



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

PAGE
1

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

*930092641 877-549-2642
 CYTOLOGY SERVICES OF MARYLAND
 13900 LAUREL LAKES AVENUE

LAUREL MD 20707-5092

VENDOR

HEALTH AND HUMAN RESOURCES
 BPH - MCH WAREHOUSE

900 BULLITT STREET
 CHARLESTON, WV
 25301 304-558-3417

SHIP TO

DATE PRINTED 09/25/2006	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
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BID OPENING DATE: 10/25/2006 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT. NO.	ITEM NUMBER	UNIT PRICE	AMOUNT
0001	1	JB		948-21		
<p>REQUEST FOR QUOTATION OPEN-END BLANKET ORDER</p> <p>THE WEST VIRGINIA DIVISION OF PURCHASING IS SOLICITING BIDS FOR DHHR, THE OFFICE OF MATERNAL, CHILD AND FAMILY HEALTH, FAMILY PLANNING PROGRAM AND BREAST AND CERVICAL CANCER SCREENING PROGRAM TO PROVIDE CYTOLOGY SERVICES.</p> <p>THE PROGRAM IS LOCATED AT 350 CAPITOL STREET, ROOM 427, CHARLESTON, WEST VIRGINIA.</p> <p>PLEASE NOTE THE FOLLOWING ATTACHMENTS: 1. MCH70449 SPECIFICATIONS 2. AFFIDAVIT</p> <p>CYTOLOGY SERVICES</p> <p>OPEN END CONTRACT</p> <p>TO PROVIDE AN OPEN-END CONTRACT FOR CYTOLOGY SERVICES FOR THE OFFICE OF MATERNAL, CHILD & FAMILY HEALTH, FAMILY PLANNING PROGRAM AND BREAST & CERVICAL CANCER</p>						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE <i>Michael...</i>	TELEPHONE 1-877-549-2642	DATE 10/23/06
--------------------------------	-----------------------------	------------------

TITLE Executive Director for CSM	FEIN 52-1575694	ADDRESS CHANGES TO BE NOTED ABOVE
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WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

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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

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				SCREENING PROGRAM PER THE ATTACHED SPECIFICATIONS.		
				THE VENDOR WILL PROVIDE CYTOLOGY SERVICES TO INCLUDE: SPECIMEN ACCESSION, SPECIMEN PROCESSING, HRHPV TESTING, PROVISION OF CYTOTECHNOLOGIST, PATHOLOGIST(S) COVERAGE, SPECIMEN EVALUATION, RECORD KEEPING, AND QUALITY ASSURANCE ACTIVITIES AND REPORTS. ALL QUOTATIONS MUST MEET THE MANDATORY REQUIREMENTS OF THIS RFQ AS DESCRIBED IN THE ATTACHED ADMINISTRATIVE AND CONTRACTUAL TERMS.		
				EXHIBIT 3		
				LIFE OF CONTRACT: THIS CONTRACT BECOMES EFFECTIVE ON NOVEMBER 1, 2006 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.		
				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.		
				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		

SEE REVERSE SIDE FOR TERMS AND CONDITIONS			
SIGNATURE	TELEPHONE	DATE	
<i>[Signature]</i>	1-877-549-2642	10/23/06	
TITLE	FEDIN	ADDRESS CHANGES TO BE NOTED ABOVE	
Executive Director for	52-1575694		

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<p>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 SERVICE 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</p>						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE	TELEPHONE	DATE
<i>Michael E. Lewis</i>	1-877-549-2642	10/23/06
TITLE	ADDRESS CHANGES TO BE NOTED ABOVE	
Executive Director for CSM	52-1575694	

