### Pennsylvania Cytology Services

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

August 30, 2013

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

ATTN: Roberta Wagner

Re: State of West Virginia RFQ MCH14020, Cytology Services

Dear Ms. Wagner:

Marlborough Holdings, LLC, d/b/a Pennsylvania Cytology Services ("PCS") is pleased to submit the enclosed Quotation for Cytology Services in response to State of West Virginia RFQ MCH14020 ("RFQ").

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

PCS offers its clients cytology services that include both Conventional and Monolayer/Liquid based Pap testing. In response to the RFQ, PCS will utilize the FDA approved Hologic ThinPrep Pap Test methodology for monolayer/liquid based Pap smears, and PCS will use the FDA approved Qiagen (aka Digene) Hybrid Capture II System for its HPV/DNA High Risk Assay System. The ThinPrep Pap test is the only technology currently FDA approved and available for Pap and HPV/DNA Reflex Testing directly from the same vial using the transport media PreservCyt.

Enclosed is PCS's technical proposal and pricing responsive to the requirements of the RFQ. A complete list of enclosures is included with the Table of Contents.

09/03/13 09:26:18 AM West Virginia Purchasing Division

College of American Pathologists Accredited Laboratory #41911-01

◆ Pennsylvania Laboratory #331 ◆

Department of Health, Education, and Welfare CLIA #39D0656968

## PENNSYLVANIA CYTOLOGY SERVICES

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

Sincerely,

Robert H. Swedarsky, MD

Medical Director

Pennsylvania Cytology Services

Enclosures

### Pennsylvania Cytology Services Proposal For Liquid Based Pap Smear Analysis/HPV DNA Testing State of West Virginia, Solicitation No. MCH14020

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\*516144449

339 OLD HAYMAKER RD

#1700 PARKWAY BLDG MONROEVILLE PA 15

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

15146

PENNSYLVANIA CYTOLOGY SERVICES

412-373-8300

Solicitation

NUMBER MCH14020 PAGE 1

ADDRESS CORRESPONDENCE TO ATTENTION OF:

ROBERTA WAGNER 304-558-0067

HEALTH AND HUMAN RESOURCES
S BPH - MCH WAREHOUSE

900 BULLITT STREET CHARLESTON, WV

25301 304-558-3417

DATE PRINTED 08/07/2013 3ID OPENING DATE: 09/04/2013 BID OPENING TIME 1:30PM CAT QUANTITY LINE UOP ITEM NUMBER UNIT PRICE AMOUNT THE WEST VIRGINIA PURCHASING DIVISION IS SOLICITING BIDS ON BEHA↓F OF|THE WEST VIRGINIA DEPARTMENT OF #EALTH AND HUMAN RESOURCES, BUREAU FOR PUBLIC HEALTH, ゆFFICE OF MATERNA↓, CHILD AND FAMILY HstALTH (OMCFH), #amily planning program (fpp) and breast and cervical ancer screening program (bccsp) to establish a conract to provide cytology services as der the attached SPECIFICATIONS. 4001 JΒ 948-21 7 CYTOLOGY SERVICES - LIQUID BASED PAP TEST w002 ĦΑ 948-21 2,700 HPV/DNA TESTING (HIGH-RISK ONLY) J03 948-21

SNATURE FOR A Sweeter & VID

Medical Director

2,600

CYTOLOGY SERVICES

TELEPHONE 412-373-8300

8-30-2013

ADDRESS CHANGES TO BE NOTED ABOVE

20-0267816

- LIQUID BASED PAP TEST (PRIVATE



\*516144449

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

PENNSYLVANIA CYTOLOGY SERVICES

412-373-8300

Solicitation

NUMBER MCH14020 2

ADDRESS CORRESPONDENCE TO ATTENTION OF

ROBERTA WAGNER

04-558-0067

HEALTH AND HUMAN RESOURCES BPH - MCH WAREHOUSE

900 BULLITT STREET CHARLESTON, WV

25301 304-558-3417

339 OLD HAYMAKER RD #1700 PARKWAY BLDG MONROEVILLE PA

DATE PRINTED 08/07/2013 RID OPENING DATE: 09/04/2013 BID OPENING TIME 1:30PM CAT. LINE QUANTITY UOP ITEM NUMBER UNIT PRICE AMOUNT THIS IS THE END OF REQ MCH14 0 20 \*\*\*\*\* TOTAL:

TELEPHONE 412-373-8300

8-30-2013

ADDRESS CHANGES TO BE NOTED ABOVE Medical Director 20-0267816 WHEN RESPONDING TO SOLICITATION, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

#### INSTRUCTIONS TO VENDORS SUBMITTING BIDS

- 1. REVIEW DOCUMENTS THOROUGHLY: The attached documents contain a solicitation for bids. Please read these instructions and all documents attached in their entirety. These instructions provide critical information about requirements that if overlooked could lead to disqualification of a Vendor's bid. All bids must be submitted in accordance with the provisions contained in these instructions and the Solicitation. Failure to do so may result in disqualification of Vendor's bid.
- 2. MANDATORY TERMS: The Solicitation may contain mandatory provisions identified by the use of the words "must," "will," and "shall." Failure to comply with a mandatory term in the Solicitation will result in bid disqualification.

PREF	BID MEETING: The item identified below shall apply to this Solicitation.
$\checkmark$	A pre-bid meeting will not be held prior to bid opening.
	A NON-MANDATORY PRE-BID meeting will be held at the following place and time:
	A MANDATORY PRE-BID meeting will be held at the following place and time:

All Vendors submitting a bid must attend the mandatory pre-bid meeting. Failure to attend the mandatory pre-bid meeting shall result in disqualification of the Vendor's bid. No one person attending the pre-bid meeting may represent more than one Vendor.

An attendance sheet provided at the pre-bid meeting shall serve as the official document verifying attendance. The State will not accept any other form of proof or documentation to verify attendance. Any person attending the pre-bid meeting on behalf of a Vendor must list on the attendance sheet his or her name and the name of the Vendor he or she is representing. Additionally, the person attending the pre-bid meeting should include the Vendor's E-Mail address, phone number, and Fax number on the attendance sheet. It is the Vendor's responsibility to locate the attendance sheet and provide the required

information. Failure to complete the attendance sheet as required may result in disqualification of Vendor's bid.

