



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
LBS80423

PAGE
1

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

VENDOR

RFQ COPY
 TYPE NAME/ADDRESS HERE

VENDOR

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
06/07/2007				

BID OPENING DATE: **07/12/2007** BID OPENING TIME **01:30PM**

LINE	QUANTITY	UOP	CAT. NO.	ITEM NUMBER	UNIT PRICE	AMOUNT
0001	100	EA		475-00-99-001		
	HEPATITIS A IGM					
	OPEN-END CONTRACT					
	TO PROVIDE REAGENTS TO PERFORM EXAMINATION FOR DETECTION OF HEPATITIS A AND B, IN SERUM SPECIMEN, PER THE ATTACHED SPECIFICATIONS.					
	ASSAY FOR DETECTION OF HEPATITIS A (IGM ANTI-HAV) ITEM #					
0002	2,000	EA		475-00-99-001		
	HEPATITIS BSAG					
	ASSAY FOR DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) ITEM #					
0003	10	EA		475-00-99-001		
	HEPATITIS BSAG CONFIRMATORY					
	ASSAY FOR DETECTION OF ANTIBODY TO HEPATITIS B SURFACE ANTIGEN (HUMAN) CONFIRMATORY ASSAY IN HUMAN SERUM, PLASMA OR CADAVER SERUM. ITEM #					

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE	TELEPHONE	DATE
TITLE	FEIN	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. All quotations are governed by the *West Virginia Code* and the *Legislative Rules* of the Purchasing Division.
4. Prior to any award, the apparent successful vendor must be properly registered with the Purchasing Division and have paid the required \$125.00 registration fee.
5. All services performed or goods delivered under State Purchase Orders/Contracts are to be continued for the term of the Purchase Order/Contract, 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.
6. Payment may only be made after the delivery and acceptance of goods or services.
7. Interest may be paid for late payment in accordance with the *West Virginia Code*.
8. Vendor preference will be granted upon written request in accordance with the *West Virginia Code*.
9. The State of West Virginia is exempt from federal and state taxes and will not pay or reimburse such taxes.
10. The Director of Purchasing may cancel any Purchase Order/Contract upon 30 days written notice to the seller.
11. The laws of the State of West Virginia and the *Legislative Rules* of the Purchasing Division shall govern all rights and duties under the Contract, including without limitation the validity of this Purchase Order/Contract.
12. Any reference to automatic renewal is hereby deleted. The Contract may be renewed only upon mutual written agreement of the parties.
13. **BANKRUPTCY:** In the event the vendor/contractor files for bankruptcy protection, this contract is automatically null and void, and is terminated without further order.
14. **HIPAA Business Associate Addendum** - The West Virginia State Government HIPAA Business Associate Addendum (BAA), approved by the Attorney General, and available online at the Purchasing Division's web site (<http://www.state.wv.us/admin/purchase/vrc/hipaa.htm>) is hereby made part of the agreement. Provided that, the Agency meets the definition of a Covered Entity (45 CFR §160.103) and will be disclosing Protected Health Information (45 CFR §160.103) to the vendor.

INSTRUCTIONS TO BIDDERS

1. Use the quotation forms provided by the Purchasing Division.
2. **SPECIFICATIONS:** 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. Complete all sections of the quotation form.
4. Unit prices shall prevail in cases of discrepancy.
5. All quotations are considered F.O.B. destination unless alternate shipping terms are clearly identified in the quotation.
6. **BID SUBMISSION:** 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.