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<p>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</p> <p>INQUIRIES: WRITTEN QUESTIONS SHALL BE ACCEPTED THROUGH CLOSE OF BUSINESS ON OCTOBER 6, 2006. 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> <p>ROBERTA WAGNER DEPARTMENT OF ADMINISTRATION PURCHASING DIVISION 2019 WASHINGTON STREET, EAST CHARLESTON, WV 25311 FAX: 304-558-4115 E-MAIL: RWAGNER@WVADMIN.GOV</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>						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS			
SIGNATURE	TELEPHONE	DATE	
<i>Michael P. ...</i>	1-877-549-2642	10/23/06	
TITLE	ADDRESS CHANGES TO BE NOTED ABOVE		
Executive Director for CSM	52-1575694		

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<p>A. APPLICATION IS MADE FOR 2.5% PREFERENCE FOR THE REASON CHECKED:</p> <p>(N/A) 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>(N/A) 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 CERTIFICATION; OR</p> <p>(N/A) 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>(N/A) 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</p>						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE <i>Michael R. [Signature]</i>	TELEPHONE 1-877-549-2642	DATE 10/23/06
--	-----------------------------	------------------

TITLE Executive Director for CSM	FEIN 52-1575694	ADDRESS CHANGES TO BE NOTED ABOVE
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Post Office Box 50130
Charleston, WV 25305-0130



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

PAGE
 6

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

*930092641 877-549-2642
 CYTOLOGY SERVICES OF MARYLAND
 13900 LAUREL LAKES AVENUE

LAUREL MD 20707-5092

HEALTH AND HUMAN RESOURCES
 BPH - MCH WAREHOUSE

900 BULLITT STREET
 CHARLESTON, WV
 25301 304-558-3417

VENDOR

SHIP TO

DATE PRINTED 09/25/2006	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
BID OPENING DATE: 10/25/2006		BID OPENING TIME 01:30PM		

LINE	QUANTITY	UOP	CAT NO	ITEM NUMBER	UNIT PRICE	AMOUNT
<p>THE STATE CONTINUOUSLY FOR THE TWO YEARS IMMEDIATELY PRECEDING SUBMISSION OF THIS BID; OR, (NA) 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 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>						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE <i>Michael H. [Signature]</i>	TELEPHONE 1-877-549-2642	DATE 10/23/06
TITLE Executive Director for	FEIN 52-1575694	ADDRESS CHANGES TO BE NOTED ABOVE

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

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Request for Quotation

RFQ NUMBER
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VENDOR

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<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 PURCHASIN DIVISION IN WRITING IMMEDIATELY.</p> <p>BIDDER: <u>AMSI d/b/a Cytology Services of Maryland (CSM)</u></p> <p>DATE: <u>10/23/06</u></p> <p>SIGNED: </p> <p>TITLE: <u>Executive Director for CSM</u></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>THE BID SHOULD CONTAIN THIS INFORMATION ON THE FACE OF THE ENVELOPE OR THE BID MAY NOT BE CONSIDERED:</p> <p>SEALED BID</p>						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS			
SIGNATURE 	TELEPHONE 1-877-549-2642	DATE 10/23/06	
TITLE Executive Director for CSM	FEIN 52-1575694	ADDRESS CHANGES TO BE NOTED ABOVE	

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BUYER:-----ROBERTA WAGNER/FILE 22----- RFQ. NO.:-----MCH70449----- BID OPENING DATE:-----10/25/06----- BID OPENING TIME:-----1:30 PM----- PLEASE PROVIDE A FAX NUMBER IN CASE IT IS NECESSARY TO CONTACT YOU REGARDING YOUR BID: (301) 206-2595----- CONTACT PERSON (PLEASE PRINT CLEARLY): Suzanne Sierra-Bodmer----- ***** THIS IS THE END OF RFQ MCH70449 ***** TOTAL: \$514,881.00						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS			
SIGNATURE <i>Michael A. Sierra</i>	TELEPHONE 1-877-549-2642	DATE 10/23/06	
TITLE Executive Director for CSM	FEIN 32-1575694	ADDRESS CHANGES TO BE NOTED ABOVE	

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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
 6. 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.