All Vendors should arrive prior to the starting time for the pre-bid. Vendors who arrive after the starting time but prior to the end of the pre-bid will be permitted to sign in, but are charged with knowing all matters discussed at the pre-bid.

Questions submitted at least five business days prior to a scheduled pre-bid will be discussed at the pre-bid meeting if possible. Any discussions or answers to questions at the pre-bid meeting are preliminary in nature and are non-binding. Official and binding answers to questions will be published in a written addendum to the Solicitation prior to bid opening.

4. VENDOR QUESTION DEADLINE: Vendors may submit questions relating to this Solicitation to the Purchasing Division. Questions must be submitted in writing. All questions must be submitted on or before the date listed below and to the address listed below in order to be considered. A written response will be published in a Solicitation addendum if a response is possible and appropriate. Non-written discussions, conversations, or questions and answers regarding this Solicitation are preliminary in nature and are non-binding.

Question Submission Deadline: August 19, 2013 - end of business

Submit Questions to:

Roberta A. Wagner

2019 Washington Street, East Charleston, WV 25305

Fax: 304-558-4115

Email:roberta.a.wagner@wv.gov

- 5. VERBAL COMMUNICATION: Any verbal communication between the Vendor and any State personnel is not binding, including that made at the mandatory pre-bid conference. Only information issued in writing and added to the Solicitation by an official written addendum by the Purchasing Division is binding.
- 6. BID SUBMISSION: All bids must be signed and delivered by the Vendor to the Purchasing Division at the address listed below on or before the date and time of the bid opening. Any bid received by the Purchasing Division staff is considered to be in the possession of the Purchasing Division and will not be returned for any reason. The bid delivery address is:

Department of Administration, Purchasing Division 2019 Washington Street East Charleston, WV 25305-0130

The bid should contain the information listed below on the face of the envelope or the bid may not be considered: SEALED BID BUYER: SOLICITATION NO.: BID OPENING DATE: BID OPENING TIME: FAX NUMBER: In the event that Vendor is responding to a request for proposal, the Vendor shall submit one original technical and one original cost proposal plus \_\_\_\_\_ convenience copies of each to the Purchasing Division at the address shown above. Additionally, the Vendor should identify the bid type as either a technical or cost proposal on the face of each bid envelope submitted in response to a request for proposal as follows: BID TYPE: Technical Cost 7. BID OPENING: Bids submitted in response to this Solicitation will be opened at the location identified below on the date and time listed below. Delivery of a bid after the bid opening date and time will result in bid disqualification. For purposes of this Solicitation, a bid is considered delivered when time stamped by the official Purchasing Division time clock.

Bid Opening Date and Time:

September 4, 2013 @ 1:30 P.M.

Bid Opening Location:

Department of Administration, Purchasing Division

2019 Washington Street East Charleston, WV 25305-0130

- 8. ADDENDUM ACKNOWLEDGEMENT: Changes or revisions to this Solicitation will be made by an official written addendum issued by the Purchasing Division. Vendor should acknowledge receipt of all addenda issued with this Solicitation by completing an Addendum Acknowledgment Form, a copy of which is included herewith. Failure to acknowledge addenda may result in bid disqualification. The addendum acknowledgement should be submitted with the bid to expedite document processing.
- 9. BID FORMATTING: Vendor should type or electronically enter the information onto its bid to prevent errors in the evaluation. Failure to type or electronically enter the information may result in bid disqualification.

### **GENERAL TERMS AND CONDITIONS:**

- 1. CONTRACTUAL AGREEMENT: Issuance of a Purchase Order signed by the Purchasing Division Director, or his designee, and approved as to form by the Attorney General's office constitutes acceptance of this Contract made by and between the State of West Virginia and the Vendor. Vendor's signature on its bid signifies Vendor's agreement to be bound by and accept the terms and conditions contained in this Contract.
- 2. **DEFINITIONS:** As used in this Solicitation / Contract, the following terms shall have the meanings attributed to them below. Additional definitions may be found in the specifications included with this Solicitation / Contract.
  - 2.1 "Agency" or "Agencies" means the agency, board, commission, or other entity of the State of West Virginia that is identified on the first page of the Solicitation or any other public entity seeking to procure goods or services under this Contract.
  - **2.2 "Contract"** means the binding agreement that is entered into between the State and the Vendor to provide the goods and services requested in the Solicitation.
  - **2.3 "Director"** means the Director of the West Virginia Department of Administration, Purchasing Division.
  - 2.4 "Purchasing Division" means the West Virginia Department of Administration, Purchasing Division.
  - 2.5 "Purchase Order" means the document signed by the Agency and the Purchasing Division, and approved as to form by the Attorney General, that identifies the Vendor as the successful bidder and Contract holder.
  - **2.6 "Solicitation"** means the official solicitation published by the Purchasing Division and identified by number on the first page thereof.
  - 2.7 "State" means the State of West Virginia and/or any of its agencies, commissions, boards, etc. as context requires.
  - 2.8 "Vendor" or "Vendors" means any entity submitting a bid in response to the Solicitation, the entity that has been selected as the lowest responsible bidder, or the entity that has been awarded the Contract as context requires.

