

PENNSYLVANIA CYTOLOGY SERVICES

SUITE 1700 PARKWAY BUILDING ♦ 339 OLD HAYMAKER ROAD ♦ MONROEVILLE, PA 15146-1447 ♦ 412-373-8300

November 12, 2009

Hand Delivered

State of West Virginia
Department of Administration
Purchasing Division
Building 15
2019 Washington Street East
P.O. Box 50130
Charleston, WV 25305-0130

ATTN: Roberta Wagner, Dept. of Admin., Purchasing Division

Re: RFQ MCH10037, Cytology Services

Dear Ms. Wagner:

Marlborough Holdings, LLC, dba Pennsylvania Cytology Services ("PCS") is pleased to submit the enclosed Quotation for Cytology Services in response to State of West Virginia RFQ MCH10037 ("RFQ").

PCS is an independent physician-owned laboratory specializing in GYN Cytology for the past thirty years. PCS is certified by the College of American Pathologists. Our Medical Director, Dr. Robert Swedarsky, is a Board Certified Pathologist and Cytopathologist licensed to practice medicine in the State of West Virginia, and all staff pathologists are Board Certified Pathologists.

PCS offers its clients cytology services that include both Conventional and Monolayer/Liquid based Pap testing. PCS utilizes the FDA approved Hologic ThinPrep Pap Test methodology for monolayer/liquid based Pap smears. The methodology for HPV DNA High Risk Assay System is Qiagen's (aka Digene) Hybrid Capture II System. The ThinPrep Pap test is the only technology currently FDA approved and available for Pap and HPV Reflex Testing directly from the same vial.

In response to your specific direction and Addendum 3, Part 3.2 to the RFQ, PCS proposes to use a reference laboratory, ClearPath Diagnostics, ("ClearPath") Syracuse, New York, to conduct HPV analysis. ClearPath is an independent physician-owned laboratory, offering tissue, cytopathology and clinical laboratory services. I have enclosed information demonstrating ClearPath's status as a responsible subcontractor that meets all the relevant RFQ requirements.

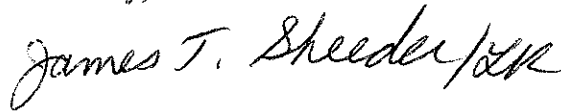
PENNSYLVANIA CYTOLOGY SERVICES

Also enclosed is PCS's pricing and detailed technical information responsive to the requirements of the RFQ. A complete list of enclosures is as follows:

1. Completed Revised Price Sheet;
2. Signed RFQ Form;
3. Signed Purchasing Affidavit;
4. Signed Preference Certification Form (n/a);
5. Signed Addendum Acknowledgements;
6. Technical Proposal Narrative;
7. Letter from Proposed Subcontractor;
8. Pennsylvania Cytology Services' CLIA Certificate;
9. Pennsylvania Department of Health Clinical Laboratory Permit;
10. Pennsylvania Cytology Services' CAP Letter and Certificate;
11. Dr. Swedarsky's West Virginia Medical License; and
12. Dr. Swedarsky's Pennsylvania Medical License.

Thank you for this opportunity to offer the services of Pennsylvania Cytology Services to the State of West Virginia.

Sincerely,



James T. Sheeder
Administrator
Pennsylvania Cytology Services

JTS/lr

Enclosures

COST SHEET FOR MCH10037

<u>Item #</u>	<u>Apprx. Annual Usage</u> <u>QUANTITY</u>	<u>DESCRIPTION</u>	<u>UNIT PRICE</u>	<u>TOTAL COST</u>
1	60,000	THIN PREP LIQUID MEDIUM/MONOLAYER OR EQUAL	\$ 11.95	\$ 717,000.00
2	2,800	HPV/DNA TESTING (HIGH-RISK ONLY) THIN PREP LIQUID MEDIUM/MONOLAYER OR EQUAL	\$ 28.00	\$ 78,400.00
3	2,600	THIN PREP LIQUID MEDIUM/MONOLAYER OR EQUAL (PRIVATE PAY BY PROGRAM ELIGIBLE CLIENT)	\$ 11.95	\$ 31,070.00
		TOTAL COST		\$ 826,470.00

Award will be made to the vendor with the lowest overall cost who meets specifications. Vendor must submit an original itemized invoice for each order. Payment will be made in arrears after receipt of each completed order. Orders will be placed on an as needed basis. If bidding on alternate testing bidder must attach pertinent testing literature.



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Request for Quotation

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

*516144449 412-373-8300
 PENNSYLVANIA CYTOLOGY SERVICES
 339 OLD HAYMAKER RD
 #1700 PARKWAY BUILDING
 MONROEVILLE PA 15146

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HEALTH AND HUMAN RESOURCES
 BPH - MCH WAREHOUSE

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

DATE PRINTED	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
09/22/2009				

BID OPENING DATE: 10/22/2009 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT NO.	ITEM NUMBER	UNIT PRICE	AMOUNT
0001	1	JB		948-21		
OPEN-END BLANKET CONTRACT CYTOLOGY SERVICES - LIQUID BASED PAP TEST OPEN END CONTRACT BLANKET OPEN-END CONTRACT FOR CYTOLOGY SERVICES FOR THE OFFICE OF MATERNAL, CHILD & FAMILY HEALTH, FAMILY PLANNING PROGRAM AND BREAST & CERVICAL CANCER 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 SPECIFICATIONS. EXHIBIT 3						

RECEIVED

2009 NOV 12 AM 10:46

WV PURCHASING DIVISION

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE: *Robert A. Swanson* TELEPHONE: 412-373-8300 DATE: 10/21/09
 TITLE: Medical Director FEIN: 20-0267816 ADDRESS CHANGES TO BE NOTED ABOVE