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

Data Requirements:

- J. The vendor must provide 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
- K. The vendor agrees to supply the FPP and BCCSP with computer 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.
- L. The vendor must respond to all requests for statistical information or 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

1. 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)

ITEM 001

DESCRIPTION: Cytology services – Conventional Pap test

QUANTITY: Approx. 48,000 Pap tests per year

PRICE: \$ 6.75 per Conventional test

ITEM 002

DESCRIPTION: Cytology services - Liquid Based Pap test

QUANTITY: Approx. 11,520 Pap tests per year

PRICE: \$ 15.50 per Liquid-Based test

Liquid-Based Test Technology: Cytoc ThinPrep Pap Test

ITEM 003

DESCRIPTION: HPV/DNA TESTING (high-risk only)

QUANTITY: Approx. 333 HPV/DNA tests (high-risk only) per year

PRICE: \$ 37.00 per HPV/DNA test

HPV/DNA Test Technology: Digene Hybrid Capture 2 Test for High-Risk HPV

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

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 from 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.

A F F I D A V I T

016

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 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.

LICENSING:

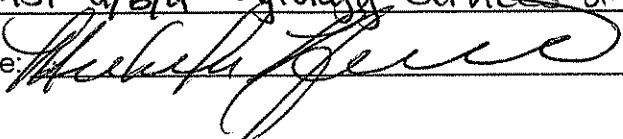
The vendor must be licensed in accordance with any and all state requirements to do business with the state of West Virginia.

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: AMSI d/b/a Cytology Services of Maryland (CSM)

Authorized Signature:  Date: 10/23/06



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

PAGE
 1

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

*930092641 877-549-2642
 CYTOLOGY SERVICES OF MARYLAND
 13900 LAUREL LAKES AVENUE

LAUREL MD 20707-5092

HEALTH AND HUMAN RESOURCES
 BPH - MCH WAREHOUSE

900 BULLITT STREET
 CHARLESTON, WV
 25301 304-558-3417

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PAID OCT 16 2006

DATE PRINTED 10/10/2006	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
BID OPENING DATE: 10/25/2006	BID OPENING TIME			01:30PM

LINE	QUANTITY	UOP	CAT NO	ITEM NUMBER	UNIT PRICE	AMOUNT
*****ADDENDUM NO. 1***** 1. QUESTIONS AND ANSWERS 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. *****END OF ADDENDUM NO. 1*****						
0001	1	JB		948-21		
				CYTOLOGY SERVICES		
***** THIS IS THE END OF RFQ MCH70449 ***** TOTAL						\$ 514,881.00

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE: *[Signature]* TELEPHONE: 1-877-549-2642 DATE: 10/23/06

TITLE: Executive Director for CSM FEIN: 52-1575694 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

ADDENDUM #1

Type of Purchase

ADDENDUM IS BEING SUBMITTED TO ANSWER VENDOR QUESTIONS

1. PART 2, PARAGRAPH K: PLEASE VERIFY THAT COMPUTER DISKETTES, HARD COPIES AND ON-LINE ACCESS" ARE ALL REQUIRED.

RESPONSE: YES, ALL ARE REQUIRED. DISKETTES AND HARD COPIES ARE SENT TO FAMILY PLANNING PROGRAM AND BCCSP PROGRAM ADMINISTRATIVE OFFICES. ONLINE ACCESS IS REQUIRED FOR FAMILY PLANNING PROGRAM AND BCCSP PROGRAM ADMINISTRATIVE OFFICES, IN ADDITION TO ALL PARTICIPATING SERVICE PROVIDER SITES.

2. PART 2, PARAGRAPH K: DOES EACH FP SITE AND BCSSP SITES RECEIVE A DISKETTE ON A REGULAR BASIS (E.G. MONTHLY) OR UPON REQUEST?

RESPONSE: NO. SEE RESPONSE#1

3. PART 2, PARAGRAPH K: DO ALL OF THE FPP AND BCCSP SITES HAVE ON-SITE INTERNET ACCESSIBILITY?

RESPONSE: MOST FAMILY PLANNING AND BCCSP PROGRAM PROVIDER SITES HAVE INTERNET ACCESS, WITH A FEW EXCEPTIONS.