SIGNED BID TO:

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



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167-ELEVENTH AVENUE
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0004	2,000	EA		475-00-99-001		
	HEPATITIS BCAB					
	ASSAY FOR DETECTION OF TOTAL ANTIBODIES TO HEPATITIS B CORE ANTIGEN (ANTI-HBC). ITEM #					
0005	100	EA		475-00-99-001		
	HEPATITIS BIGM					
	ASSAY FOR THE DETECTION OF IGM ANTIBODY TO HEPATITIS B CORE ANTIGEN (IGM ANTI-HBC). ITEM #					
0006	1,000	EA		475-00-99-001		
	HEPATITIS BSAB					
	ASSAY FOR DETECTION OF ANTIBODY TO HEPATITIS B SURFACE ANTIGEN (ANTI-HBS). ITEM #					
	EXHIBIT 3					
	LIFE OF CONTRACT: THIS CONTRACT BECOMES EFFECTIVE ON					

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<p>..... 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, THE TERMS, CONDITIONS AND PRICING SET 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> <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>						

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<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> <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 INQUIRIES WRITTEN QUESTIONS SHALL BE ACCEPTED THROUGH CLOSE OF BUSINESS ON JUNE 26, 2007. 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:</p>						

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<p>ROBERTA WAGNER DEPARTMENT OF ADMINISTRATION PURCHASING DIVISION 2019 WASHINGTON STREET, EAST CHARLESTON, WV 25311</p> <p>FAX: 304-558-4115 E-MAIL: RWAGNER@WVADMIN.GOV</p> <p>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 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</p>						

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<p>TO WAIVE MINOR IRREGULARITIES IN BIDS OR SPECIFICATIONS IN ACCORDANCE WITH SECTION 148-1-4(F) OF THE WEST VIRGINIA LEGISLATIVE RULES AND REGULATIONS.</p> <p>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 FOR ORDERS THAT ARE LESS THAN \$2,500 AS A CONDITION OF AWARD.</p> <p>VENDOR PREFERENCE CERTIFICATE</p> <p>CERTIFICATION AND APPLICATION* IS HEREBY MADE FOR PREFERENCE IN ACCORDANCE WITH WEST VIRGINIA CODE, 5A-3-37 (DOES NOT APPLY TO CONSTRUCTION CONTRACTS).</p> <p>A. APPLICATION IS MADE FOR 2.5% PREFERENCE FOR THE REASON CHECKED:</p> <p>() 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</p> <p>() BIDDER IS A PARTNERSHIP, ASSOCIATION OR CORPORATION RESIDENT VENDOR AND HAS MAINTAINED ITS HEAD-QUARTERS 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</p>						

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<p>CERTIFICATION; OR</p> <p>() BIDDER IS A CORPORATION 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.</p> <p>B. APPLICATION IS MADE FOR 2.5% PREFERENCE FOR THE REASON CHECKED:</p> <p>() 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;</p> <p>OR</p> <p>() 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 BIDDERS' 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.</p> <p>BIDDER UNDERSTANDS IF THE SECRETARY OF TAX & 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</p>						

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<p>PURCHASING TO: (A) RESCIND THE CONTRACT OR PURCHASE ORDER ISSUED; OR (B) ASSESS A PENALTY AGAINST SUCH BIDDER IN AN AMOUNT NOT TO EXCEED 5% OF THE BID AMOUNT AND THAT SUCH PENALTY WILL BE PAID TO THE CONTRACTING AGENCY OR DEDUCTED FROM ANY UNPAID BALANCE ON THE CONTRACT OR PURCHASE ORDER.</p> <p>BY SUBMISSION OF THIS CERTIFICATE, BIDDER AGREES TO DISCLOSE ANY REASONABLY REQUESTED INFORMATION TO THE PURCHASING DIVISION AND AUTHORIZES THE DEPARTMENT OF TAX AND REVENUE TO DISCLOSE TO THE DIRECTOR OF PURCHASING APPROPRIATE INFORMATION VERIFYING THAT BIDDER HAS PAID THE REQUIRED BUSINESS TAXES, PROVIDED THAT SUCH INFORMATION DOES NOT CONTAIN THE AMOUNTS OF TAXES PAID NOR ANY OTHER INFORMATION DEEMED BY THE TAX COMMISSIONER TO BE CONFIDENTIAL.</p> <p>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.</p> <p>BIDDER: -----</p> <p>DATE: -----</p> <p>SIGNED: -----</p> <p>TITLE: -----</p>						