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



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<p>LIFE OF CONTRACT: THIS CONTRACT BECOMES EFFECTIVE ON NOVEMBER 15, 2009 AND EXTENDS FOR A PERIOD OF ONE (1) YEAR OR UNTIL SUCH "REASONABLE TIME" THEREAFTER AS IS NECESSARY TO OBTAIN A NEW CONTRACT OR RENEW THE ORIGINAL CONTRACT. THE "REASONABLE TIME" PERIOD SHALL NOT EXCEED TWELVE (12) MONTHS. DURING THIS "REASONABLE TIME" THE VENDOR MAY TERMINATE THIS CONTRACT FOR ANY REASON UPON GIVING THE DIRECTOR OF PURCHASING 30 DAYS WRITTEN NOTICE.</p> <p>UNLESS SPECIFIC PROVISIONS ARE STIPULATED ELSEWHERE IN THIS CONTRACT DOCUMENT, THE TERMS, CONDITIONS AND PRICING SET HEREIN ARE FIRM FOR THE LIFE OF THE CONTRACT.</p> <p>RENEWAL: THIS CONTRACT MAY BE RENEWED UPON THE MUTUAL WRITTEN CONSENT OF THE SPENDING UNIT AND VENDOR, SUBMITTED TO THE DIRECTOR OF PURCHASING THIRTY (30) DAYS PRIOR TO THE EXPIRATION DATE. SUCH RENEWAL SHALL BE IN ACCORDANCE WITH THE TERMS AND CONDITIONS OF THE ORIGINAL CONTRACT AND SHALL BE LIMITED TO TWO (2) ONE (1) YEAR PERIODS.</p> <p>CANCELLATION: THE DIRECTOR OF PURCHASING RESERVES THE RIGHT TO CANCEL THIS CONTRACT IMMEDIATELY UPON WRITTEN NOTICE TO THE VENDOR IF THE COMMODITIES AND/OR SERVICES SUPPLIED ARE OF AN INFERIOR QUALITY OR DO NOT CONFORM TO THE SPECIFICATIONS OF THE BID AND CONTRACT HEREIN.</p> <p>OPEN MARKET CLAUSE: THE DIRECTOR OF PURCHASING MAY AUTHORIZE A SPENDING UNIT TO PURCHASE ON THE OPEN MARKET, WITHOUT THE FILING OF A REQUISITION OR COST ESTIMATE, ITEMS SPECIFIED ON THIS CONTRACT FOR IMMEDIATE DELIVERY IN EMERGENCIES DUE TO UNFORESEEN CAUSES (INCLUDING BUT NOT LIMITED TO DELAYS IN TRANSPORTATION OR AN UNANTICIPATED INCREASE IN THE VOLUME O</p>						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE: *Robert H. Swain* TELEPHONE: 412-373-8300 DATE: 10/25/09
 TITLE: Medical Director FEN: 20-0267816 ADDRESS CHANGES TO BE NOTED ABOVE

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HEALTH AND HUMAN RESOURCES
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 CHARLESTON, WV
 25301 304-558-3417

SHIP TO

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<p>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 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 10/6/2009. QUESTIONS MAY BE SENT VIA USPS, FAX, COURIER OR E-MAIL. IN ORDER TO ASSURE</p>						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE <i>Roberta Wagner</i>	TELEPHONE 412-373-8300	DATE 10/23/09
TITLE Medical Director	FAX 20-0267816	ADDRESS CHANGES TO BE NOTED ABOVE

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VENDOR

SHIP TO

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<p>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>EXHIBIT 4</p> <p>LOCAL GOVERNMENT BODIES: UNLESS THE VENDOR INDICATES IN THE BID HIS REFUSAL TO EXTEND THE PRICES, TERMS, AND CONDITIONS OF THE BID TO COUNTY, SCHOOL, MUNICIPAL AND OTHER LOCAL GOVERNMENT BODIES, THE BID SHALL EXTEND TO POLITICAL SUBDIVISIONS OF THE STATE OF WEST VIRGINIA. IF THE VENDOR DOES NOT WISH TO EXTEND THE PRICES, TERMS, AND CONDITIONS OF THE BID TO ALL POLITICAL SUBDIVISIONS OF THE STATE, THE VENDOR MUST CLEARLY INDICATE SUCH REFUSAL IN HIS BID. SUCH REFUSAL SHALL NOT PREJUDICE THE AWARD OF THIS CONTRACT IN ANY MANNER.</p> <p>REV. 3/88</p> <p>PURCHASING CARD ACCEPTANCE: THE STATE OF WEST VIRGINIA CURRENTLY UTILIZES A VISA PURCHASING CARD PROGRAM WHICH IS ISSUED THROUGH A BANK. THE SUCCESSFUL VENDOR MUST ACCEPT THE STATE OF WEST VIRGINIA VISA PURCHASING CARD FOR PAYMENT OF ALL ORDERS PLACED BY ANY STATE AGENCY AS A CONDITION OF AWARD.</p>						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE: <i>Robert Wagner</i>		TELEPHONE: 412-373-8300	DATE: 10/21/09
TITLE: Medical Director	FEIN: 20-0267816	ADDRESS CHANGES TO BE NOTED ABOVE	