4. PART 2, PARAGRAPH K: WILL ALL OF THE FPP AND BCCSP SITES REQUIRE ON-LINE ACCESS TO PATIENT REPORTS?

RESPONSE: ALL FAMILY PLANNING BCCSP SITES SHOULD HAVE ACCESS TO ONLINE REPORTS. SOME MAY OPT NOT TO USE THE ONLINE REPORTS.

5. PART 2, PARAGRAPH 1: CLIA REGULATIONS MANDATE A SLIDE RETENTION OF FIVE (5) YEARS. WILL A 20-YEAR RETENTION OF ELECTRONICALLY STORED IMAGES OF CELLULAR ABNORMALITIES FOUND ON POSITIVE SLIDES MEET THE CONTRACT REQUIREMENT FOR A POSITIVE SLIDE RETENTION OF 20 YEARS?

RESPONSE: YES

6. PAGE 1 OF MCH70449, TITLE SECTION, "OPEN-END BLANKET ORDER". DOES "OPEN-END BLANKET ORDER" MEAN THAT THIS CONTRACT MAY BE AWARDED TO MULTIPLE LABS? PLEASE DEFINE STATEMENT.

7. NO IT DOES NOT MEAN THAT IT WILL BE AWARDED TO MULTIPLE LABS. THIS MEANS THAT THE CONTRACT IS OPEN ENDED IN THAT IT'S FOR UNLIMITED DOLLARS AND THERE'S NO DEFINITE QUANTITY OF TESTS SET FOR THE CONTRACT.

AMSI d/b/a
Vendor: Cytology Services of Maryland
(CSM)

Spending Unit:

Requisition No.: MCH70449

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 the addendum(s) is cause for rejection of bids.


Signature

AMSI d/b/a Cytology Services of
Company Maryland (CSM)

10/23/06
Date

CSM

Description of Laboratory Services

RFQ# MCH70449
State of West Virginia

October 19, 2006

AMSI d/b/a

Cytology Services of Maryland (CSM)

13900 Laurel Lakes Ave, Ste 100, Laurel, MD 20707-5092
Ph: 301-206-2555, Fx: 301-206-2595



CSM

13900 Laurel Lakes Avenue
Laurel, Maryland 20707-5092
Phone: 301-206-2555 • Fax: 301-206-2595

Cytology & Histology Services

ELLEN D. MANLUCU, M.D.
PATHOLOGIST AND DIRECTOR

CLIA ID NO.: 21D0649632
CAP NO.: 13479-01
MARYLAND LAB PERMIT #080



SERVICES PROVIDED

Location

Cytology Services of Maryland (CSM) will provide an off-site reference clinical laboratory for tests in cytology and immunology for the Office of Maternal, Child and Family Health, Family Planning Program and Breast and Cervical Cancer Screening Program in West Virginia. These tests will be performed at the laboratory's testing facility located at 13900 Laurel Lakes Avenue, Suite 100, Laurel, Maryland 20707-5092.

Licensure Accreditation

Cytology Services of Maryland is accredited by the College of American Pathologists, licensed by the State of Maryland and the Center for Medicare and Medicaid Services (CMS) [formally HCFA] under the Clinical Laboratory Improvement Act of 1988. Our pathologists are board certified in anatomical, clinical pathology and cytopathology. All cytotechnologists have passed the American Society of Clinical Pathologists National Board Registry and are ASCP certified. All cytotechnologists are enrolled in the College of American Pathologists Proficiency Testing Program and the State of Maryland Proficiency Testing Program.

Background

Cytology Services of Maryland is an established, state-of-the-art laboratory located in Laurel, Maryland. Specializing in the field of anatomic pathology, we have served the medical community nationwide for over 40 years.

Cytology Services has earned the reputation as the "**Gold Standard**" through quality diagnostic and customer service – quality that extends beyond laboratory expertise to include our pathologists, consultations of problem cytology and virology cases and research, as well as technical assistance.