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<p>* CHECK ANY COMBINATION OF PREFERENCE CONSIDERATION(S) IN EITHER "A" OR "B", OR BOTH "A" AND "B" WHICH YOU ARE ENTITLED TO RECEIVE. YOU MAY REQUEST UP TO THE MAXIMUM 5% PREFERENCE FOR BOTH "A" AND "B". (REV. 12/00)</p> <p style="text-align: center;">NOTICE</p> <p>A SIGNED BID MUST BE SUBMITTED TO:</p> <p style="text-align: center;">DEPARTMENT OF ADMINISTRATION PURCHASING DIVISION BUILDING 15 2019 WASHINGTON STREET, EAST CHARLESTON, WV 25305-0130</p> <p>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:-----ROBERTA WAGNER/FILE 22-----</p> <p>RFQ. NO.:-----LBS80423-----</p> <p>BID OPENING DATE:-----JULY 12, 2007-----</p> <p>BID OPENING TIME:-----1:30 PM-----</p> <p>PLEASE PROVIDE A FAX NUMBER IN CASE IT IS NECESSARY</p>						

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<p>TO CONTACT YOU REGARDING YOUR BID:</p> <p>-----</p> <p>CONTACT PERSON (PLEASE PRINT CLEARLY):</p> <p>-----</p> <p>***** THIS IS THE END OF RFQ LBS80423 ***** TOTAL: _____</p>						

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SPECIFICATIONS

A. REAGENT SPECIFICATIONS

1. Reagents must be bar-coded.
2. Must have ability to support up to 31 controls and calibrators.
3. Must be able to support multi-size reagent bottle volumes (milliliters) 3, 8, 15, 30, 60 and 125.
4. Must have lot and expiration management for reagents.
5. Must have disposable graphite tips, 300-1000 micro liters.
6. Must have at least an on-board capacity of 480 tips (5 boxes of 96 tips).
7. Must be able to track tip usage on instrument and use partially filled tip racks.
8. Must have tip waste capacity of >1000 tips.
9. Must have mechanical tip detection.
10. Must have liquid level and clot detection.
11. Positive sample identification must be on plates and reagents.
12. The test kit must have a minimum shelf life of 90 days or more beyond date of receipt.

INDIVIDUAL TEST TYPE & SPECIFICATIONS FOR EACH TEST

I. Assay specifications for detection of Hepatitis A (IgM anti-HAV)

- a. Must detect IgM Antibodies to Hepatitis A virus in human serum or plasma.
- b. Must meet the following criteria for a qualitative assay of IgM Antibody to Hepatitis A Virus.
 1. Must have a 96-well test plate.
 2. Must use monoclonal antibodies to human IgM as the basis for the enzyme immunoassay.
 3. Must be an FDA approved method.
 4. Must have positive agreement for acute profile samples of 100% with FDA approved comparator methods.
 5. Must have negative agreement for past infection profile samples of 100% with FDA approved comparator methods.
- c. The principle must be direct antibody, sandwich EIA in a solid phase Micro well.
- d. Sample size must not be greater than 100 microliters.
- e. All steps in the method must be adaptable to automation.

II. Assay specifications for detection of Hepatitis B Surface Antigen (HBsAg)

- a. Must detect Hepatitis B Surface Antigen in human serum, plasma, or cadaveric serum.
- b. Must meet the following criteria for a qualitative enzyme immunoassay of Hepatitis B Surface Antigen.
 1. Must have a 96-well test plate.

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2. Must use a monoclonal antibody to Hepatitis B Surface Antigen.
 3. Must be a FDA approved method.
 4. Must have a specificity of at least 99%.
- c. The principle must be direct antibody, sandwich EIA in a solid phase microwell.
 - d. Sample size must not be greater than 100 microliters.
 - e. All steps in the method must be adaptable to automation.

III. Assay specifications for detection of antibody to Hepatitis B Surface Antigen (Human) confirmatory assay in human serum, plasma or cadaver serum.

- a. Must be a confirmatory neutralization of HBsAg enzyme immunoassay Reactive specimens.
- b. Must be compatible with the enzyme immunoassay used to detect antibody to Hepatitis B Surface Antigen assay.
- c. Must be FDA approved.
- d. All steps in the method must be adaptable to automation.