3.	3. CONTRACT TERM; RENEWAL; EXTENSION: The term of this Contract shall be determined in accordance with the category that has been identified as applicable to this Contract below:	
	$\checkmark$	Term Contract
		Initial Contract Term: This Contract becomes effective on upon award
		and extends for a period of one (1) year(s).
		Renewal Term: This Contract may be renewed upon the mutual written consent of the Agency, and the Vendor, with approval of the Purchasing Division and the Attorney General's office (Attorney General approval is as to form only). Any request for renewal must be submitted to the Purchasing Division Director thirty (30) days prior to the expiration date of the initial contract term or appropriate renewal term. A Contract renewal shall be in accordance with the terms and conditions of the original contract. Renewal of this Contract is limited to two (2) successive one (1) year periods. Automatic renewal of this Contract is prohibited. Notwithstanding the foregoing, Purchasing Division approval is not required on agency delegated or exempt purchases. Attorney General approval may be required for vendor terms and conditions.
		Reasonable Time Extension: At the sole discretion of the Purchasing Division Director, and with approval from the Attorney General's office (Attorney General approval is as to form only), this Contract may be extended for a reasonable time after the initial Contract term or after any renewal term as may be necessary to obtain a new contract or renew this Contract. Any reasonable time extension shall not exceed twelve (12) months. Vendor may avoid a reasonable time extension by providing the Purchasing Division Director with written notice of Vendor's desire to terminate this Contract 30 days prior to the expiration of the then current term. During any reasonable time extension period, the Vendor may terminate this Contract for any reason upon giving the Purchasing Division Director 30 days written notice. Automatic extension of this Contract is prohibited. Notwithstanding the foregoing, Purchasing Division approval is not required on agency delegated or exempt purchases, but Attorney General approval may be required.
		Release Order Limitations: In the event that this contract permits release orders, a release order may only be issued during the time this Contract is in effect. Any release order issued within one year of the expiration of this Contract shall be effective for one year from the date the release order is issued. No release order may be extended beyond one year after this Contract has expired.
		Fixed Period Contract: This Contract becomes effective upon Vendor's receipt of the notice to proceed and must be completed within days.

		One Time Purchase: The term of this Contract shall run from the issuance of the Purchase Order until all of the goods contracted for have been delivered, but in no event shall this Contract extend for more than one fiscal year.	
		Other: See attached.	
1.	receiv	ICE TO PROCEED: Vendor shall begin performance of this Contract immediately upon ing notice to proceed unless otherwise instructed by the Agency. Unless otherwise specified, the xecuted Purchase Order will be considered notice to proceed	
5.	•	QUANTITIES: The quantities required under this Contract shall be determined in accordance with the category that has been identified as applicable to this Contract below.	
	$\checkmark$	<b>Open End Contract:</b> Quantities listed in this Solicitation are approximations only, based on estimates supplied by the Agency. 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.	
		Service: The scope of the service to be provided will be more clearly defined in the specifications included herewith.	
		Combined Service and Goods: The scope of the service and deliverable goods to be provided will be more clearly defined in the specifications included herewith.	
		One Time Purchase: This Contract is for the purchase of a set quantity of goods that are identified in the specifications included herewith. Once those items have been delivered, no additional goods may be procured under this Contract without an appropriate change order approved by the Vendor, Agency, Purchasing Division, and Attorney General's office.	

- 6. PRICING: The pricing set forth herein is firm for the life of the Contract, unless specified elsewhere within this Solicitation/Contract by the State. A Vendor's inclusion of price adjustment provisions in its bid, without an express authorization from the State in the Solicitation to do so, may result in bid disqualification.
- 7. EMERGENCY PURCHASES: The Purchasing Division Director may authorize the Agency to purchase goods or services in the open market that Vendor would otherwise provide under this Contract if those goods or services are for immediate or expedited delivery in an emergency. Emergencies shall include, but are not limited to, delays in transportation or an unanticipated increase in the volume of work. An emergency purchase in the open market, approved by the Purchasing Division Director, shall not constitute of breach of this Contract and shall not entitle the Vendor to any form of compensation or damages. This provision does not excuse the State from fulfilling its obligations under a One Time Purchase contract.
- 8. REQUIRED DOCUMENTS: All of the items checked below must be provided to the Purchasing Division by the Vendor as specified below.

	BID BOND: All Vendors shall furnish a bid bond in the amount of five percent (5%) of the total amount of the bid protecting the State of West Virginia. The bid bond must be submitted with the bid.
	PERFORMANCE BOND: The apparent successful Vendor shall provide a performance bond in the amount of . The performance bond must be issued and received by the Purchasing Division prior to Contract award. On construction contracts, the performance bond must be 100% of the Contract value.
	<b>LABOR/MATERIAL PAYMENT BOND:</b> The apparent successful Vendor shall provide a labor/material payment bond in the amount of 100% of the Contract value. The labor/material payment bond must be issued and delivered to the Purchasing Division prior to Contract award.
certific or irres same labor/r	of the Bid Bond, Performance Bond, and Labor/Material Payment Bond, the Vendor may provide ed checks, cashier's checks, or irrevocable letters of credit. Any certified check, cashier's check vocable letter of credit provided in lieu of a bond must be of the same amount and delivered on the schedule as the bond it replaces. A letter of credit submitted in lieu of a performance and material payment bond will only be allowed for projects under \$100,000. Personal or business are not acceptable.
	MAINTENANCE BOND: The apparent successful Vendor shall provide a two (2) year maintenance bond covering the roofing system. The maintenance bond must be issued and delivered to the Purchasing Division prior to Contract award.
	WORKERS' COMPENSATION INSURANCE: The apparent successful Vendor shall have appropriate workers' compensation insurance and shall provide proof thereof upon request.
$\checkmark$	<b>INSURANCE:</b> The apparent successful Vendor shall furnish proof of the following insurance prior to Contract award and shall list the state as a certificate holder:
	Commercial General Liability Insurance: \$ 1,000,000.00 or more.  Builders Risk Insurance: builders risk – all risk insurance in an amount equal to 100% of the amount of the Contract.  Professional Liability - \$ 1,000,000.00

The apparent successful Vendor shall also furnish proof of any additional insurance requirements contained in the specifications prior to Contract award regardless of whether or not that insurance requirement is listed above.

LICENSE(S) / CERTIFICATIONS / PERMITS: In addition to anything required under the Section entitled Licensing, of the General Terms and Conditions, the apparent successful Vendor shall furnish proof of the following licenses, certifications, and/or permits prior to Contract		
award, in a	form acceptable to the Purchasing Division.	
$\checkmark$	Clinical Laboratory Improvement Amendment (CLIA) certification	
$\checkmark$	Business License to perform Cytology services	

The apparent successful Vendor shall also furnish proof of any additional licenses or certifications contained in the specifications prior to Contract award regardless of whether or not that requirement is listed above.