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LINE	QUANTITY	UOP	CAT NO.	ITEM NUMBER	UNIT PRICE	AMOUNT
NOTICE						
A SIGNED BID MUST BE SUBMITTED TO:						
DEPARTMENT OF ADMINISTRATION PURCHASING DIVISION BUILDING 15 2019 WASHINGTON STREET, EAST CHARLESTON, WV 25305-0130						
PLEASE NOTE: A CONVENIENCE COPY WOULD BE APPRECIATED.						
THE BID SHOULD CONTAIN THIS INFORMATION ON THE FACE OF THE ENVELOPE OR THE BID MAY NOT BE CONSIDERED:						
SEALED BID						
BUYER:-----RW/FILE 22-----						
RFQ. NO.:-----MCH10037-----						
BID OPENING DATE:----10/22/2009-----						
BID OPENING TIME:----1:30 PM-----						
PLEASE PROVIDE A FAX NUMBER IN CASE IT IS NECESSARY TO CONTACT YOU REGARDING YOUR BID:						
-----412-373-7027-----						
CONTACT PERSON (PLEASE PRINT CLEARLY):						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE <i>Roberta Wagner</i>	TELEPHONE 412-373-8300	DATE 10/25/09
TITLE Medical Director	FEIN 20-0267816	ADDRESS CHANGES TO BE NOTED ABOVE

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----- Lisa Ritchey -----						
002	2,800	EA		948-21		
HPV/DNA TESTING (HIGH-RISK ONLY)						
003	2,600	EA		948-21		
CYTOLOGY SERVICES - LIQUID BASED PAP TEST (PRIVATE						
PAY BY PROGRAM ELIGIBLE CLIENT)						
AWARD WILL BE MADE TO THE VENDOR WITH THE LOWEST OVER-						
ALL COST WHO MEETS SPECIFICATIONS.						
VENDOR MUST SUBMIT AN ORIGINAL ITEMIZED INVOICE FOR						
EACH ORDER. PAYMENT WILL BE MADE IN ARREARS AFTER						
RECEIPT OF EACH COMPLETED ORDER. ORDERS WILL BE PLACED						
ON AN AS NEEDED BASIS.						

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***** THIS IS THE END OF RFQ MCH10037 ***** TOTAL:						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE <i>Robert A. Swisher</i>	TELEPHONE 412-373-8300	DATE 10/27/09
TITLE Medical Director	FEIN 20-0267816	ADDRESS CHANGES TO BE NOTED ABOVE

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WV Department of Health and Human Resources
 Bureau for Public Health
 Office of Maternal, Child and Family Health

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 150 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 185 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 60,000 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 of Liquid-Based Pap test specimens. These supplies shall include, but not be limited to, requisition forms, mailers, specimen containers that provide space for writing the patient's name, cervical scrapers and cytobrushes.

WV Department of Health and Human Resources
Bureau for Public Health
Office of Maternal, Child and Family Health

- B. The vendor will require that the following minimum 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. Date of Birth
 7. Specimen type
 8. Date of previous Pap test
 9. Class of previous Pap test
 10. 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 ten (10) calendar days from the date the specimens are received by the vendor.
- D. The vendor will be responsible for strictly adhering to reporting specimen test results, using the 2001 Bethesda System, including specimen adequacy, general categorization, interpretation and results. Results will be reported to the ordering physician/clinic at the address supplied by the Program provider.
- E. The vendor assumes all responsibility and liability for reading and processing of all Pap tests.
- F. The vendor must have written criteria for rejection of specimens and for categorizing specimens as unsatisfactory.
- G. The vendor must retain negative and unsatisfactory slides for five (5) years and positive slides for twenty (20) years.

Data Requirements:

- H. The vendor must provide a Program specific electronic report (using a Microsoft program such as an Excel spread sheet or PDF) to FPP and BCCSP with the following data accessible as needed:
- Total number of Pap tests received, interpreted and categorized according to 2001 Bethesda System, including specimen adequacy
 - Total number of hrHPV tests performed

WV Department of Health and Human Resources
Bureau for Public Health
Office of Maternal, Child and Family Health

- I. The vendor agrees to supply the FPP, BCCSP and all participating Program providers with on-line access to test results via a website, including HPV results. 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.
- J. The vendor must respond to all requests for statistical information or data within five (5) working days.

Quality Assurance:

- K. The vendor must allow the FPP and BCCSP and/or any designated cytotechnologist to perform on-site reviews to their laboratory facility and to have access to any slides and records from the programs for review purposes, upon request
- L. The vendor must allow any cytotechnologist designated by the programs to review the cytology procedure manual for the quality control and quality assurance programs upon request.
- M. The vendor is required to meet all CLIA requirements and to obtain CLIA certification. The contractor agrees to follow all rules and regulations in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88).
- N. The vendor must have a CLIA-88 qualified pathologist as director (technical supervisor), qualified cytology general supervisor, and qualified cytotechnologist(s) on site.
- O. The vendor's staff shall be available upon request to consult with participating providers by telephone during normal working hours to discuss the vendor's procedures and to explain test results. Consultation will include on-site specimen collection and handling training if deemed necessary. Vendor will attend on-site meeting as requested by either FPP or BCCSP.
- P. The vendor must retrieve stored FPP or BCCSP Pap tests the same day as requested by either program.
- Q. The vendor must document the receipt, circulation, referral and transfer of original Pap tests.

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Bureau for Public Health
Office of Maternal, Child and Family Health

- R. 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.
- S. The vendor must show documentation of a maintenance schedule for equipment and microscopes and implement said schedule.
- T. 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
- U. The vendor must show documentation for continuing education for the staff cytotechnologist(s).
- V. Vendor must have been in business and maintained a business license to perform cytology services for a minimum of five (5) years.

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 must meet all requirements within the specification. By signing the bid, the vendor is agreeing to meet these requirements.
- 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.

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.

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 hospital licensure, 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 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.

WV Department of Health and Human Resources
Bureau for Public Health
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 written notice.

