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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

RFQ NUMBER MCH70449

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ROBERTA WAGNER
304-558-0067

8 H - P T O HEALTH AND HUMAN RESOURCES BPH - MCH WAREHOUSE

900 BULLITT STREET CHARLESTON, WV 25301 304

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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. 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 Viginia 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.
- 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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900 BULLITT STREET CHARLESTON, WV

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Part 1 PURPOSE

1.1 PURPOSE

The purpose of this Request for Quotation (RFQ) is to engage the services of a vendor to provide cytology services for the Office of Maternal, Child and Family Health, Family Planning Program and Breast and Cervical Cancer Screening Program located at 350 Capitol Street, Room 427, Charleston, West Virginia.

1.2 BACKGROUND

Within the West Virginia Department of Health and Human Resources (WVDHHR), Bureau for Public Health, the Office of Maternal, Child and Family Health (OMCFH) offers preventive health care and screening services through a community-based network of health care providers throughout the State. The Family Planning Program (FPP) provides comprehensive reproductive health care, medical services, counseling and education, contraceptive methods, and laboratory services, including cytology screening. Family Planning Program services are offered through a statewide network of 145 participating provider agencies.

The Breast and Cervical Cancer Screening Program (BCCSP) provides early detection, screening, and referral services for breast and cervical cancers which include a pelvic examination, Pap test collection, clinical breast examination, patient education and referrals for mammography and other appropriate diagnostic and treatment services. These services are offered through a network of 165 participating provider agencies, most of which are also providers of the Family Planning Program.

Part 2 CONTRACTUAL SERVICES

2.1 REQUIRED SERVICES

The vendor will provide cytology services for approximately 50,000 Pap tests per year to include: specimen accession, specimen processing, hrHPV testing, provision of cytotechnologists, pathologist(s) coverage, specimen evaluation, record keeping, and quality assurance activities and reports.

Specimen Processing, Evaluation, and Reporting:

A. The vendor will provide participating FPP and BCCSP providers all supplies necessary for collection and submission of both Conventional and Liquid-Based Pap test specimens. These supplies shall include, but not be limited to, requisition forms, mailers, superfrost slides that provide space for writing the patient's name, cervical scrapers and cytobrushes.

- B. The vendor will require that the following information be submitted with the specimen:
 - 1. Clinic code number
 - 2. Patient social security number
 - 3. Patient name
 - 4. Clinic visit date (date specimen collected)
 - 5. Age
 - Race
 - 7. Marital status
 - 8. Specimen type
 - 9. Date of previous Pap test
 - 10. Class of previous Pap test
 - 11. Date of last menstrual period
 - 12. Date of pelvic surgery
 - 13. Date of pelvic radiation
 - 14. Date of endocrine within last 6 months
 - 15. Date of biopsy
 - 16. Number of pregnancies
 - 17. Menopausal status
 - 18. History of oral contraceptive usage
 - 19. Other pertinent medical history
 - 20. Name and address of program provider
- C. The vendor will examine, interpret, and report results on all Pap tests submitted by the FPP and BCCSP Program providers not to exceed ten (10) calendar days from the date the specimens are received by the vendor. For specimens requiring HPV testing, the vendor will examine, interpret and report results not to exceed twenty (20) calendar days from the date the specimens are received by the vendor.
- D. All specimens must be stained, mounted, and adequately labeled showing unique I.D. number and patient name.
- E. The vendor will be responsible for reporting specimen test results, using the Bethesda 2001 System. Results will be reported to the ordering physician/clinic at the address supplied by the Program provider.
- F. The vendor assumes all responsibility and liability for reading and processing of all Pap tests.
- G. The vendor must have written criteria for rejection of specimens and for categorizing specimens as unsatisfactory.

- Η. The vendor must track patients with previous unsatisfactory Pap results to determine if appropriate repeat specimens are submitted.
- The vendor must retain negative and unsatisfactory slides for five (5) Ι. years and positive slides for twenty (20) years.