- 9. LITIGATION BOND: The Director reserves the right to require any Vendor that files a protest of an award to submit a litigation bond in the amount equal to one percent of the lowest bid submitted or \$5,000, whichever is greater. The entire amount of the bond shall be forfeited if the hearing officer determines that the protest was filed for frivolous or improper purpose, including but not limited to, the purpose of harassing, causing unnecessary delay, or needless expense for the Agency. All litigation bonds shall be made payable to the Purchasing Division. In lieu of a bond, the protester may submit a cashier's check or certified check payable to the Purchasing Division. Cashier's or certified checks will be deposited with and held by the State Treasurer's office. If it is determined that the protest has not been filed for frivolous or improper purpose, the bond or deposit shall be returned in its entirety.
- 10. ALTERNATES: Any model, brand, or specification listed herein establishes the acceptable level of quality only and is not intended to reflect a preference for, or in any way favor, a particular brand or vendor. Vendors may bid alternates to a listed model or brand provided that the alternate is at least equal to the model or brand and complies with the required specifications. The equality of any alternate being bid shall be determined by the State at its sole discretion. Any Vendor bidding an alternate model or brand should clearly identify the alternate items in its bid and should include manufacturer's specifications, industry literature, and/or any other relevant documentation demonstrating the equality of the alternate items. Failure to provide information for alternate items may be grounds for rejection of a Vendor's bid.
- 11. EXCEPTIONS AND CLARIFICATIONS: The Solicitation contains the specifications that shall form the basis of a contractual agreement. Vendor shall clearly mark any exceptions, clarifications, or

other proposed modifications in its bid. Exceptions to, clarifications of, or modifications of a requirement or term and condition of the Solicitation may result in bid disqualification.

12. LIQUIDATED DAMAGES: Vendor shall pay liquidated damages in the amount for

This clause shall in no way be considered exclusive and shall not limit the State or Agency's right to pursue any other available remedy.

- 13. ACCEPTANCE/REJECTION: The State may accept or reject any bid in whole, or in part. Vendor's signature on its bid signifies acceptance of the terms and conditions contained in the Solicitation and Vendor agrees to be bound by the terms of the Contract, as reflected in the Purchase Order, upon receipt.
- 14. REGISTRATION: Prior to Contract award, the apparent successful Vendor must be properly registered with the West Virginia Purchasing Division and must have paid the \$125 fee if applicable.
- 15. COMMUNICATION LIMITATIONS: In accordance with West Virginia Code of State Rules §148-1-6.6, communication with the State of West Virginia or any of its employees regarding this Solicitation during the solicitation, bid, evaluation or award periods, except through the Purchasing Division, is strictly prohibited without prior Purchasing Division approval. Purchasing Division approval for such communication is implied for all agency delegated and exempt purchases.
- 16. FUNDING: This Contract shall continue for the term stated herein, contingent upon funds being appropriated by the Legislature or otherwise being made available. In the event funds are not appropriated or otherwise made available, this Contract becomes void and of no effect beginning on July 1 of the fiscal year for which funding has not been appropriated or otherwise made available.
- 17. PAYMENT: Payment in advance is prohibited under this Contract. Payment may only be made after the delivery and acceptance of goods or services. The Vendor shall submit invoices, in arrears, to the Agency at the address on the face of the purchase order labeled "Invoice To."
- 18. UNIT PRICE: Unit prices shall prevail in cases of a discrepancy in the Vendor's bid.
- 19. DELIVERY: All quotations are considered freight on board destination ("F.O.B. destination") unless alternate shipping terms are clearly identified in the bid. Vendor's listing of shipping terms that contradict the shipping terms expressly required by this Solicitation may result in bid disqualification.
- 20. INTEREST: Interest attributable to late payment will only be permitted if authorized by the West Virginia Code. Presently, there is no provision in the law for interest on late payments.
- 21. PREFERENCE: Vendor Preference may only be granted upon written request and only in accordance with the West Virginia Code § 5A-3-37 and the West Virginia Code of State Rules. A Resident Vendor Certification form has been attached hereto to allow Vendor to apply for the preference. Vendor's

failure to submit the Resident Vendor Certification form with its bid will result in denial of Vendor Preference. Vendor Preference does not apply to construction projects.

- 22. SMALL, WOMEN-OWNED, OR MINORITY-OWNED BUSINESSES: For any solicitations publicly advertised for bid on or after July 1, 2012, in accordance with West Virginia Code §5A-3-37(a)(7) and W. Va. CSR § 148-22-9, any non-resident vendor certified as a small, women-owned, or minority-owned business under W. Va. CSR § 148-22-9 shall be provided the same preference made available to any resident vendor. Any non-resident small, women-owned, or minority-owned business must identify itself as such in writing, must submit that writing to the Purchasing Division with its bid, and must be properly certified under W. Va. CSR § 148-22-9 prior to submission of its bid to receive the preferences made available to resident vendors. Preference for a non-resident small, women-owned, or minority owned business shall be applied in accordance with W. Va. CSR § 148-22-9.
- 23. TAXES: The Vendor shall pay any applicable sales, use, personal property or any other taxes arising out of this Contract and the transactions contemplated thereby. The State of West Virginia is exempt from federal and state taxes and will not pay or reimburse such taxes.
- 24. CANCELLATION: The Purchasing Division Director reserves the right to cancel this Contract immediately upon written notice to the vendor if the materials or workmanship supplied do not conform to the specifications contained in the Contract. The Purchasing Division Director may cancel any purchase or Contract upon 30 days written notice to the Vendor in accordance with West Virginia Code of State Rules § 148-1-7.16.2.
- 25. WAIVER OF MINOR IRREGULARITIES: The Director reserves the right to waive minor irregularities in bids or specifications in accordance with West Virginia Code of State Rules § 148-1-4.6.
- 26. TIME: Time is of the essence with regard to all matters of time and performance in this Contract.
- 27. APPLICABLE LAW: This Contract is governed by and interpreted under West Virginia law without giving effect to its choice of law principles. Any information provided in specification manuals, or any other source, verbal or written, which contradicts or violates the West Virginia Constitution, West Virginia Code or West Virginia Code of State Rules is void and of no effect.
- 28. COMPLIANCE: Vendor shall comply with all applicable federal, state, and local laws, regulations and ordinances. By submitting a bid, Vendors acknowledge that they have reviewed, understand, and will comply with all applicable law.
- 29. PREVAILING WAGE: On any contract for the construction of a public improvement, Vendor and any subcontractors utilized by Vendor shall pay a rate or rates of wages which shall not be less than the fair minimum rate or rates of wages (prevailing wage), as established by the West Virginia Division of Labor under West Virginia Code §§ 21-5A-1 et seq. and available at <a href="http://www.sos.wv.gov/administrative-law/wagerates/Pages/default.aspx">http://www.sos.wv.gov/administrative-law/wagerates/Pages/default.aspx</a>. Vendor shall be responsible for ensuring compliance with prevailing wage requirements and determining when prevailing wage

