any language in the agreement waiving the Agency's right to set-off, counterclaim, recoupment, or other defense is hereby deleted.

FISCAL YEAR FUNDING - Service performed under the agreement may be continued in succeeding fiscal years for the term of the agreement, contingent upon funds being appropriated by the Legislature or otherwise being available for this service. In the event funds are not appropriated or otherwise available for this service, the agreement shall terminate without penalty on June 30. After that date, the agreement becomes of no effect and is null and void. However, the Agency agrees to use its best efforts to have the amounts contemplated under the agreement included in its budget. Non-appropriation or non-funding shall not be considered an event of default.

STATUTE OF LIMITATION - Any clauses limiting the time in which the Agency may bring suit against the Vendor, lessor, individual, or any other party are deleted.

SIMILAR SERVICES - Any provisions limiting the Agency's right to obtain similar services or equipment in the event of default or non-funding during the term of the agreement are hereby deleted.

ATTORNEY FEES - The Agency recognizes an obligation to pay attorney's fees or costs only when assessed by a court of competent jurisdiction. Any other provision is invalid and considered null and void.

ASSIGNMENT - Notwithstanding any clause to the contrary, the Agency reserves the right to assign the agreement to another State of West Virginia agency, board or commission upon thirty (30) days written notice to the Vendor and Vendor shall obtain the written consent of Agency prior to assigning the agreement.

LIMITATION OF LIABILITY - The Agency, as a State entity, cannot agree to assume the potential liability of a Vendor. Accordingly, any provision limiting the Vendor's liability for direct damages to a certain dollar amount or to the amount of the agreement is hereby deleted. Limitations on special, incidental or consequential damages are acceptable. In addition, any limitation is null and void to the extent that it precludes any action for injury to persons or for damages to personal property.

RIGHT TO TERMINATE - Agency shall have the right to terminate the agreement upon thirty (30) days written notice to Vendor. Agency agrees to pay Vendor for services rendered or goods received prior to the effective date of termination.

TERMINATION CHARGES - Any provision requiring the Agency to pay a fixed amount or liquidated damages upon termination of the agreement is hereby deleted. The Agency may only agree to reimburse a Vendor for actual costs incurred or losses sustained during the current fiscal year due to wrongful termination by the Agency prior to the end of any current agreement term.

RENEWAL - Any reference to automatic renewal is hereby deleted. The agreement may be renewed only upon mutual written agreement of the parties.

INSURANCE - Any provision requiring the Agency to insure equipment or property of any kind and name the Vendor as beneficiary or as an additional insured is hereby deleted.

RIGHT TO NOTICE - Any provision for repossession of equipment without notice is hereby deleted. However, the Agency does recognize a right of repossession with notice.

ACCELERATION - Any reference to acceleration of payments in the event of default or non-funding is hereby deleted.

CONFIDENTIALITY - Any provision regarding confidentiality of the terms and conditions of the agreement is hereby deleted. State contracts are public records under the West Virginia Freedom of Information Act.

AMENDMENTS - All amendments, modifications, alterations or changes to the agreement shall be in writing and signed by both parties. No amendment, modification, alteration or change may be made to this addendum without the express written approval of the Purchasing Division and the Attorney General.

ACCEPTED BY:

STATE OF WEST VIRGINIA

Spending Unit: _____

Signed: _____

Title: _____

Date: _____

VENDOR

Company Name: Trinity Biotech Distribution

Signed: James E. Siegan

Title: Clinical Sales Representative

Date: 02/14/2014

3/08

State of West Virginia

VENDOR PREFERENCE CERTIFICATE

ation and application* is hereby made for Preference in accordance with *West Virginia Code*, §5A-3-37. (Does not apply to auction 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 Resident Vendor Preference, if applicable.

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

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

Application is made for 2.5% resident 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,

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

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

Application is made for 5% resident vendor preference for the reason checked:

Bidder meets either the requirement of both subdivisions (1) and (2) or subdivision (1) and (3) as stated above; or,

Application is made for 3.5% resident 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,

Application is made for 3.5% resident vendor preference who is a veteran for the reason checked:

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

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

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

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

No Vendor Preference Requested

Bidder: Trinity Biotech Distribution

Signed: James E. Siegma

Date: 02/14/2012

Title: Clinical Sales Representation

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

RFQ No. LBS12065

STATE OF WEST VIRGINIA
Purchasing Division

PURCHASING AFFIDAVIT

West Virginia Code §5A-3-10a states: 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 the debt owed is an amount greater than one thousand dollars in the aggregate.