In 1990 Cytology Services of Maryland began utilizing the new thin-layer cytology produced and developed by Cytyc Corporation. Cytology Services of Maryland gained invaluable expertise in the field of thin-layer cytology to become one of the most experienced laboratories in the nation utilizing this new technology. In 1995, Cytology Services of Maryland began utilizing the Digene Hybrid Capture technology for the detection of Human Papilloma Viruses. Through our association with Digene Corporation, which continues today, Cytology Services has assisted in many research projects with Digene Corporation in developing its new technologies. In 1999, following FDA approval, Cytology Services became the second laboratory in the nation qualified to perform the new Hybrid Capture 2 HPV testing. Cytology Services of Maryland became the *first* laboratory in Maryland, Washington, D.C. and Northern Virginia, to acquire the newly FDA-approved *Cytyc ThinPrep® Imaging System*, which further improves the performance of the *ThinPrep® Pap Test™*. With these new technologies we have continued our reputation as the "**Gold Standard**" in anatomic pathology laboratories.



The "**Gold Standard**" begins with the expertise of our professional staff. Our pathologists are board certified in anatomical, clinical pathology and cytopathology. Our cytotechnologists have passed the American Society of Clinical Pathologists National Board Registry and are A.S.C.P. certified. Our supervising cytotechnologists have an average of over **30 years** of experience in their profession. Continuing education requirements for our cytotechnologists exceed the standards established by the State of Maryland. Cytotechnologists are enrolled in the College of American Pathologists Proficiency Testing Program and the State of Maryland Proficiency Testing Program.

At Cytology Services of Maryland, we employ the **highest possible quality control and quality assurance** standards. Our quality control and quality assurance standards meet or exceed those set by the College of American Pathologists Center for Medicare and Medicaid Services (CMS). These standards minimize the risk of error and assure the patient of consistent, high-quality results.

Our support staff has earned a reputation for **excellent service** – from specimen collection to post-report inquiry, analysis and correlation. Personalized services are offered by our administrative staff, support staff, expert technologists, and medical professionals. We are proud of the reputation we have earned over the years and are happy to furnish references from our clients.

Supplies

Cytology Services of Maryland will provide all supplies necessary for the purpose of collection, preparation and preservation of all cytologic and immunologic specimens submitted to the laboratory, at laboratory's expense. CSM will provide universal laboratory request forms for cytology and immunology testing. Additional supplies will be available and replenished as needed upon request for each clinic site.

Specimen Rejection

CSM will try to resolve any issue via telephone or fax, whenever possible, to avoid returning a specimen and request form to the provider. Criteria for specimen rejection are the following:

1. Specimen received without a requisition form.
2. Name on specimen does not match name on the accompanying requisition.
3. Slides and/or specimen containers are not labeled with patient's name.
4. Requisition is incomplete, lacking essential/required information.
5. Fluid specimen container not secured with resulting leakage into the transport bag.
6. Breakage of slide(s) and /or fluid specimen container(s) during transport.
7. Received a sealed container/no specimen.
8. Specimen collected in improper fixative and/or specimen container.
9. Test requested is not performed at CSM.
10. CSM is not contracted with the clinician to perform requested test.
11. ThinPrep specimen received more than six weeks past the collection date.



Cytology & Histology Services

ELLEN D. MANLUCU, M.D.
 PATHOLOGIST AND DIRECTOR

If the specimen and request form must be returned to the Provider, labels containing an assigned accession number are placed on the specimen and on the request form. The following information, if available, is entered into CSM's computer system:

- | | |
|----------------------------|----------------------------------|
| 1. Accession number | 6. Type of specimen |
| 2. Patient's name | 7. Date of collection |
| 3. Patient's date of birth | 8. Date received |
| 4. Patient ID number | 9. Reason(s) for return specimen |
| 5. Provider Account Number | |

A report stating the reason(s) for the specimen return/rejection is printed and sent to the Provider. Cases in which the patient's name is not written on the request form *and* on the specimen, the request form and specimen will be returned to the Provider. It will not receive a label containing an assigned accession number, and therefore, cannot be entered into our computer system. A form/letter will be attached to the request form or specimen stating the reason for return.