- requirements are applicable. The required contract provisions contained in West Virginia Code of State Rules § 42-7-3 are specifically incorporated herein by reference.
- 30. ARBITRATION: Any references made to arbitration contained in this Contract, Vendor's bid, or in any American Institute of Architects documents pertaining to this Contract are hereby deleted, void, and of no effect.
- 31. MODIFICATIONS: This writing is the parties' final expression of intent. Notwithstanding anything contained in this Contract to the contrary, no modification of this Contract shall be binding without mutual written consent of the Agency, and the Vendor, with approval of the Purchasing Division and the Attorney General's office (Attorney General approval is as to form only). No Change shall be implemented by the Vendor until such time as the Vendor receives an approved written change order from the Purchasing Division.
- 32. WAIVER: The failure of either party to insist upon a strict performance of any of the terms or provision of this Contract, or to exercise any option, right, or remedy herein contained, shall not be construed as a waiver or a relinquishment for the future of such term, provision, option, right, or remedy, but the same shall continue in full force and effect. Any waiver must be expressly stated in writing and signed by the waiving party.
- 33. SUBSEQUENT FORMS: The terms and conditions contained in this Contract shall supersede any and all subsequent terms and conditions which may appear on any form documents submitted by Vendor to the Agency or Purchasing Division such as price lists, order forms, invoices, sales agreements, or maintenance agreements, and includes internet websites or other electronic documents. Acceptance or use of Vendor's forms does not constitute acceptance of the terms and conditions contained thereon.
- 34. ASSIGNMENT: Neither this Contract nor any monies due, or to become due hereunder, may be assigned by the Vendor without the express written consent of the Agency, the Purchasing Division, the Attorney General's office (as to form only), and any other government agency or office that may be required to approve such assignments. Notwithstanding the foregoing, Purchasing Division approval may or may not be required on certain agency delegated or exempt purchases.
- 35. WARRANTY: The Vendor expressly warrants that the goods and/or services covered by this Contract will: (a) conform to the specifications, drawings, samples, or other description furnished or specified by the Agency; (b) be merchantable and fit for the purpose intended; and (c) be free from defect in material and workmanship.
- 36. STATE EMPLOYEES: State employees are not permitted to utilize this Contract for personal use and the Vendor is prohibited from permitting or facilitating the same.
- 37. BANKRUPTCY: In the event the Vendor files for bankruptcy protection, the State of West Virginia may deem this Contract null and void, and terminate this Contract without notice.

### 38. [RESERVED]

- 39. CONFIDENTIALITY: The Vendor agrees that it 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 <a href="http://www.state.wv.us/admin/purchase/privacy/default.html">http://www.state.wv.us/admin/purchase/privacy/default.html</a>.
- 40. DISCLOSURE: Vendor's response to the Solicitation and the resulting Contract are considered public documents and will be disclosed to the public in accordance with the laws, rules, and policies governing the West Virginia Purchasing Division. Those laws include, but are not limited to, the Freedom of Information Act found in West Virginia Code § 29B-1-1 et seq.

If a Vendor considers any part of its bid to be exempt from public disclosure, Vendor must so indicate by specifically identifying the exempt information, identifying the exemption that applies, providing a detailed justification for the exemption, segregating the exempt information from the general bid information, and submitting the exempt information as part of its bid but in a segregated and clearly identifiable format. Failure to comply with the foregoing requirements will result in public disclosure of the Vendor's bid without further notice. A Vendor's act of marking all or nearly all of its bid as exempt is not sufficient to avoid disclosure and WILL NOT BE HONORED. Vendor's act of marking a bid or any part thereof as "confidential" or "proprietary" is not sufficient to avoid disclosure and WILL NOT BE HONORED. In addition, a legend or other statement indicating that all or substantially all of the bid is exempt from disclosure is not sufficient to avoid disclosure and WILL NOT BE HONORED. Vendor will be required to defend any claimed exemption for nondiclosure in the event of an administrative or judicial challenge to the State's nondisclosure. Vendor must indemnify the State for any costs incurred related to any exemptions claimed by Vendor. Any questions regarding the applicability of the various public records laws should be addressed to your own legal counsel prior to bid submission.

- 41. LICENSING: In accordance with West Virginia Code of State Rules §148-1-6.1.7, Vendor 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 agency or political subdivision. Upon request, the Vendor must provide all necessary releases to obtain information to enable the Purchasing Division Director or the Agency to verify that the Vendor is licensed and in good standing with the above entities.
- 42. ANTITRUST: In submitting a bid to, signing a contract with, or accepting a Purchase Order from any agency of the State of West Virginia, the Vendor agrees to 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 Vendor.

43. VENDOR CERTIFICATIONS: By signing its bid or entering into this Contract, Vendor certifies (1) that its bid was made without prior understanding, agreement, or connection with any corporation, firm, limited liability company, partnership, person or entity submitting a bid for the same material, supplies, equipment or services; (2) that its bid is in all respects fair and without collusion or fraud; (3) that this Contract is accepted or entered into without any prior understanding, agreement, or connection to any other entity that could be considered a violation of law; and (4) that it has reviewed this RFQ in its entirety; understands the requirements, terms and conditions, and other information contained herein. Vendor's signature on its bid also affirms that neither it nor its representatives have any interest, nor shall acquire any interest, direct or indirect, which would compromise the performance of its services hereunder. Any such interests shall be promptly presented in detail to the Agency.

The individual signing this bid on behalf of Vendor certifies that he or she is authorized by the Vendor to execute this bid or any documents related thereto on Vendor's behalf; that he or she is authorized to bind the Vendor in a contractual relationship; and that, to the best of his or her knowledge, the Vendor has properly registered with any State agency that may require registration.