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.

"Debtor" means any individual, corporation, partnership, association, limited liability company or any other form or business association owing a debt to the state or any of its political subdivisions. "Political subdivision" means any county commission; municipality; county board of education; any instrumentality established by a county or municipality; any separate corporation or instrumentality established by one or more counties or municipalities, as permitted by law; or any public body charged by law with the performance of a government function or whose jurisdiction is coextensive with one or more counties or municipalities. "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 exceeds five percent of the total contract amount.

EXCEPTION: The prohibition of this section does not apply where a vendor has contested any tax administered pursuant to chapter eleven of this 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.

Under penalty of law for false swearing (*West Virginia Code §61-5-3*), it is hereby certified that the vendor affirms and acknowledges the information in this affidavit and is in compliance with the requirements as stated.

WITNESS THE FOLLOWING SIGNATURE

Vendor's Name: Trinity Biotech Distribution

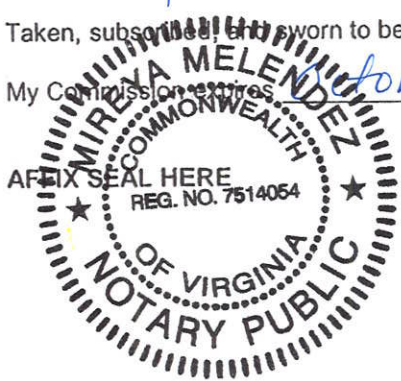
Authorized Signature: James E. Siegman Date: 2/16/12

State of Virginia

County of Spotsylvania, to-wit:

Taken, subscribed, and sworn to before me this 16 day of February, 2012.

My Commission expires October 31, 2012.



NOTARY PUBLIC Mireya Melendez



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

Request for Quotation

RFQ NUMBER
 LBS12065

PAGE
 1

ADDRESS CORRESPONDENCE TO ATTENTION OF
 ROBERTA WAGNER
 304-558-0067

RFQ COPY

TYPE NAME/ADDRESS HERE
 Trinity Biotech Distribution
 2823 Girls Road
 Jamestown, NY 14701

SHIP TO
 HEALTH AND HUMAN RESOURCES
 BPH - LABORATORY SERVICES
 167-ELEVENTH AVENUE
 SOUTH CHARLESTON, WV
 25303 304-558-3530

DATE PRINTED	TERMS OF SALE	SHIP VIA	FOB	FREIGHT TERMS
02/13/2012				

BID OPENING DATE: 02/23/2012 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT NO	ITEM NUMBER	UNIT PRICE	AMOUNT
ADDENDUM NO. 1						
1. QUESTIONS AND ANSWERS ARE ATTACHED. 2. ADDENDUM ACKNOWLEDGEMENT IS ATTACHED. THIS DOCUMENT SHOULD BE SIGNED AND RETURNED WITH YOUR BID. FAILURE TO SIGN AND RETURN MAY RESULT IN DISQUALIFICATION OF YOUR BID.						
EXHIBIT 10						
REQUISITION NO.: LBS12065						
ADDENDUM ACKNOWLEDGEMENT						
I HEREBY ACKNOWLEDGE RECEIPT OF THE FOLLOWING CHECKED ADDENDUM(S) AND HAVE MADE THE NECESSARY REVISIONS TO MY PROPOSAL, PLANS AND/OR SPECIFICATIONS, ETC.						
ADDENDUM NO.'S:						
NO. 1..... <input checked="" type="checkbox"/>						
NO. 2.....						
NO. 3.....						
NO. 4.....						
NO. 5.....						
I UNDERSTAND THAT FAILURE TO CONFIRM THE RECEIPT OF						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE <i>James E. Sigman</i>	TELEPHONE 540-273-5054	DATE 02/14/2012
TITLE Clinical Sales Rep.	FEIN 161614982	ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

GENERAL TERMS & CONDITIONS REQUEST FOR QUOTATION (RFQ) AND REQUEST FOR PROPOSAL (RFP)

