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

Request for Quotation

EHP11107

PAGE 1

ADDRESS CORRESPONDENCE TO ATTENTION OF

ROBERTA WAGNER 304-558-0067

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T O

RFQ COPY

Oxford Diagnostic Laboratories 2 Mount Royal Ave., Suite 100 Marlborough, MA 01752 HEALTH AND HUMAN RESOURCES BPH - TUBERCULOSIS CONTROL

350 CAPITOL STREET, ROOM 125 CHARLESTON, WV 25301-3715 304-558-3669

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

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HEALTH AND HUMAN RESOURCES BPH - TUBERCULOSIS CONTROL

350 CAPITOL STREET, ROOM 125 CHARLESTON, WV 25301-3715 304-558-3669

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350 CAPITOL STREET, ROOM 125 CHARLESTON, WV 25301-3715 304-558-3669

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

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HEALTH AND HUMAN RESOURCES BPH - TUBERCULOSIS CONTROL

350 CAPITOL STREET, ROOM 125 CHARLESTON, WV 25301-3715 304-558-3669

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

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OPEN END CONTRACT

SCOPE

The West Virginia Office of Epidemiology & Prevention Services, Division of Tuberculosis Elimination is seeking a qualified vendor to perform Interferon Gamma Release Assay (IGRA) blood testing services to screen for tuberculosis (TB) infection/TB disease statewide.

The contract shall extend for a period of one (1) year, with renewal provisions for two (2) one (1) year periods.

Contract will be awarded based on the lowest "grand total" cost meeting specifications.

All terms and conditions in the written specifications are absolute and cannot be waived. Mandatory terms are indicated by the use of the words shall, will, must, maximum or minimum.

IGRA blood testing must not boost responses measured by subsequent tests (boosting).

IGRA blood testing must not cross react with Bacillus Calmette-Guerin (BCG) vaccine.

Sample collection must be completed at the local health department. No special lab equipment will be required by local health department for collection; i.e., centrifuge, incubator.

Cost sheet must be completed. Bidders must complete the unit price and total cost. Award will be made to the lowest total cost, meeting specification. NOTE: As this is an open end contract, quantities listed are estimates only. It is understood that actual needs of the Agency will be met, whether they be greater than or less than estimates.

Services Under this Contract

- 1. Lab will provide in vitro blood testing.
- 2. Lab must use standard collection tubes that are not specialized.
- 3. Lab must provide to the health departments all blood collection supplies; i.e., tubes, packaging, materials, mailers needed to perform tests.

EHP11107 - Interferon Gamma Release Assay (IGRA)

- 4. Lab must report both qualitative interpretation and quantitative assay measurements to determine result interpretations; i.e., positive, negative.
- 5. Lab must report IGRA blood testing results to the local health departments within 36-72 hours of submission of specimen.
- 6. Bid must include supplies, draw fee, shipping and handling and courier service. Courier service will pick up specimens at the local health departments. A list of the county health departments is attached.
- 7. Lab must provide training at no cost to local health department personnel for proper specimen collection, storing and shipping process.
- 8. Lab must be accredited by the Clinical Laboratory Improvements Act/Amendments (CLIA) and by the College of American Pathologists (CAP) to perform IGRA blood testing services. Tests must be FDA approved.



State of West Virginia RFQ: EHP11107 – Interferon Gamma Release Assay (IGRA)

This document is meant to provide additional support to Oxford Immunotec. Inc.'s ability to fulfill the requirements of the bid.

- 1. Lab will provide in vitro blood testing.
 - Oxford Diagnostic Laboratories offers the T-SPOT. TB test which is an *in vitro* diagnostic test for the detection of *M. tuberculosis* infection.
- 2. Lab must use standard collection tubes that are not specialized
 - The T-SPOT. TB test uses a standard 6ml lithium heparin or sodium heparin (green top) collection tube. No specialized tubes are required and there are no specialized collection procedures required, such as drawing the specialized tubes in a specific order. The T-SPOT. TB test does not require shaking of the collection tubes at the correct intensity of shaking and for a specific amount of time. The use of a purge tube when using a butterfly needle is not required with the test offered by Oxford Diagnostic Laboratories. When filling the standard collection tubes it is not necessary to ensure that the tubes are filled within +/- .2mls of a specific fill volume to avoid erroneous results. All that is required is standard phlebotomy practices with a standard collection tube.
- 3. The lab must provide to the Health Departments all blood collection supplies; i.e., tubes, packing materials, mailers needed to perform the tests.
 - The cost of these supplies along with the shipping cost is included in the price of the test.
- 4. Lab must report both qualitative interpretation and quantitative assay measurements to determine result interpretations; i.e., Positive, Negative.
 - Oxford Diagnostic Laboratories test result reporting protocol is to provide both a qualitative result (i.e., Positive, Negative) and a quantitative result (the number of spots per specific antigen and control wells). The Centers for Disease Control and Prevention specifically recommends in the Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium tuberculosis Infection United States, 2010 that "Both the standard qualitative test interpretation and quantitative assay measurements should be reported together with the criteria used for test interpretation. This will permit more refined assessment of results and promote understanding of the tests"
- 5. Lab must report IGRA blood testing results to the local health department within 36 72 hours of submission of specimen.
 - Oxford Diagnostic Laboratories will report the IGRA blood test result (T-SPOT.TB test) to the local health department within 36 to 48 hours of shipment of specimens to the laboratory. Specimens are to be shipped the day of collection.