- 44. PURCHASING CARD ACCEPTANCE: The State of West Virginia currently utilizes a Purchasing Card program, administered under contract by a banking institution, to process payment for goods and services. The Vendor must accept the State of West Virginia's Purchasing Card for payment of all orders under this Contract unless the box below is checked.
  - Vendor is not required to accept the State of West Virginia's Purchasing Card as payment for all goods and services.
- 45. VENDOR RELATIONSHIP: The relationship of the Vendor to the State shall be that of an independent contractor and no principal-agent relationship or employer-employee relationship is contemplated or created by this Contract. The Vendor as an independent contractor is solely liable for the acts and omissions of its employees and agents. Vendor shall be responsible for selecting,

supervising, and compensating any and all individuals employed pursuant to the terms of this Solicitation and resulting contract. Neither the Vendor, nor any employees or subcontractors of the Vendor, shall be deemed to be employees of the State for any purpose whatsoever. Vendor shall be exclusively responsible for payment of employees and contractors for all wages and salaries, taxes, withholding payments, penalties, fees, fringe benefits, professional liability insurance premiums, contributions to insurance and pension, or other deferred compensation plans, including but not limited to, Workers' Compensation and Social Security obligations, licensing fees, etc. and the filing of all necessary documents, forms and returns pertinent to all of the foregoing. Vendor shall hold harmless the State, and shall provide the State and Agency with a defense against any and all claims including, but not limited to, the foregoing payments, withholdings, contributions, taxes, Social Security taxes, and employer income tax returns.

**46. INDEMNIFICATION:** The Vendor agrees to indemnify, defend, and hold harmless the State and the Agency, their officers, and employees from and against: (1) Any claims or losses for services rendered

by any subcontractor, person, or firm performing or supplying services, materials, or supplies in connection with the performance of the Contract; (2) Any claims or losses resulting to any person or entity injured or damaged by the Vendor, its officers, employees, or subcontractors by the publication, translation, reproduction, delivery, performance, use, or disposition of any data used under the Contract in a manner not authorized by the Contract, or by Federal or State statutes or regulations; and (3) Any failure of the Vendor, its officers, employees, or subcontractors to observe State and Federal laws including, but not limited to, labor and wage and hour laws.

- 47. PURCHASING AFFIDAVIT: In accordance with West Virginia Code § 5A-3-10a, all Vendors are required to sign, notarize, and submit the Purchasing Affidavit stating that neither the Vendor nor a related party owe a debt to the State in excess of \$1,000. The affidavit must be submitted prior to award, but should be submitted with the Vendor's bid. A copy of the Purchasing Affidavit is included herewith.
- 48. ADDITIONAL AGENCY AND LOCAL GOVERNMENT USE: This Contract may be utilized by and extends to other agencies, spending units, and political subdivisions of the State of West Virginia; county, municipal, and other local government bodies; and school districts ("Other Government Entities"). This Contract shall be extended to the aforementioned Other Government Entities on the same prices, terms, and conditions as those offered and agreed to in this Contract. If the Vendor does not wish to extend the prices, terms, and conditions of its bid and subsequent contract to the Other Government Entities, the Vendor must clearly indicate such refusal in its bid. A refusal to extend this Contract to the Other Government Entities shall not impact or influence the award of this Contract in any manner.
- 49. CONFLICT OF INTEREST: Vendor, its officers or members or employees, shall not presently have or acquire any interest, direct or indirect, which would conflict with or compromise the performance of its obligations hereunder. Vendor shall periodically inquire of its officers, members and employees to ensure that a conflict of interest does not arise. Any conflict of interest discovered shall be promptly presented in detail to the Agency.
- **50. REPORTS:** Vendor shall provide the Agency and/or the Purchasing Division with the following reports identified by a checked box below:
  - Such reports as the Agency and/or the Purchasing Division may request. Requested reports may include, but are not limited to, quantities purchased, agencies utilizing the contract, total contract expenditures by agency, etc.
  - Quarterly reports detailing the total quantity of purchases in units and dollars, along with a listing of purchases by agency. Quarterly reports should be delivered to the Purchasing Division via email at <a href="mailto:purchasing.requisitions@wv.gov">purchasing.requisitions@wv.gov</a>.
- 51. BACKGROUND CHECK: In accordance with W. Va. Code § 15-2D-3, the Director of the Division of Protective Services shall require any service provider whose employees are regularly employed on the grounds or in the buildings of the Capitol complex or who have access to sensitive or critical information to submit to a fingerprint-based state and federal background inquiry through the state Revised 07/25/2013

repository. The service provider is responsible for any costs associated with the fingerprint-based state and federal background inquiry.

After the contract for such services has been approved, but before any such employees are permitted to be on the grounds or in the buildings of the Capitol complex or have access to sensitive or critical information, the service provider shall submit a list of all persons who will be physically present and working at the Capitol complex to the Director of the Division of Protective Services for purposes of verifying compliance with this provision.

The State reserves the right to prohibit a service provider's employees from accessing sensitive or critical information or to be present at the Capitol complex based upon results addressed from a criminal background check.

Service providers should contact the West Virginia Division of Protective Services by phone at (304) 558-9911 for more information.

- 52. PREFERENCE FOR USE OF DOMESTIC STEEL PRODUCTS: Except when authorized by the Director of the Purchasing Division pursuant to W. Va. Code § 5A-3-56, no contractor may use or supply steel products for a State Contract Project other than those steel products made in the United States. A contractor who uses steel products in violation of this section may be subject to civil penalties pursuant to W. Va. Code § 5A-3-56. As used in this section:
  - a. "State Contract Project" means any erection or construction of, or any addition to, alteration of or other improvement to any building or structure, including, but not limited to, roads or highways, or the installation of any heating or cooling or ventilating plants or other equipment, or the supply of and materials for such projects, pursuant to a contract with the State of West Virginia for which bids were solicited on or after June 6, 2001.
  - b. "Steel Products" means products rolled, formed, shaped, drawn, extruded, forged, cast, fabricated or otherwise similarly processed, or processed by a combination of two or more or
    - such operations, from steel made by the open heath, basic oxygen, electric furnace, Bessemer or other steel making process.