1. Awards will be made in the best interest of the State of West Virginia.
 2. The State may accept or reject in part, or in whole, any bid.
 3. Prior to any award, the apparent successful vendor must be properly registered with the Purchasing Division and have paid the required \$125 fee.
 4. All services performed or goods delivered under State Purchase Order/Contracts are to be continued for the term of the Purchase Order/Contracts, contingent upon funds being appropriated by the Legislature or otherwise being made available. In the event funds are not appropriated or otherwise available for these services or goods this Purchase Order/Contract becomes void and of no effect after June 30.
 5. Payment may only be made after the delivery and acceptance of goods or services.
 6. Interest may be paid for late payment in accordance with the *West Virginia Code*.
 7. Vendor preference will be granted upon written request in accordance with the *West Virginia Code*.
 8. The State of West Virginia is exempt from federal and state taxes and will not pay or reimburse such taxes.
 9. The Director of Purchasing may cancel any Purchase Order/Contract upon 30 days written notice to the seller.
 10. The laws of the State of West Virginia and the *Legislative Rules* of the Purchasing Division shall govern the purchasing process.
 11. Any reference to automatic renewal is hereby deleted. The Contract may be renewed only upon mutual written agreement of the parties.
 12. **BANKRUPTCY:** In the event the vendor/contractor files for bankruptcy protection, the State may deem this contract null and void, and terminate such contract without further order.
 13. **HIPAA BUSINESS ASSOCIATE ADDENDUM:** The West Virginia State Government HIPAA Business Associate Addendum (BAA), approved by the Attorney General, is available online at www.state.wv.us/admin/purchase/vrc/hipaa.html and is hereby made part of the agreement provided that the Agency meets the definition of a Cover Entity (45 CFR §160.103) and will be disclosing Protected Health Information (45 CFR §160.103) to the vendor.
 14. **CONFIDENTIALITY:** The vendor agrees that he or she will not disclose to anyone, directly or indirectly, any such personally identifiable information or other confidential information gained from the agency, unless the individual who is the subject of the information consents to the disclosure in writing or the disclosure is made pursuant to the agency's policies, procedures, and rules. Vendor further agrees to comply with the Confidentiality Policies and Information Security Accountability Requirements, set forth in <http://www.state.wv.us/admin/purchase/privacy/noticeConfidentiality.pdf>.
 15. **LICENSING:** Vendors 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, and the West Virginia Insurance Commission. The vendor must provide all necessary releases to obtain information to enable the director or spending unit to verify that the vendor is licensed and in good standing with the above entities.
 16. **ANTITRUST:** In submitting a bid to any agency for the State of West Virginia, the bidder offers and agrees that if the bid is accepted the bidder will 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 the bidder.
- I certify that this bid is made without prior understanding, agreement, or connection with any corporation, firm, limited liability company, partnership, or person or entity submitting a bid for the same material, supplies, equipment or services and is in all respects fair and without collusion or fraud. I further certify that I am authorized to sign the certification on behalf of the bidder or this bid.

INSTRUCTIONS TO BIDDERS

1. Use the quotation forms provided by the Purchasing Division. Complete all sections of the quotation form.
2. Items offered must be in compliance with the specifications. Any deviation from the specifications must be clearly indicated by the bidder. Alternates offered by the bidder as **EQUAL** to the specifications must be clearly defined. A bidder offering an alternate should attach complete specifications and literature to the bid. The Purchasing Division may waive minor deviations to specifications.
3. Unit prices shall prevail in case of discrepancy. All quotations are considered F.O.B. destination unless alternate shipping terms are clearly identified in the quotation.
4. All quotations must be delivered by the bidder to the office listed below prior to the date and time of the bid opening. Failure of the bidder to deliver the quotations on time will result in bid disqualifications: Department of Administration, Purchasing Division, 2019 Washington Street East, P.O. Box 50130, Charleston, WV 25305-0130
5. Communication during the solicitation, bid, evaluation or award periods, except through the Purchasing Division, is strictly prohibited (W.Va. C.S.R. §148-1-6.6).



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

Request for Quotation

RFQ NUMBER
 LBS12065

PAGE
 2

ADDRESS CORRESPONDENCE TO ATTENTION OF
 ROBERTA WAGNER
 304-558-0067


RFQ COPY

TYPE NAME/ADDRESS HERE
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 2823 Girts Road
 Jamestown, NY 14701

SHIP TO
 HEALTH AND HUMAN RESOURCES
 BPH - LABORATORY SERVICES
 167-ELEVENTH AVENUE
 SOUTH CHARLESTON, WV
 25303 304-558-3530