3.6 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. Vendor will submit FPP monthly invoices electronically. State law forbids payment of invoices prior to receipt of services.

STATE OF WEST VIRGINIA
Purchasing Division

PURCHASING AFFIDAVIT

VENDOR OWING A DEBT TO THE STATE:

West Virginia Code §5A-3-10a provides that: 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.

PUBLIC IMPROVEMENT CONTRACTS & DRUG-FREE WORKPLACE ACT:

If this is a solicitation for a public improvement construction contract, the vendor, by its signature below, affirms that it has a written plan for a drug-free workplace policy in compliance with Article 1D, Chapter 21 of the **West Virginia Code**. The vendor **must** make said affirmation with its bid submission. Further, public improvement construction contract may not be awarded to a vendor who does not have a written plan for a drug-free workplace policy in compliance with Article 1D, Chapter 21 of the **West Virginia Code** and who has not submitted that plan to the appropriate contracting authority in timely fashion. For a vendor who is a subcontractor, compliance with Section 5, Article 1D, Chapter 21 of the **West Virginia Code** may take place before their work on the public improvement is begun.

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 materials, 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.

LICENSING:

Vendors must be licensed and in good standing in accordance with any and all state and local laws and requirements by any state or local agency of West Virginia, including, but not limited to, the West Virginia Secretary of State's Office, the West Virginia Tax Department, West Virginia Insurance Commission, or any other state agencies or political subdivision. Furthermore, the vendor must provide all necessary releases to obtain information to enable the Director or spending unit to verify that the vendor is licensed and in good standing with the above entities

CONFIDENTIALITY:

The vendor agrees that he or she will not disclose to anyone, directly or indirectly, any such personally identifiable information or other confidential information gained from the agency, unless the individual who is the subject of the information consents to the disclosure in writing or the disclosure is made pursuant to the agency's policies, procedures and rules. 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>.

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.

Vendor's Name: Robert H. Swedarsky MD

Authorized Signature: Robert H. Swedarsky

Date: 10/25/09

N/A

VENDOR PREFERENCE CERTIFICATE

Certification and application* is hereby made for Preference in accordance with West Virginia Code, §5A-3-37. (Does not apply to construction contracts) West Virginia Code, §5A-3-37, provides an opportunity for qualifying vendors to request (at the time of bid) preference for their residency status. Such preference is an evaluation method only and will be applied only to the cost bid in accordance with the West Virginia Code. This certificate for application is to be used to request such preference. The Purchasing Division will make the determination of the Resident Vendor Preference, if applicable

N/A

- 1. Application is made for 2.5% resident vendor preference for the reason checked: 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, Bidder is a partnership, association or corporation resident vendor and 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 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, Bidder is a 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; or,

N/A

- 2. Application is made for 2.5% resident vendor preference for the reason checked: Bidder is a resident vendor who certifies that, during the life of the contract, on average at least 75% of the employees working on the project being bid are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; or,

N/A

- 3. Application is made for 2.5% resident vendor preference for the reason checked: 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 Bidder's 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; or,

N/A

- 4. Application is made for 5% resident vendor preference for the reason checked: Bidder meets either the requirement of both subdivisions (1) and (2) or subdivision (1) and (3) as stated above; or,

N/A

- 5. Application is made for 3.5% resident vendor preference who is a veteran for the reason checked: Bidder is an individual resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard and has resided in West Virginia continuously for the four years immediately preceding the date on which the bid is submitted; or,

N/A

- 6. Application is made for 3.5% resident vendor preference who is a veteran for the reason checked: Bidder is a resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard, if, for purposes of producing or distributing the commodities or completing the project which is the subject of the vendor's bid and continuously over the entire term of the project, on average at least seventy-five percent of the vendor's employees are residents of West Virginia who have resided in the state continuously for the two immediately preceding years.

Bidder understands if the Secretary of 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) reject the bid; 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.

By submission of this certificate, Bidder agrees to disclose any reasonably requested information to the Purchasing Division and authorizes the Department of 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.

Under penalty of law for false swearing (West Virginia Code, §61-5-3), Bidder hereby certifies that this certificate is true and accurate in all respects; and that if a contract is issued to Bidder and if anything contained within this certificate changes during the term of the contract, Bidder will notify the Purchasing Division in writing immediately.

Bidder: Robert H. Swedarsky, MD Signed: Robert H. Swedarsky, MD

Date: 11-10-09 Title: Medical Director

*Check any combination of preference consideration(s) indicated above which you are entitled to receive.



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
 MCH10037

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

*516144449 412-373-8300
 PENNSYLVANIA CYTOLOGY SERVICES
 339 OLD HAYMAKER RD
 #1700 PARKWAY BUILDING
 MONROEVILLE PA 15146

VENDOR

SHIP TO

HEALTH AND HUMAN RESOURCES
 BPH - MCH WAREHOUSE
 900 BULLITT STREET
 CHARLESTON, WV
 25301 304-558-3417

DATE PRINTED 10/08/2009	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
BID OPENING DATE: 10/22/2009		BID OPENING TIME 01:30PM		

LINE	QUANTITY	UOP	CAT NO	ITEM NUMBER	UNIT PRICE	AMOUNT
ADDENDUM NO. 1 1. QUESTIONS AND ANSWERS ARE ATTACHED. 2. ADDENDUM ACKNOWLEDGEMENT IS ATTACHED. THIS DOCUMENT SHOULD BE SIGNED AND RETURNED WITH YOUR BID. FAILURE TO SIGN AND RETURN MAY RESULT IN DISQUALIFICATION OF YOUR BID. EXHIBIT 10 REQUISITION NO.: MCH10037 ADDENDUM ACKNOWLEDGEMENT I HEREBY ACKNOWLEDGE RECEIPT OF THE FOLLOWING CHECKED ADDENDUM(S) AND HAVE MADE THE NECESSARY REVISIONS TO MY PROPOSAL, PLANS AND/OR SPECIFICATION, 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) MAY BE CAUSE FOR REJECTION OF BIDS. VENDOR MUST CLEARLY UNDERSTAND THAT ANY VERBAL						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE <i>Roberta Wagner</i>	TELEPHONE 412-373-8300	DATE 10/22/09
TITLE Medical Director	FEIN 20-0267816	ADDRESS CHANGES TO BE NOTED ABOVE