Specimen Adequacy and Unsatisfactory Specimens

All procedures for specimen adequacy, unsatisfactory and rejected specimens are documented in CSM's Standard Operating Procedures. Pap adequacy is determined by evaluation of several aspects of the preparation: squamous cellularity, endocervical/transformation zone component, obscuring factors.

Squamous Cellularity	<u>Conventional Pap Smear</u> Minimum of 8,000 well-preserved, well-visualized squamous epithelial cells.	<u>ThinPrep® Pap Test™</u> Minimum of 5,000 well-preserved well-visualized squamous epithelial cells.
	Note: The minimum cell range should be an estimate, not an exact cell count. Preparations having less than the above required squamous cellularity are given an unsatisfactory result due to paucity of cells.	
Endocervical Transformation Zone Component	For both conventional smears and ThinPreps, an adequate transformation zone component requires a minimum of 10 well-preserved endocervical or squamous metaplastic cells, singly or in clusters. Preparations having fewer than 10 cells representative of the transformation zone are not given an unsatisfactory result however, the absence of endocervical component is noted on the specimen report under "Specimen Adequacy".	
Obscuring Factors	Specimens with more than 75% of squamous cells obscured are termed unsatisfactory. Obscuring factors may include, but are not limited to, blood, inflammation, excessive mucus, contaminants, overgrowth of bacteria and excessive cytolysis. When 50% to 75% of the cells are obscured, a comment is made in the specimen adequacy category of the report stating that squamous cells are partially obscured	



Cytology & Histology Services

ELLEN D. MANLUCU, M.D.
PATHOLOGIST AND DIRECTOR

An HPV test will not be performed under the following conditions:

- Obscuring factors in specimen (e.g. lubricant) or specimen contamination.
- Insufficient volume of specimen to perform HPV test.
- Specimen medium has expired.
- Specimen is expired (beyond three (3) months from the date it was collected).
- Incorrect collection device/medium used.

Cytologic Classifications and Laboratory Interpretation

Cytology Services of Maryland utilizes the nomenclature set by the National Cancer Institute Terminology and Classification for Cervical/Vaginal Cytology, otherwise known as The Bethesda System.

Reports

Cytology Services of Maryland will provide a uniform cytology report and histology report. The Bethesda System will be used to provide a descriptive classification of patient results.

Cytology Reports

Cytology Services of Maryland will provide a uniform cytologic report that will contain the following:

- Patient's name
- Provider's name, address, account number
- Patient's identification number (if applicable)
- Record of all clinical history provided by the referring physician
- Classification by cellular abnormality (using the Bethesda System of reporting)
- A presence or absence of parasites, fungus, herpes simplex and HPV
- A presence or absence of endocervical components
- Appropriate and pertinent comments by the cytopathologists

Immunology Reports

Cytology Services of Maryland will provide a uniform immunologic report that will contain the following:

- Patient's name
- Provider's name, address, account number
- Patient's identification number (if applicable)
- Record of all clinical history provided by the referring physician
- A presence or absence of HPV



Cytology & Histology Services

ELLEN D. MANLUCU, M.D.
PATHOLOGIST AND DIRECTOR

Abnormal results of a suspicious nature or higher requiring a diagnostic procedure will be faxed to the requesting location within 24 hours of completion. All abnormal cases transmitted by fax include the following:

- Adenocarcinoma
- Squamous cell carcinoma
- High-grade squamous intraepithelial lesion (SIL), encompassing:
 - Moderate dysplasia/CIN 2
 - Severe dysplasia/CIN 3
 - Carcinoma in situ
- Low-grade squamous intraepithelial lesion (SIL), encompassing:
 - Human papilloma virus (HPV)
 - Mild dysplasia/CIN 1

Cytology Services of Maryland will automatically provide a “**Monthly Cytology Follow-up Listing**” reported by classification with the current period’s abnormal and suspicious findings. CSM will provide a “**Follow-up Letter**” to each participating location of all cases of LGSIL and HGSIL.