- Bid must include supplies, draw fee, shipping and handling and courier service. Courier service will pick up specimens at the local health departments. A list of the county health departments is attached.
 - Oxford Diagnostic Laboratories will provide the collection tubes. We assume that the county health departments will draw the specimen at the local health departments. Patients will not be required to go to an off-site draw location. Drawing samples by employees of the county health departments will eliminate costs associated with a draw fee. Shipping and handling and costs associated with a courier service are included in the price per test. Oxford Diagnostic Laboratories uses FedEx as our courier service. FedEx will pick up the specimens at the local health departments.
- 7. Lab must provide training at no cost to local health departments personnel for proper specimen collection, storing and shipping process.
 - Oxford Diagnostic Laboratories will provide training at no cost to the local health departments personnel on the proper collection of specimens, storing of specimens and the shipping process.
- 8. Lab must be accredited by the Clinical Laboratory Improvements Act/Amendments (CLIA) and by the College of American Pathologists (CAP) to perform IGRA Blood testing services. Tests must be FDA approved.
 - Oxford Diagnostic Laboratories is both CLIA certified (CLIA Number 22D1099017) and CAP accredited (LAP Number 7726056). The T-SPOT. TB Test was approved by the FDA in July of 2008.

In addition, based on the bid specifications as listed in this bid it appears that any laboratory responding to this bid would not be eligible to receive the award if they are planning to offer the health departments the QuantiFERON Gold - In Tube test (QFT-IT). This is based on the fact that the QFT-IT test uses three specialized collection tubes (Bid Spec # 2). These tubes are specifically manufactured for the In-Tube test and cannot be used for any other test. Their specialized procedure requires the following:

- Phlebotomist must draw three specialized tubes.
- The three specialized tubes must be drawn in a specific order.
- A specific amount of blood must be drawn in each tube +/- .2ml. Under or overfilling may lead to erroneous results.
- Once the specialized collection tubes are filled the phlebotomist is required to vigorously shake the tubes up and down for 5 seconds (10 times).
- A purge tube is required when a butterfly needle is used to draw the specimen.

A laboratory offering the In-Tube test would not meet the requirement outlined in the # 2 bid specification.

COST SHEET FOR EHP11107

Itam #	Approx Applial Lisage	Description	Unit Price	. Total Cost
# 11231	אלוויים המפרי ייטומלי			
(-1	800 tests processed	Interferon Gamma Release Assay (IGRA) blood testing	20. bh\$	\$ 34,200,50

Award will be made to vendor with the lowest overall cost who meets specifications.

Vendor Name: Oxtord (m

Vendor Signature:

Date:

/John Helly - Operations Director Oxford Immynofec Inc.

NOTE: THIS IS AN OPEN END CONTRACT. THE NUMBER OF TESTS ARE ESTIMATES ONLY. ACTUAL NEEDS OF THE AGENCY WILL BE PROVIDED, WHETHER IT BE GREATER THAN OR LESS THAN ESTIMATES.