Data Requirements:

- The vendor must provider the FPP and BCCSP with the following data on a monthly basis:
 - Total number of Pap tests received and interpreted as well as numerical breakdown of the number of Conventional and Liquid-**Based Pap tests**
 - Total number of unsatisfactory Pap tests and a numerical breakdown as to why the Pap tests were unsatisfactory
 - Total number of tests with no endocervical cells
 - Total number of tests within normal limits
 - Total number of atypical squamous cells of undetermined significance
 - Total number of atypical glandular cells of undetermined significance
 - Total number of low grade squamous intraepithelial lesion (CIN I)
 - Total number of high grade squamous intraepithelial lesion (CIN II) and (CIN III)
 - Total number of invasive carcinomas
 - Total number of hrHPV tests performed on BCCSP clients
- The vendor agrees to supply the FPP and BCCSP with computer K. diskettes, appropriate hard copy, and on-line access containing designated information related to specimen results for the purpose of patient tracking, upon request. To the extent consistent with applicable laws and regulations, the parties hereto shall maintain patient test records in confidence and comply with privacy, patient access and confidentiality provisions.
- The vendor must respond to all requests for statistical information or L. data within five (5) working days.

Quality Assurance:

- M. The vendor must allow the FPP and BCCSP and/or any designated cytotechnologist to have access to any slides and records from the programs for review purposes, within five (5) working days.
- N. The vendor must allow any cytotechnologist designated by the programs to review the cytology procedure manual for the quality control and quality assurance programs, within five (5) working days.
- O. The vendor is required to meet all CLIA requirements and to obtain CLIA certification. The vendor agrees to follow all rules and regulations in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88).
- P. The vendor must have a CLIA-88 qualified pathologist as director (technical supervisor), qualified cytology general supervisor, and qualified cytotechnologist(s) on site.
- Q. The vendor's staff shall be available upon request to consult with participating providers by telephone during normal working hours (9:00am-5:00pm) to discuss the vendor's procedures and to explain test results. Consultation will include on-site specimen collection and handling training if deemed necessary.
- R. The vendor must retrieve stored FPP or BCCSP Pap tests the same day as requested by either program.
- S. The vendor must document the circulation, referral, transfer, and receipt of original Pap tests.
- T. The vendor must have documentation including acknowledgment of receipt, when slides from the programs are loaned to special programs such as the College of American Pathologists Interlaboratory Comparison Program in Cervical Vaginal Cytology.
- U. The vendor must show documentation of a maintenance schedule for equipment and microscopes and implement said schedule.
- V. The vendor must show documentation of and perform at least an annual review of all procedures in the cytology section by current laboratory director or designee.

W. The vendor must show documentation for continuing education for the staff cytotechnologist(s).

2.2 ADMINISTRATIVE AND OPERATIONAL REQUIREMENTS

- The vendor shall designate a project administrator. The vendor's project administrator shall report to the FPP and BCCSP program directors regarding all matters related to cytology services.
- 2. The vendor shall provide its written procedures for rejection of specimens and categorizing specimens as unsatisfactory consistent with the requirements of this RFQ, including but not limited to those requirements in RFQ Section 2.1 above.
- 3. The vendor shall comply with all applicable provisions of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, 110 Stat. 1936 (HIPAA) and regulations promulgated thereunder (HIPAA Regulations), if applicable.

2.3 PRICING OF SERVICES

The vendor's quotation must include bids for cytology screening of Pap test for OMCFH as follows:

PRICE PER TEST	(LINE ITEM)
DESCRIPTION:	Cytology services – Conventional Pap test
QUANTITY: PRICE:	Approx. 48,000 Pap tests per year \$ per Conventional test
ITEM 002 DESCRIPTION:	Cytology convices Liquid Recod Dan test
QUANTITY:	Cytology services - Liquid Based Pap test Approx. 11,520 Pap tests per year
PRICE: Liquid-Based Test	\$ per Liquid-Based test Technology:
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ITEM 003	
DESCRIPTION:	HPV/DNA TESTING (high-risk only)
QUANTITY: PRICE:	Approx. 333 HPV/DNA tests (high-risk only) per year \$ per HPV/DNA test
HPV/DNA Test Tec	· · · · · · · · · · · · · · · · · · ·