Delivery of Specimens and Hard Copy Reports

Cytology Services of Maryland will provide pre-paid and pre-addressed UPS/FedEx shipping materials for the delivery of specimens to CSM. Delivery of hard copy reports will be sent via first class mail at the laboratory’s expense.

Processing and Test Results

Cytology Services of Maryland will provide completed cytology (Pap) reports within 10 calendar days from the date the specimen is received. All abnormal results of a suspicious nature or higher requiring a diagnostic procedure will be telephoned and/or faxed directly to the requesting clinic location within 24 hours of final evaluation.

CSM will provide completed immunology (HPV) reports within 20 calendar days from the date the specimen is received. All positive HPV results will be telephone and/or faxed directly to the requesting clinic location within 24 hours of final evaluation.

Computer Requirements

Cytology Services of Maryland provide diskettes and on-line access as specified in RFQ# MCH70449.

Data Requirements

Cytology Services of Maryland provide data, statistics, materials (slides/records) as specified in RFQ# MCH70449. Requests will be completed within five (5) business days.



Technical Support

Cytology Services of Maryland will make available during normal business hours pathologists/technologists for telephone consultations to resolve any questions or concerns of the clinician. Normal business hours shall be between 6:00 a.m. and 6:00 p.m. Eastern time, Monday through Friday, excluding holidays.

Slide Retention

Cytology Services of Maryland will retain all slides for five (5) years. After five (5) years, positive slides will be either retained for twenty (20) years. The positive slides will either be physically stored or electronically stored using digital imaging.

Billing

CSM will provide an itemized "Statement of Professional Services" performed on a monthly basis to the FPP and BCCSP. This statement will include the following:

- | | |
|-----------------------------|---------------------------|
| ▪ Federal Tax ID Number | ▪ Description of Services |
| ▪ Patient's Name | ▪ CPT Codes |
| ▪ Date of Service | ▪ Units |
| ▪ Specimen/Accession Number | ▪ Fees for Each Service |

* Payment for all services will be due and payable within 30 days of date of invoice.

Costs

This proposal is based on specific services being provided by Cytology Services of Maryland. Prices may be subject to increase on a yearly basis based on the CPI (U.S. Department of Labor Medical Index) for the previous 12-month period. (see *Exhibit A*)

Terms of Contract/Renewal

This Contract is effective as of the date of execution and shall remain effective for twelve (12) months from the date. All prices are fixed for twelve (12) months from the date of execution of this contract. This agreement shall automatically renew for an additional twelve (12) months unless CSM is notified to the contrary in writing sixty (60) days in advance of the expiration date of the then current term. Should the contract renew for an additional year after the initial twelve (12) month contract period, there may be an increase in the base price (based on CPI-U).

Contract Monitor

Suzanne Sierra-Bodmer, Manager of Support Services/Contract Manager
1-877-549-2642 ext. 14; suzanne.sierra@csmlab.com

CSM

13900 Laurel Lakes Avenue
Laurel, Maryland 20707-5092
Phone: 301-206-2555 • Fax: 301-206-2595

Cytology & Histology Services

ELLEN D. MANLUCU, M.D.
PATHOLOGIST AND DIRECTOR

CLIA ID NO.: 21D0649632
CAP NO.: 13479-01
MARYLAND LAB PERMIT #080



Exhibit I

- 2006 Fee Schedule

CSM

13900 Laurel Lakes Avenue
Laurel, Maryland 20707-5092
Phone: 301-206-2555 • Fax: 301-206-2595



Cytology & Histology Services

ELLEN D. MANLUCU, M.D.
PATHOLOGIST AND DIRECTOR

CLIA ID NO.: 21D0649632
CAP NO.: 13479-01
MARYLAND LAB PERMIT #080

FEE SCHEDULE

RFQ# MCH70449

October 2006

CPT	CYTOLOGY	AMOUNT
88164	Conventional Pap Smear	\$6.75
88175	Cytoc's ThinPrep [®] Pap Test [™]	\$15.50
88141	MD Interpretation	NO CHARGE
CPT	IMMUNOLOGY	AMOUNT
87621	Digene's High-Risk HPV DNA Hybrid Capture 2 Test (B Probe)	\$37.00