The Purchasing Division Director may, in writing, authorize the use of foreign steel products if:

- a. The cost for each contract item used does not exceed one tenth of one percent (.1%) of the total contract cost or two thousand five hundred dollars (\$2,500.00), whichever is greater. For the purposes of this section, the cost is the value of the steel product as delivered to the project; or
- b. The Director of the Purchasing Division determines that specified steel materials are not produced in the United States in sufficient quantity or otherwise are not reasonably available to meet contract requirements.
- 53. PREFERENCE FOR USE OF DOMESTIC ALUMINUM, GLASS, AND STEEL: In Accordance

with W. Va. Code § 5-19-1 et seq., and W. Va. CSR § 148-10-1 et seq., for every contract or subcontract, subject to the limitations contained herein, for the construction, reconstruction, alteration, repair, improvement or maintenance of public works or for the purchase of any item of machinery or equipment to be used at sites of public works, only domestic aluminum, glass or steel products shall be supplied unless the spending officer determines, in writing, after the receipt of offers or bids, (1) that the cost of domestic aluminum, glass or steel products is unreasonable or inconsistent with the public interest of the State of West Virginia, (2) that domestic aluminum, glass or steel products are not produced in sufficient quantities to meet the contract requirements, or (3) the available domestic aluminum, glass, or steel do not meet the contract specifications. This provision only applies to public works contracts awarded in an amount more than fifty thousand dollars (\$50,000) or public works contracts that require more than ten thousand pounds of steel products.

The cost of domestic aluminum, glass, or steel products may be unreasonable if the cost is more than twenty percent (20%) of the bid or offered price for foreign made aluminum, glass, or steel products. If the domestic aluminum, glass or steel products to be supplied or produced in a "substantial labor surplus area", as defined by the United States Department of Labor, the cost of domestic aluminum, glass, or steel products may be unreasonable if the cost is more than thirty percent (30%) of the bid or offered price for foreign made aluminum, glass, or steel products.

This preference shall be applied to an item of machinery or equipment, as indicated above, when the item is a single unit of equipment or machinery manufactured primarily of aluminum, glass or steel, is part of a public works contract and has the sole purpose or of being a permanent part of a single public works project. This provision does not apply to equipment or machinery purchased by a spending unit for use by that spending unit and not as part of a single public works project.

All bids and offers including domestic aluminum, glass or steel products that exceed bid or offer prices including foreign aluminum, glass or steel products after application of the preferences provided in this provision may be reduced to a price equal to or lower than the lowest bid or offer price for foreign aluminum, glass or steel products plus the applicable preference. If the reduced bid or offer prices are made in writing and supersede the prior bid or offer prices, all bids or offers, including the reduced bid or offer prices, will be reevaluated in accordance with this rule.

# REQUEST FOR QUOTATION MCH14020 CYTOLOGY SERVICES

### **SPECIFICATIONS**

- 1. PURPOSE AND SCOPE: The West Virginia Purchasing Division is soliciting bids on behalf of the West Virginia Department of Health and Human Resources, Bureau for Public Health, Office of Maternal, Child and Family Health (OMCFH), Family Planning Program (FPP) and Breast and Cervical Cancer Screening Program (BCCSP) to establish a contract to provide cytology services to include specimen accession, specimen processing, high risk human papilloma virus (HRHPV) testing, provision of cytotechnologist, pathologist(s) coverage, specimen evaluation, record keeping and quality assurance activities and reports. OMCFH offers preventive health care and screening services through a community-based network of health care providers throughout the State. FPP provides comprehensive reproductive health care, medical services, counseling and education, contraceptive methods and laboratory services, including cytology screening. FPP services are offered through a statewide network of 150 participating provider agencies. 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 FPP.
- 2. **DEFINITIONS:** The terms listed below shall have the meanings assigned to them below. Additional definitions can be found in section 2 of the General Terms and Conditions.
  - 2.1 "Contract Services" means cytology services for OMCFH and BCCSP.
  - 2.2 "Pricing Page" means the pages upon which Vendor should list its proposed price for the Contract Services. The Pricing Page is either included on the last page of this RFQ or attached hereto as Exhibit A.
  - 2.3 "RFQ" means the official request for quotation published by the Purchasing Division and identified as MCH14020.
- 3. QUALIFICATIONS: Vendor shall have the following minimum qualifications:
  - 3.1. Vendor must have been in business and maintained a business license to perform cytology services for a minimum of five (5) years.

## REQUEST FOR QUOTATION MCH14020 CYTOLOGY SERVICES

### 4. MANDATORY REQUIREMENTS:

**4.1 Mandatory Contract Services Requirements and Deliverables:** Contract Services must meet or exceed the mandatory requirements listed below.

### 4.1.1 Specimen Processing, Evaluation and Reporting

- 4.1.1.1 Vendor must provide participating FPP and BCCSP providers all supplies necessary for collection of approximately 60,000 Thin Prep Liquid Medium/Monolayer System test specimens or equal annually for program funded clients or approximately 2,600 private pay program eligible clients annually. These supplies shall include requisition forms mailers, specimen containers that provide space for writing the patient's name, cervical scrapers and cytobrushes. Additionally, HPV/DNA testing must be conducted per program algorithm, with approximately 2,700 tests conducted annually.
- 4.1.1.2 Vendor must provide the clinic code number, patient Social Security number, patient name, clinic visit date (date specimen collected), date of birth, specimen type, date of previous Pap test, class of previous Pap test and name and address of program provider be submitted with the specimen.
- **4.1.1.3** Vendor must examine, interpret and report results on all Pap tests submitted by the FPP and BCCSP providers not to exceed ten (10) calendar days from the date the specimens are received. 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.
- 4.1.1.4 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.
- **4.1.1.5** Vendor will assume all responsibility and liability for reading and processing of all Pap tests.

# REQUEST FOR QUOTATION MCH14020 CYTOLOGY SERVICES

- **4.1.1.6** Vendor must have written criteria for rejection of specimens and for categorizing specimens as unsatisfactory.
- **4.1.1.7** Vendor must retain negative and unsatisfactory slides for five (5) years and positive slides for twenty (20) years.
- **4.1.1.8** Prior to award, vendor must attach pertinent testing literature if bidding on alternate testing.