PART 3 GENERAL TERMS AND CONDITIONS

3.1 REJECTION OF QUOTATION/BIDS

The State reserves the right to accept any or all quotations/bids if it is determined to be in the State's best interests. The Department may withdraw this RFQ at any time for any reason. Receipt of a quotation confers no rights upon the bidder. A contract based upon this RFQ may or may not be awarded. Then, said contract must be approved as to form by the Attorney General's Office.

3.2 SUBCONTRACTS PROHIBITED

The successful vendor will be solely responsible for all work performed under the contract. The vendor shall not enter into written or oral subcontracts for performance of work under the contract without written permission of the agency. Vendor must have been in business and maintained a business license to perform cytology services within the past five (5) years.

3.3 COMPLIANCE WITH LAW AND REGULATIONS

The vendor shall pay any sales, use, and personal property taxes arising out of this contract and the transactions contemplated thereby. Any other taxes levied upon this contract, the transaction, or the equipment, or services delivered pursuant hereto shall be borne by the vendor.

The vendor shall comply with all applicable laws, rules and regulations including, but not limited to those relating to State and Federal labor laws and laws, rules and policies related to the WVDHHR.

The vendor shall be responsible for compliance with all workplace safety requirements, including, but not limited to compliance with applicable OSHA and all other applicable environmental agency requirements for storage, labeling, handling and disposal of all items used in the performance of duties associated with cytology services. The vendor shall appropriately train its employees in proper workplace safety requirements.

3.4 RECORD RETENTION AND CONFIDENTIALITY

The vendor will maintain financial records pertaining to the contract for five (5) years following the end of the State fiscal year during which the contract is terminated or State and Federal audits of the contract have been completed, whichever is later. If questions about accounting records arise during an audit, the accounting records pertaining to the contract shall be retained until resolution of all pending audit questions and for one (1) year following the termination of any litigation relating to the contract if the litigation has not

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terminated within the above five (5) year period. Accounting records and procedures shall be subject to State and Federal approval.

3.5 CHANGES IN SCOPE

Formal contract amendments and change orders will be negotiated by the Department with the vendor, whenever necessary, to address changes to the terms and conditions, costs of, or scope of work included under the contract. An approved contract amendment means one approved by the WV Department of Health and Human Resources, the WV Department of Administration, and all other applicable State agencies prior to the effective date of such amendment. An approved contract amendment is required whenever the change affects the payment provision and the scope of work performed by the vendor. Vendor shall not change the scope of services to be conducted without the approval of the State. As soon as possible after receipt of a written change request, but in no event more than thirty (30) days thereafter, the vendor shall provide the State a written statement that the change has no price impact on the contract or if there is a price impact, provide a description of the price increase or decrease involved in implementing the change.

3.6 TERMINATION OF THE CONTRACT

The Department may terminate a contract resulting form this RFQ at any time that the vendor fails to carry out its responsibilities under the terms of any contract resulting from this RFQ to satisfaction of the Department, Bureau or Office of Maternal, Child and Family Health.

The Department shall provide the vendor with notice of conditions endangering performance. If after such notice the vendor fails to remedy this conditions contained in this notice, within the time period contained in the notice, the Department shall issue the vendor an order to stop all work immediately. The Department shall be obligated only for services rendered and accepted prior to the date of the notice of termination.

The contract may also be terminated upon mutual agreement of the parties with thirty (30) days prior notice.

3.7 INVOICE AND PAYMENTS

The vendor shall submit separate monthly invoices, in arrears, to the FPP and BCCSP for all services provided pursuant to the terms of the contract. State law forbids payment of invoices prior to receipt of services.

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AFFIDAVIT

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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:

The vendor must be licensed in accordance with any and all state requirements to do business with the state of West Virginia.

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:

No Debt Affidavit Revised 02/08/06