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



State of West Virginia
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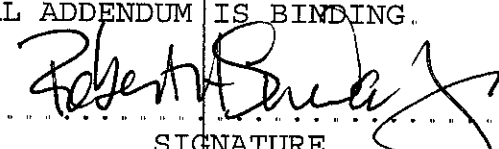
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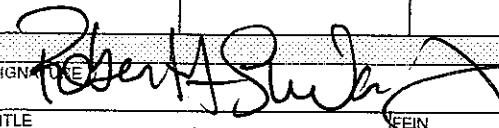
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SIGNATURE 	TELEPHONE 412-373-8300	DATE 10/25/09
TITLE Medical Director	FAX 20-0267816	ADDRESS CHANGES TO BE NOTED ABOVE

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DATE PRINTED 10/15/2009	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
BID OPENING DATE: 10/30/2009		BID OPENING TIME 01:30PM		

LINE	QUANTITY	UOP	CAT NO.	ITEM NUMBER	UNIT PRICE	AMOUNT
ADDENDUM NO. 2 1. TO MOVE BID OPENING DATE FROM 10/22/9 TO 10/30/9. 2. ADDENDUM ACKNOWLEDGEMENT IS ATTACHED. THIS DOCUMENT SHOULD BE SIGNED AND RETURNED WITH YOUR BID. FAILURE TO SIGN AND RETURN MAY RESULT IN DISQUALIFICATION OF YOUR BID. EXHIBIT 10 REQUISITION NO.: MCH10037 ADDENDUM ACKNOWLEDGEMENT I HEREBY ACKNOWLEDGE RECEIPT OF THE FOLLOWING CHECKED ADDENDUM(S) AND HAVE MADE THE NECESSARY REVISIONS TO MY PROPOSAL, PLANS AND/OR SPECIFICATION, ETC. ADDENDUM NO. S: NO. 1 ✓ NO. 2 ✓ NO. 3 NO. 4 NO. 5						
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TITLE Medical Director	FEIN 20-0267816	ADDRESS CHANGES TO BE NOTED ABOVE

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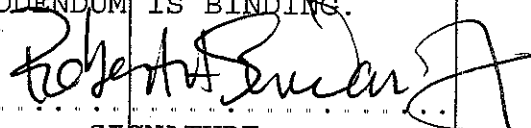
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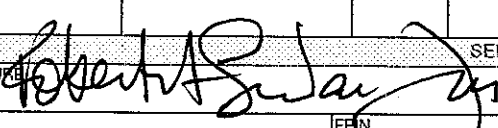
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TITLE Medical Director	FERN 20-0267816	ADDRESS CHANGES TO BE NOTED ABOVE

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10/28/2009				

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LINE	QUANTITY	UOP	CAT NO.	ITEM NUMBER	UNIT PRICE	AMOUNT
ADDENDUM NO. 3						
1. QUESTIONS AND ANSWERS ARE ATTACHED. REVISIONS TO SPECIFICATIONS ARE ATTACHED.						
2. TO MOVE THE BID OPENING DATE FROM 10/30/2009 TO 11/12/2009.						
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EXHIBIT 10						
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ADDENDUM NO. S:						
NO. 1 ✓						
NO. 2 ✓						
NO. 3 ✓						
NO. 4 						
NO. 5 						
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SIGNATURE <i>Roberta Wagner</i>	TELEPHONE 412-373-8300	DATE 11/30/09
TITLE Medical Director	FEIN 20-0267816	ADDRESS CHANGES TO BE NOTED ABOVE

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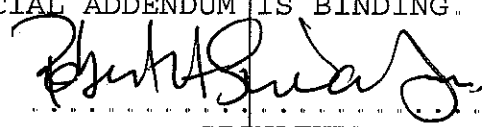
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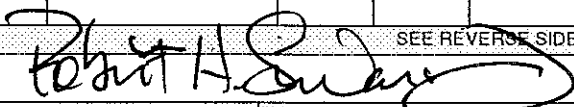
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SIGNATURE 	TELEPHONE 412-373-8300	DATE 11/3/09
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DATE PRINTED	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
10/30/2009				

BID OPENING DATE: 11/12/2009 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT NO.	ITEM NUMBER	UNIT PRICE	AMOUNT
ADDENDUM NO. 4						
1. QUESTIONS AND ANSWERS ATTACHED.						
2. ADDENDUM ACKNOWLEDGEMENT IS ATTACHED. THIS DOCUMENT SHOULD BE SIGNED AND RETURNED WITH YOUR BID. FAILURE TO SIGN AND RETURN MAY RESULT IN DISQUALIFICATION OF YOUR BID.						
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REQUISITION NO.: MCH10037						
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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) MAY BE CAUSE FOR REJECTION OF BIDS.						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE <i>Robert Wagner</i>	TELEPHONE 412-373-8300	DATE 11/3/09
TITLE Medical Director	FEIN 20-0267816	ADDRESS CHANGES TO BE NOTED ABOVE

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Robert A. Seaman, Jr.