Advancing Excellence

**Accredited
Laboratory**



The College of American Pathologists

certifies that the laboratory named below

***Cytology Services of Maryland, Inc.
William J. Jaffurs, Sr., MD***

LAP Number: 1347901

AU-ID: 1178994

has met all applicable standards for accreditation and is hereby fully accredited by the College of American Pathologists Laboratory Accreditation Program. Reinspection is required within 30 days prior to February 27, 2006 to maintain accreditation.

Accreditation does not automatically survive a change in direction, ownership or location and assumes that all interim requirements are met.

Conrad S. Kypke

Chair, Commission on Laboratory Accreditation

Robert J. ...

President



MARYLAND
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
OFFICE OF HEALTH CARE QUALITY
SPRING GROVE CENTER
BLAND BRYANT BUILDING
55 WADE AVENUE
CATONSVILLE, MARYLAND 21228

MEDICAL LABORATORY PERMIT

NUMBER: 080

EFFECTIVE PERIOD: 07/01/2005 — 06/30/2007

Pursuant to the provisions of TITLE 17, subtitle 2, Health-General Article § 17-201 et seq., Annotated Code of Maryland, this permit is issued to:

CYTOLOGY SERVICES OF MD, INC

13900 Laurel Lakes Avenue #100

Laurel, MD 20707

Director: Ellen D. Manlucu, M.D.

Owner: Adventist Healthcare Inc.

For the performance of Medical Laboratory Tests in the following disciplines:

01 - MICROBIOLOGY: (e) Virology

06 - PATHOLOGY: (a) Tissue pathology (d) GYN Cytology (e) Non-GYN Cytology

CONTROL: 084916


Director

CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS
CYTOLOGY SERVICES OF MD INC
13900 LAUREL LAKES AVENUE
LAUREL, MD 20707-5091

CLIA ID NUMBER
21D0649632

EFFECTIVE DATE
11/12/2004

LABORATORY DIRECTOR
WILLIAM J JAFFURS SR MD

EXPIRATION DATE
11/11/2006

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.



Judith A. Yost

Judith A. Yost, Director
Division of Laboratory Services
Survey and Certification Group
Center for Medicaid and State Operations

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

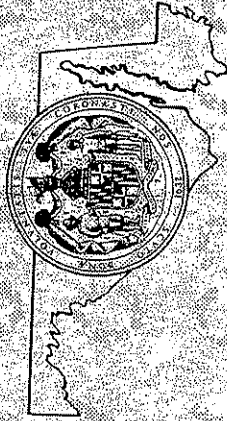
<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>	<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
VIROLOGY (140)	09/30/2004		
HISTOPATHOLOGY (610)	11/12/1996		
CYTOLOGY (630)	11/12/1996		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.HHS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

Control No. 916782

916782

State of



Maryland

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

LICENSE OR CERTIFICATION

MARYLAND BOARD OF PHYSICIANS

CERTIFIES THAT

IS AN AUTHORIZED ELLEN FATIMA DANNUG MANLUUCU

PHYSICIAN AND SURGEON

IN ACCORDANCE WITH THE HEALTH OCCUPATIONS ARTICLE OF THE ANNOTATED CODE OF MARYLAND

LIC. CERT. NO.	EXPIRATION DATE
D0063172	09/30/2007

SIGNATURE OF BEARER

S. Anthony McCann

S. Anthony McCann
Secretary of Health and Mental Hygiene

WHERE REQUIRED BY LAW THIS MUST BE CONSPICUOUSLY DISPLAYED IN OFFICE TO WHICH IT APPLIES