WY COUNTY HEALTH DEPARTMENT LIST

Barbour County Health Department

23 Wabash Avenue Philippi, West Virginia 26416

Beckley-Raleigh Health Department

1602 Harper Road Beckley, West Virginia 25801

Berkeley County Health Department

800 Emmett Rousch Drive Martinsburg, West Virginia 25401

Boone County Health Department

Post Office Box 209 Madison, West Virginia 25130

Braxton County Health Department

495 Old Turnpike Road Sutton, West Virginia 26601

Brooke County Health Department

204 Courthouse Square Wellsburg, West Virginia 26070

Cabell-Huntington Health Department

703 7th Avenue Huntington, West Virginia 25701

Clay County Health Department

Post Office Box 36 Clay, West Virginia 25043

Doddridge County Health Department

Route 2, Box 54 West Union, West Virginia 26456

Fayette County Health Department

202 Church Street Fayetteville, West Virginia 25840

Gilmer County Health Department

809 Mineral Road Glanville, West Virginia 26351

Grafton-Taylor Health Department

Post Office Box 15 Grafton, West Virginia 26354

Grant County Health Department

Post Office Box 608, Route 28 Petersburg, West Virginia 26847

Greenbrier County Health Department

9207 Seneca Trail South Ronceverte, West Virginia 24970

Hampshire County Health Department

HC 71, Box 9 Augusta, West Virginia 26704

Hancock County Health Department

Post Office Box 578

New Cumberland, West Virginia 26047

Hardy County Health Department

411 Spring Avenue, Suite 101 Moorefield, West Virginia 26836

Harrison-Clarksburg Health Department

330 West Main Street Clarksburg, West Virginia 26301

Jackson County Health Department

504 South Church Street Ripley, West Virginia 25271

Jefferson County Health Department

1948 Wiltshire Road, Suite 1 Kearneysville, West Virginia 25430

Kanawha-Charleston Health Department

Post Office Box 927 Charleston, West Virginia 25323

Lewis County Health Department

125 Court Avenue WESTON, West Virginia 26452

Lincoln County Health Department

Post Office Box 527 Hamlin, West Virginia 25523

Logan County Health Department

300 Stratton Street, Room 203 Logan, West Virginia 25601

Marion County Health Department

300 Second Street Fairmont, West Virginia 26554

Marshall County Health Department

Post Office Box 429 Moundsville, West Virginia 26041

Mason County Health Department

216 Fifth Street
Point Pleasant, West Virginia 25550

McDowell County Health Department

Post Office Box 218 Wilcoe, West Virginia 24895

Mercer County Health Department

Route 2, Box 382 Bluefield, West Virginia 24701

Mid-Ohio Valley Health Department

211 Sixth Street
Parkersburg, West Virginia 26101

Mineral County Health Department

Route 3, Box 3045 Keyser, West Virginia 26726

Mingo County Health Department

Post Office Box 1096 Williamson, West Virginia 25661

Monongalia County Health Department

453 Van Voorhis Road Morgantown, West Virginia 26505

Monroe County Health Department

Post Office Box 590 Union, West Virginia 24983

Morgan County Health Department

187 South Green Street, Suite 2 Berkeley Springs, West Virginia 25411

Nicholas County Health Department

One Stevens Road
Summersville, West Virginia 26651

Pendleton County Health Department

Post Office Box 520 Franklin, West Virginia 26807

Pocahontas County Health Department

900 Tenth Avenue Marlinton, West Virginia 24954

Preston County Health Department

106 West Main Street, Suite 203 Kingwood, West Virginia 26537

Putnam County Health Department

1401 Hospital Drive, Sulte 304 Hurricane, West Virginia 25526

Randolph County Health Department

201 Henry Avenue Elkins, West Virginia 26241

Summers County Health Department

Post Office Box 898 Hinton, West Virginia 25951

Tucker County Health Department

206 1/2 Third Street Parsons, West Virginia 26287

Upshur-Buckhannon Health Department

15 North Locust Street

Buckhannon, West Virginia 26201

Wayne County Health Department

Post Office Box 368 Wayne, West Virginia 25570

Webster County Health Department

112 Bell Street, Sulte C Webster Springs, West Virginia 26288

Wetzel-Tyler Health Department

425 South Fourth Avenue Paden City, West Virginia 26159

Wheeling-Ohio Health Department

1500 Chapline Street Wheeling, West Virginia 26003

Wyoming County Health Department

Post Office Box 1679 Pineville, West Virginia 248741679

REQNO. EMP 11107

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 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.

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 Immunotec. Inc. Authorized Signature: County of Middlesek Taken, subscribed, and sworn to before me this 7 day of March My Commission expires AFFIX SEAL HERE



MARK LOZIER

Notary Public Commonwealth of Massachusetts My Commission Expires March 7, 2014



RFQ COPY

Oxford Diagnostic Laboratories

2 Mount Royal Ave, Suite 100

Marlborough, MA 01752

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

Request for Quotation

RECNUMBER EHP11107

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ROBERTA WAGNER 304-558-0067

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DESCRIPTION STREET, ROOM 125 CHARLESTON, WV 25301-3715 304-558-3669

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VENDOR

RFQ COPY

TYPE NAME/ADDRESS HERE

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

Request for Quotation

P

EHP11107

2

ADDRESS CORRESPONDENCE TO ATTENTION OF

ROBERTA WAGNER 304-558-0067

HEALTH AND HUMAN RESOURCES BPH - TUBERCULOSIS CONTROL

350 CAPITOL STREET, ROOM 125 CHARLESTON, WV

25301-3715 304-558-3669

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

Request for Quotation

EHP11107

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304-558-3669

ROBERTA WAGNER 304-558-0067

CHARLESTON, WV 25301-3715

HEALTH AND HUMAN RESOURCES BPH - TUBERCULOSIS CONTROL 350 CAPITOL STREET, ROOM 125

TYPE NAME/ADDRESS HERE

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Question: Is it OK to submit additional documentation of the lab's ability to meet the requirements of the bid?

Answer: Yes, it is acceptable to submit additional documentation of the lab's ability to meet the requirements of the bid. Bids must only meet the specifications as written in the Request for Quotations to be considered.