SIGNATURE
 Marlborough Holdings, LLC
 d/b/a. Pennsylvania Cytology Services
 COMPANY

11-3-09
 DATE

NOTE: THIS ADDENDUM ACKNOWLEDGEMENT SHOULD BE SUBMITTED WITH THE BID.

REV. 09/21/2009

END OF ADDENDUM NO. 4

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE <i>Robert A. Seaman, Jr.</i>	TELEPHONE 412-373-8300	DATE 11/3/09
TITLE Medical Director	FEIN 20-2367816	ADDRESS CHANGES TO BE NOTED ABOVE

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

PCS TECHNICAL PROPOSAL MCH10037

I. INTRODUCTION

Marlborough Holdings, LLC, dba Pennsylvania Cytology Services (“PCS”) is an independent physician-owned laboratory specializing in GYN Cytology for the past thirty years. PCS offers its clients cytology services that include both Conventional and Monolayer/Liquid based Pap testing. In response to RFQ MCH10037 (“RFQ”), PCS will utilize the FDA approved Hologic ThinPrep Pap Test methodology for monolayer/liquid based Pap smears (“ThinPrep”). The methodology for HPV DNA High Risk Assay System is Qiagen’s (aka Digene) Hybrid Capture II System. PCS currently offers HPV testing using the reference laboratory, ClearPath Diagnostics, (“ClearPath”) Syracuse, New York. ClearPath, as explained in more detail below, is an independent physician-owned laboratory, offering tissue, cytopathology and clinical laboratory services.

II. QUALIFICATIONS

PCS’s staff meet and surpass CLIA-88 qualifications as required by the RFQ. (RFQ Part 2.1 Quality Assurance) PCS’s services are provided by Board Certified Pathologists with extensive experience in gynecologic pathology. Our Medical Director, Dr. Swedarsky, is also subspecialty Board Certified in Cytopathology. Dr. Swedarsky is licensed to practice medicine in West Virginia, among other states. Our staff of fifteen cytotechnologists, including the on site cytology general supervisor, Ms. Sharon Copley, BS, CT (ASCP)^{cm}, are certified by the American Society of Clinical Pathologists (“ASCP”). More than half of these cytotechnologists have greater than 10 years of experience.

Pennsylvania Cytology Services also meets and surpasses CLIA clinical laboratory requirements. PCS is accredited by the College of American Pathologists (“CAP”) (No. 41911-01). It is licensed by CLIA (No. 39D0656968) and the State of Pennsylvania (No. 331). PCS has been designated an American Society of Cytopathology Laboratory.

As identified above, PCS currently offers HPV testing using the services of the reference laboratory ClearPath Diagnostics, an independent physician owned tissue and cytopathology practice. ClearPath is CLIA certified (No. 33D0654580), and licensed and inspected by the New York State Department of Health (No. PFI2217). ClearPath has been conducting HPV testing since 1999, and was the first in New York State to perform reflex HPV testing from a ThinPrep specimen. ClearPath medical personnel are Board Certified Pathologists, one of whom is also subspecialty Board Certified in Cytopathology. ClearPath technologists are certified by the ASCP. Please refer to the attached detailed information regarding ClearPath Diagnostics. As noted, additional information is also available at www.clearpathdiagnostics.com.

III. REQUIRED MONOLAYER/LIQUID BASED PAP/HPV TESTING

In response to RFQ MCH10037, PCS will utilize the FDA approved Hologic ThinPrep Pap Test methodology for monolayer/liquid based Pap smears. The

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methodology for HPV DNA High Risk Assay System is Qiagen's (aka Digene) Hybrid Capture II System. The ThinPrep Pap test is the only technology currently FDA approved and available for Pap and HPV Reflex Testing directly from the same vial.

PCS uses ThinPrep Liquid Based technology because the alternate liquid based system is not FDA approved for same sample HPV testing. Use of the alternate system would oblige our clients to obtain a second sample specifically for possible reflex HPV testing. Applying the ASCCP guidelines for reflex HPV testing of patients with an ASC-US Pap result, the population requiring a second tube, would include, at a minimum all females 21 years or older on initial visit/Pap and all females 21 years or older with a history of negative Paps. Double sampling would create a significant practice, logistic and administrative burden for care givers.

IV. PROCESSING, EVALUATION AND REPORTING REQUIREMENTS

PCS will comply with all requirements listed in the RFQ, specifically including, but not limited to, Subparts 2.1, 2.2, 3.3, 3.4, and 3.6. Further, as a CAP and CLIA certified laboratory, PCS processes all specimens, including those referred to ClearPath for HPV testing, and maintains records in accordance with all applicable certification guidelines, and which are in compliance with Part 2.1 of the RFQ. PCS's record keeping system allows for timely access to and retrieval of information as required by the RFQ. PCS maintains a Standard Operations Manual that is updated regularly, and has a continuous quality improvement program in accordance with CAP guidelines.

PCS also produces for its clients a monthly summary of cytology findings. This summary can be forwarded to individual clinics. This at-a-glance report lists, in order of result category, those patients with positive Pap smears through those patients with negative smears. In addition, monthly totals and percentages for the following are also listed:

- Total Pap specimens for the month
- Negative for intraepithelial lesion or malignancy
- Unsatisfactory
- Inflammation, no epithelial cell abnormalities
- Organisms
- Reactive cellular changes
- Other (endometrials in patient over 40 years old)
- Atypical squamous cells
- Atypical glandular cells
- Squamous Intraepithelial lesion – low grade
- Squamous Intraepithelial lesion – high grade
- Squamous carcinoma
- Adenocarcinoma
- Other neoplasm

PCS TECHNICAL PROPOSAL MCH10037

Results will be reported within the required 10 calendar days from the date of receipt of specimens as required by RFQ Part 2.1 C. PCS routinely reports results in this timeframe. PCS has a past performance reputation of producing timely results.

