



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

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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..... | | | | | | |
| 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 | TELEPHONE | DATE |
|-----------|-----------|------|

| | | |
|-------|------|-----------------------------------|
| TITLE | FEIN | ADDRESS CHANGES TO BE NOTED ABOVE |
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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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PAGE
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ADDRESS CORRESPONDENCE TO ATTENTION OF
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VENDOR

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 |
|--------------|---------------|----------|--------|---------------|
| 02/13/2012 | | | | |

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| 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>..... SIGNATURE</p> <p>..... COMPANY</p> <p>..... DATE</p> <p>NOTE: THIS ADDENDUM ACKNOWLEDGEMENT SHOULD BE SUBMITTED WITH THE BID.</p> <p>REV. 09/21/2009</p> <p>END OF ADDENDUM NO. 1</p> | | | | | | |

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WV-36 (Rev. 01/01/07)

STATE OF WEST VIRGINIA

PURCHASE CONTINUATION SHEET

Page ____ of ____ Pages

Requisition / P.O. No.:
LBS12065

File:

Acct. No.:
5163-2012-2961-099-371

Vendor: _____ P.O. Date: _____

Spending Unit:
DHHR/OLS

| 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" <[dhuiie\(3primusdiagnostics.com\)](mailto:dhuiie(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.cfmPfr=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 Blicher; '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

| New Search | Back To Search Results |
|---|--|
| 510(k) Premarket Notification Database | |
| Device Classification Name | Abnormal Hemoglobin Quantitation |
| 510(k) Number | K955283 |
| Device Name | PRIMUS VARIANT SYSTEM PVS99 PRIMUS CORP. P.O. Box 22599 Kansas City, MO 64113 |
| Applicant | Jim Noffsinger |
| Contact | 864.7415 |
| Regulation Number | GKA |
| Classification Product Code | 11/16/1995 |
| Date Received | 03/01/1996 |
| Decision Date | Substantially Equivalent (SE) |
| Decision | Classification Advisory Committee Hematology |
| Classification Advisory Committee | Review Advisory Committee Hematology |
| Statement/Summary/Purged Status | Statement/purged 510(k) |
| Type | Traditional |
| Reviewed By Third Party | No |
| Expedited Review | |

Database Updated 02/06/2009