IV. Assay specifications for detection of total antibodies to Hepatitis B Core Antigen (Anti- HBc).

- a. Must detect total antibodies to Hepatitis B Core Antigen in human serum or plasma.
- b. Must meet the following criteria for a qualitative assay of total antibodies to Hepatitis B Core Antigen.
 1. Must have a 96-well test plate.
 2. Must use a monoclonal antibody directed to the immunodominant of Hepatitis B Core Antigen as the basis for the enzyme immunoassay.
 3. Must be a FDA approved method.
 4. Must have an analytical sensitivity of 0.4 u/ml using single-point serial dilutions of a standard preparation from the Paul-Ehrlich-Institute (PEI) "or equal to or better than".
- c. The principle must be direct antibody, sandwich EIA in a solid phase microwell.
- d. Sample size must not be greater than 100 microliters.
- e. All steps in the method must be adaptable to automation.

V. Assay specifications for the detection of IgM Antibody to Hepatitis B Core Antigen (IgM anti-HBc)

- a. Must detect IgM Antibody to Hepatitis B Core Antigen in human serum or plasma.
- b. Must meet the following criteria for a qualitative assay of IgM antibody to Hepatitis B Core Antigen.
 1. Must have a 96-well test plate.

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2. Must use monoclonal antibody to human IgM as the basis for the enzyme immunoassay.
 3. Must be a FDA approved method.
 4. Must agree with 95% exact confidence intervals with reference IgM Anti-HBc assay results.
 5. Must have an analytical sensitivity of 25 u/ml using single-point serial dilutions of a standard preparation from the Paul-Ehrlich-Institut (PEI) "or equal to or better than."
- c. The principle must be direct antibody, sandwich EIA in a solid phase microwell.
 - d. Sample size must not be greater than 100 microliters.
 - e. All steps in the method must be adaptable to automation.

VI. Assay specifications for detection of antibody to Hepatitis B Surface Antigen (Anti-HBs)

- a. Must detect antibodies to Hepatitis B Surface Antigen in human serum or plasma.
- b. Must meet the following criteria for a qualitative assay of antibodies to Hepatitis B Surface Antigen.
 1. Must have a 96-well test plate.
 2. Must be a direct, non-competitive enzyme immunoassay based on the use of polystyrene micro wells coated with recombinant HBsAg.
 3. Must be a FDA approved method.
 4. Must show percent agreement with 95% exact confidence intervals with the reference Anti-HBs Assay results.
- c. Sample size must not be greater than 100 microliters.
- d. All steps in the method must be adaptable to automation.

DELIVERY / SHIPPING REQUIREMENTS

1. F.O.B. Destination unless vendor states otherwise in submitted quotation.
2. Reagents must be shipped no more than 3 days after receiving order.

LIFE OF CONTRACT:

This contract is to become effective for a period of one (1) year, or until such "reasonable time" thereafter as is necessary to obtain a new contract. 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 periods.

ORDERING PROCEDURE:

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Spending unit shall issue a written state contract order (Form Number WV-39) to the vendor for commodities covered by this contract, except when purchases are of a dollar amount allowable to be made with the WV State Credit Card (P-Card).

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 COST SHEET

	Test Type Description	Estimated Annual Test Usage	Unit Cost	Total Cost
I.	Hepatitis AIgM	100		
II.	Hepatitis BsAg	2000		
III.	Hepatitis BsAg confirmatory	10		
IV.	Hepatitis BcAb	2000		
V.	Hepatitis BIgM	100		
VI.	Hepatitis BsAb	1000		

TOTAL UNIT COST \$ _____

TOTAL ANNUAL COSTS \$ _____

STATE OF WEST VIRGINIA
Purchasing Division

016

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 owned 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 exceed 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.

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, West Virginia Insurance Commission, or any other state agencies or political subdivision. Furthermore, 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.

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. Vendors should visit www.state.wv.us/admin/purchase/privacy for the Notice of Agency Confidentiality Policies.

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

Vendor's Name: _____

Authorized Signature: _____ Date: _____