DATE PRINTED	TERMS OF SALE	SHIP VIA	FOB	FREIGHT TERMS
02/13/2012				

BID OPENING DATE: 02/23/2012 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT. NO.	ITEM NUMBER	UNIT PRICE	AMOUNT
<p>THE ADDENDUM(S) MAY BE CAUSE FOR REJECTION OF BIDS.</p> <p>VENDOR MUST CLEARLY 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.</p> <p style="text-align: center;">  SIGNATURE Trinity Biotech Distribution COMPANY 02/14/2012 DATE </p> <p>NOTE: THIS ADDENDUM ACKNOWLEDGEMENT SHOULD BE SUBMITTED WITH THE BID.</p> <p>REV. 09/21/2009</p> <p style="text-align: center;">END OF ADDENDUM NO. 1</p>						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE <i>James E. Sigman</i>	TELEPHONE 540-273-5054	DATE 02/14/2012
TITLE Clinical Sales Rep.	FEIN 161614982	ADDRESS CHANGES TO BE NOTED ABOVE

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STATE OF WEST VIRGINIA
PURCHASE CONTINUATION SHEET

Page ____ of ____ Pages		Requisition / P.O. No.: LBS12065
File:	Acct. No.: 5163-2012-2961-099-371	
Spending Unit: DHHR/OLS		

Vendor: Trinity Biotech Dist P.O. Date: _____

Item No.	Quantity	Description	Unit Price	Amount
		<p>VENDOR QUESTION #1:</p> <p>Given the stated specifications, Contractor would like clarification on West Virginia Department of Administration Purchasing Departments verification of Contractors' claims of FDA clearance of reagents and test protocol for use in neonatal screening. Are claims of FDA clearance verified through review of the intended use and data included in the FDA 510(k) Decision Summary, or solely through supply an FDA clearance letter, which may not include the intended use population.</p> <p>RESPONSE:</p> <p>It is a class II device, verified with 510(k) Premarket Notification. Please see attachment.</p>		

Eckerd, Barbara M

From: Eckerd, Barbara M
 Sent: Friday, February 13, 2009 1:45 PM
 To: Eckerd, Barbara
 Subject: Fwd: RE: Primus GeneSys FDA Clearance
 Attachments: TEXT.htm

«TEXT.htm»

>> "Dan Huie" <[dhuie\(3primusdiagnostics.com\)](mailto:dhuie(3primusdiagnostics.com))> 11/20/2008 2:59:22 PM >>

Hi Krista!

Please pass this on to the Agency for further clarification of the Primus GeneSys' FDA "approval."

Our Primus QA Manager also contacted the FDA regarding the question you had asked. Mr. Young Pak of the FDA responded with the following information.

Question from Britt Einspahr, Primus QA Manager:

Do you have a guidance document that you could point me to that discusses 510(k) clearance versus FDA approval - that the FDA does not specifically "approve" of devices? (IVD in this case)

Answer from Mr. Young Pak, FDA:

Dear Britt,

FDA approval refers to class III devices; 510(k) clearance (also refers as market clearance) refers to class I, II devices. You also see 510(k) as "substantial equivalence" determination by FDA - what this means is that the 510(k) applicant has demonstrated that their new device is substantially equivalent to other legally marketed device.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=814.2&SearchTerm=pma>
 - regulation re: PMA arroba

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=807.81>
 - regulation re: Premarket notification (510(k))

Best Regards, Mr. Young Pak Center for Devices and Radiological Health U.S. Food and Drug Administration

Hope that helps! Once again Primus has received 510(k) clearance from the FDA and thus has the highest level of approval from the FDA for IVD medical instruments. Dan Huie

From: Dan Huie
 Sent: Wednesday, November 19, 2008 1:54 PM
 To: 'krista.s.ferrell@wv.gov'
 Cc: Stacey Blichar; 'Doe Randolph'
 Subject: Primus GeneSys FDA Clearance

Hi Krista!

This is Dan Huie from Trinity Biotech. I am West Virginia's representative for the Primus GeneSys product. It was good speaking with you on the phone today. I am happy to provide you the information needed to show that the GeneSys is indeed FDA approved. Please see the attached Introduction letter that explains the rest of the attached documents.

If you have any questions, please call me at 215.498.8933 or email me. I want to make sure we have answered all your questions by the end of the day.

I look forward to hearing from you soon!

Best Regards, Dan
Huie

Dan Huie | Technical Sales Representative | Primus Diagnostics |
www.primusdiagnostics.com <<http://www.primusdiagnostics.com/>>
Direct: 1.215.498.8933 | Main: 1.800.377.4752 | Fax: 1.816.361.1974