In response to the requirement set forth in Part 2.1 I, PCS is currently in the final stages of testing a new website with on-line access to test results. PCS will make this service available in time for performance of the contract awarded under RFQ MCH10037.

V. PRICING

Our prices for Pap and HPV testing are included herein as required by the RFQ. Our price includes all supplies as required by Part 2.1A of the RFQ.

CLEARPATH DIAGNOSTICS, SYRACUSE, NEW YORK

General Information

CLEARPATH
diagnostics
Your pathology partner.

October 28, 2009

Mr. James T. Sheeder
Pennsylvania Cytology Services
339 Old Haymaker Road
Monroeville, Pennsylvania 15146

Dear Jim,

Regarding our HPV testing program, we are New York State Department of Health inspected and licensed (see enclosed copy of license) By virtue of our New York State license, we are automatically CLIA certified (note our CLIA number in the upper right corner of the license). We started testing for HPV in February, 1999 and were the first in New York State to perform reflexive HPV testing from a thinlayer Pap specimen. We perform testing using Qiagen's Hybrid Capture 2 system and are currently looking to incorporate genotyping for high risk types 16 and 18. In 2008 we performed 31,468 HPV tests and are on a pace to perform approximately 35,000 tests this year. We perform both high risk and low risk testing with over 80% of our volume being high risk only. Turnaround is 2-3 days from receipt of the specimen, unless testing is reflexed from the Pap result in which case, turnaround is 2-3 days from Pap signout. Most of our volume is derived from private physician practices. We also receive specimens from hospital labs and health department clinics

For more information on our HPV program, or ClearPath Diagnostics, please feel free to suggest viewing our website at www.clearpathdiagnostics.com

Sincerely,



Michael J. Warner
Chief Operating Officer

www.ClearPathDiagnostics.com

Main Office:

600 E. Genesee St.
Suite 305
Syracuse NY 13202
(315) 234-3300
(315) 234-3305 [Fax]

Cytology

(315) 234-3300
(315) 234-3305 [Fax]

Tissue Pathology

(315) 234-9640
(315) 234-9646[Fax]

Medical Center West:

5700 W Genesee St.
Camillus, NY 13031
(315) 234-3300
(315) 234-3305 [Fax]

New York State Department of Health

PFI: 2217

Clinical Laboratory Permit

CLIA: 33D0654580

Cytology Outreach PLLC dba ClearPath Diagnostics

600 East Genesee St Suite 305

Syracuse NY 13202

Director: Kenneth B. Strumpf, M.D.

Owner: Cytology Outreach PLLC

is hereby authorized to perform laboratory procedures at the above location in the following categories in accordance with Article 5, Title V, Section 575 of the Public Health Law. This permit shall become void upon a change in the director, owner or location of the laboratory, and an application for a new permit shall be made to the Department.

Cytopathology
Gynecological Testing, not including HPV
Non-gynecological Testing
Oncology
Human Papillomavirus (HPV) Testing

Renewal

Effective Date: July 1, 2009

Expiration Date: June 30, 2010

Subject to Revocation
Permit Not Transferable

POST CONSPICUOUSLY

Serial: LAP46136

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

LABORATORY NAME AND ADDRESS
 MARLBOROUGH HOLDINGS LLC DBA PENNSYLVA
 CYTOLOGY SERVICES
 339 OLD HAYMAKER ROAD STE 1700
 PARKWAY BUILDING
 MONROEVILLE, PA 15146
 LABORATORY DIRECTOR
 ROBERT H SWEDARSKY MD

CLIA ID NUMBER
 39D0656968
 EFFECTIVE DATE
 06/28/2009
 EXPIRATION DATE
 06/27/2011

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

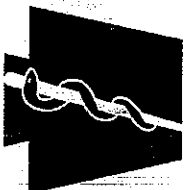
29 certs2_053009

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>
HISTOPATHOLOGY (610)	10/27/2005		
CYTOLOGY (630)	06/16/2003		

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

CLINICAL LABORATORY PERMIT



pennsylvania
DEPARTMENT OF HEALTH

Pursuant to the act of September 26, 1951, P.L. 1539 as amended, a Permit to operate a Clinical Laboratory is hereby granted to:

Laboratory Identification Number: 000331A

Name and Director of Laboratory:

PENNSYLVANIA CYTOLOGY SERVICES
ROBERT SWEDARSKY
339 OLD HAYMAKER ROAD PARKWAY BUILDING SUITE 1700
MONROEVILLE, PA 15146

AUTHORIZED CATEGORIES:

EXFOLIATIVE CYTOLOGY
TISSUE PATHOLOGY

Owner:

ROBERT H SWEDARSKY MD


Issued: August 15, 2009

This permit is subject to revocation, suspension, or limitation for violation of the Act or the Regulations promulgated thereunder.

DATE EXPIRES: August 15, 2010



Michael Duff
Deputy Secretary for Health Planning and Assessment



Evette James
Secretary of Health

DISPLAY THIS CERTIFICATE PROMINENTLY



College of American Pathologists

325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • <http://www.cap.org>

Advancing Excellence

LAP#: 4191101
AU-ID: 1190340
July 18, 2008

Robert H. Swedarsky, MD
Pennsylvania Cytology Services
Cytology Laboratory
339 Old Haymaker Rd, Ste 1700
Parkway Bldg
Monroeville, Pennsylvania 15146-1435

Dear Dr. Swedarsky:

The College of American Pathologists Laboratory Accreditation Program's Accreditation Committee is pleased to advise you that the medical laboratory you direct, Pennsylvania Cytology Services Cytology Laboratory, in Monroeville, Pennsylvania, successfully met the Laboratory Accreditation Program (LAP) Standards for Accreditation in the area(s) listed on the attached sheet. **Please retain this letter and list of accredited services in your records, as this is your official notification of accreditation.**

Your Certificate of Accreditation is enclosed. Accreditation is valid for a two-year period and may be maintained on a continuous basis *provided the following terms are met:*

1. Provide a trained and appropriately experienced inspection team comparable in size and scope to that required for its own inspection, if requested by the regional and/or state commissioner, at least once during the two year accreditation period;
2. Submit an application for reinspection in sufficient time that the reinspection may be accomplished prior to your anniversary date. Application materials will automatically be sent to you to be completed and must be returned within 35 days of date sent;
3. Successfully participate in the CAP Surveys or a CAP-accepted proficiency testing program;
4. Notify the Commission of changes in location, ownership, or directorship of the laboratory. Accreditation does not automatically survive such changes. Documentation, including a copy of the new director's curriculum vitae and an organizational chart, will be requested for evaluation of the accreditation status;
5. Notify the Commission when there is a change in the laboratory's test menu;
6. Notify the Commission whenever the laboratory finds itself the subject of an investigation by a state or federal agency or adverse media attention related to laboratory performance;
7. Submit a completed Self-Evaluation Verification Form in the interim year.

The Accreditation Committee congratulates you on the accreditation of the laboratory under your direction and the excellence of the services being provided. Please be reminded that CAP accreditation is not a substitute for the continuous in-depth monitoring by the laboratory and its personnel. Only such monitoring can produce a safe and properly functioning laboratory.

Sincerely,

Robert R. Rickert, MD
Chair, Accreditation Committee

cc: R. Bruce Williams, MD, Chair, Commission on Laboratory Accreditation
Enrique E. Cotes, MD

Ref: LAPACCLTR

Pennsylvania Cytology Services
Cytology Laboratory

LAP Number: 4191101
AU ID: 1190340
Reference Number: 39D0656968

The Laboratory Accreditation Program currently has the subspecialty information listed below on file for your laboratory. This information is used for reporting to regulatory agencies.

Cytology
Histopathology

Pennsylvania Cytology Services
Cytology Laboratory

LAP Number: 4191101
AU ID: 1190340
Reference Number: 800016595

The Laboratory Accreditation Program currently has the subspecialty information listed below on file for your laboratory. This information is used for reporting to regulatory agencies.

Cytology
Histopathology

Pennsylvania Cytology Services
Cytology Laboratory

LAP Number: 4191101

AU ID: 1190340

The above Laboratory is accredited by the College of American Pathologists Laboratory Accreditation Program for the following services:

Anatomic Pathology Processing
Cytology Processing
Cytology Screening
Director/Organizational Assessment
Gynecologic Cytopathology
Laboratory General
Non-Gynecologic Cytopathology
Surgical Pathology

This accreditation is valid for the period ending June 25, 2010



Advancing Excellence

**Accredited
Laboratory**



The College of American Pathologists

certifies that the laboratory named below

***Pennsylvania Cytology Services
Cytology Laboratory
Monroeville, Pennsylvania
Robert H. Swedarsky, MD***

LAP Number: 4191101

AU-ID: 1190340

CLIA Number: 39D0656968

has met all applicable standards for accreditation and is hereby fully accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to June 25, 2010 to maintain accreditation.

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

Robert Wilkins, MD

Chair, Commission on Laboratory Accreditation

James R. Schwartz, MD PhD FCAP

President, College of American Pathologists

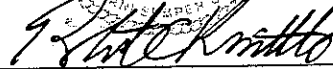
WEST VIRGINIA BOARD OF MEDICINE

LICENSE NO. 18130 ISSUED 5/8/1995

THIS IS TO CERTIFY THAT THE LICENSE OF

ROBERT HUTCHER SWEDARSKY, M.D.

TO PRACTICE **MEDICINE AND SURGERY** IN THE
STATE OF WEST VIRGINIA HAS BEEN RENEWED FOR
THE PERIOD OF **7/1/2009 TO 6/30/2011**

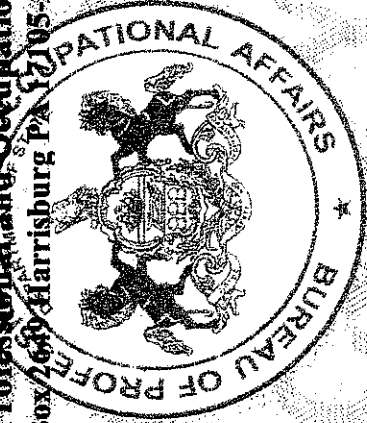


ROBERT C. KNITTLE *Executive Director*

DISPLAY THIS CERTIFICATE PROMINENTLY • NOTIFY AGENCY WITHIN 10 DAYS OF ANY CHANGE

08 0826694

Commonwealth of Pennsylvania
Department of State
Bureau of Professional and Occupational Affairs
PO Box 2649 Harrisburg PA 17105-2649



License Status
Active

Initial License Date
08/05/1983

Expiration Date
12/31/2010

License Type
Medical Physician and Surgeon

License Number
MD029726E

ROBERT HUTCHER SWEDARSKY
5839 MARLBOROUGH AVENUE
PITTSBURGH PA 15217

Robert Hutcher Swedarsky
Signature

David L. Mowbray
Commissioner of Professional and Occupational Affairs

ALTERATION OF THIS DOCUMENT IS A CRIMINAL OFFENSE UNDER P.A.C.S. §911