### 4.1.2 Data Requirements

- 4.1.2.1 Vendor must provide a program-specific electronic report (using a Microsoft program such as an Excel spreadsheet or PDF) to FPP and BCCSP with the total number of Pap tests received, interpreted and categorized according to 2001 Bethesda System, including specimen adequacy and total number of HRHPV tests performed.
- 4.1.2.2 Vendor must agree 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.
- **4.1.2.3** Vendor must respond to all requests for statistical information or data within five (5) working days.

### 4.1.3 Quality Assurance

- **4.1.3.1** 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
- **4.1.3.2** 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.

## REQUEST FOR QUOTATION MCH14020 CYTOLOGY SERVICES

- 4.1.3.3 Prior to award, vendor is required to meet all Clinical Laboratory Improvements (CLIA) requirements and to obtain CLIA certification. The contractor agrees to follow all rules and regulations in accordance with the Clinical Laboratory Improvements Amendments of 1988 (CLIA-1988)
- 4.1.3.4 Prior to award, vendor must have a CLIA-88 qualified pathologist as director (technical supervisor), qualified cytology general supervisor and qualified cytotechnologist(s) on site.
- 4.1.3.5 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. The time for the on-site meeting would vary based on necessity.
- **4.1.3.6** Vendor must retrieve stored FPP or BSSCP Pap tests the same day as requested by either program.
- **4.1.3.7** Vendor must document the receipt, circulation, referral and transfer of original Pap tests.
- **4.1.3.8** 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.
- **4.1.3.9** Vendor must show documentation of a maintenance schedule for equipment and microscopes and implement said schedule annually.
- **4.1.3.10** 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.
- **4.1.3.11** Vendor must show documentation for continuing education for the staff cytotechnologist(s), prior to award.

### 4.1.4 Administrative and Operational Requirements

# REQUEST FOR QUOTATION MCH14020 CYTOLOGY SERVICES

- **4.1.4.1** Vendor shall designate a project administrator. The vendor's project administrator shall report to the FPP and BCCSP program directors monthly regarding all matters related to cytology services.
- 4.1.4.2 Vendor must meet all requirements within the specification and 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.

#### 5. CONTRACT AWARD:

- 5.1 Contract Award: The Contract is intended to provide Agency with a purchase price for the Contract Services. The Contract shall be awarded to the Vendor that provides the Contract Services meeting the required specifications for the lowest overall total cost as shown on the Pricing Pages.
- **5.2 Pricing Page:** Vendor should complete the Pricing Page by completing the Unit Price, Extended Cost and Overall Total Cost of each item. Vendor should complete the Pricing Page in full as failure to complete the Pricing Page in its entirety may result in Vendor's bid being disqualified.

Notwithstanding the foregoing, the Purchasing Division may correct errors as it deems appropriate. Vendor should type or electronically enter the information into the Pricing Page to prevent errors in the evaluation.

- 6. PERFORMANCE: Vendor and Agency shall agree upon a schedule for performance of Contract Services and Contract Services Deliverables, unless such a schedule is already included herein by Agency. In the event that this Contract is designated as an open-end contract, Vendor shall perform in accordance with the release orders that may be issued against this Contract.
- 7. PAYMENT: Agency shall pay per test, as shown on the Pricing Pages, for all Contract Services performed and accepted under this Contract. Vendor shall accept payment in accordance with the payment procedures of the State of West Virginia.
- 8. TRAVEL: Vendor shall be responsible for all mileage and travel costs, including travel time, associated with performance of this Contract. Any anticipated mileage or travel costs

## REQUEST FOR QUOTATION MCH14020 CYTOLOGY SERVICES

may be included in the flat fee or hourly rate listed on Vendor's bid, but such costs will not be paid by the Agency separately.

- 9. FACILITIES ACCESS: Performance of Contract Services may require access cards and/or keys to gain entrance to Agency's facilities. In the event that access cards and/or keys are required:
  - **9.1.** Vendor must identify principal service personnel which will be issued access cards and/or keys to perform service.
  - **9.2.** Vendor will be responsible for controlling cards and keys and will pay replacement fee, if the cards or keys become lost or stolen.
  - **9.3.** Vendor shall notify Agency immediately of any lost, stolen, or missing card or key.
  - **9.4.** Anyone performing under this Contract will be subject to Agency's security protocol and procedures.
  - 9.5. Vendor shall inform all staff of Agency's security protocol and procedures.

#### 10. VENDOR DEFAULT:

- 10.1. The following shall be considered a vendor default under this Contract.
  - **10.1.1.** Failure to perform Contract Services in accordance with the requirements contained herein.
  - **10.1.2.** Failure to comply with other specifications and requirements contained herein.
  - 10.1.3. Failure to comply with any laws, rules, and ordinances applicable to the Contract Services provided under this Contract.

## REQUEST FOR QUOTATION MCH14020 CYTOLOGY SERVICES

- **10.1.4.** Failure to remedy deficient performance upon request.
- 10.2. The following remedies shall be available to Agency upon default.
  - 10.2.1. Cancellation of the Contract.
  - 10.2.2. Cancellation of one or more release orders issued under this Contract.
  - 10.2.3. Any other remedies available in law or equity.

#### 11. MISCELLANEOUS:

11.1. Contract Manager: During its performance of this Contract, Vendor must designate and maintain a primary contract manager responsible for overseeing Vendor's responsibilities under this Contract. The Contract manager must be available during normal business hours to address any customer service or other issues related to this Contract. Vendor should list its Contract manager and his or her contact information below.

Contract Manager: Lisa Ritchey
Telephone Number: 1-800-344-1026

Fax Number: 412-373-7027

Email Address: lisaritchey@pacytology.com

### **WV STATE GOVERNMENT**

#### HIPAA BUSINESS ASSOCIATE ADDENDUM

This Health Insurance Portability and Accountability Act of 1996 (hereafter, HIPAA). Business Associate Addendum ("Addendum") is made a part of the Agreement ("Agreement"), by and between the State of West Virginia ("Agency"), and Business Associate ("Associate"), and is effective as of the date of execution of the Addendum.

The Associate performs certain services on behalf of or for the Agency pursuant to the underlying Agreement that requires the exchange of information including protected health information protected by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the American Recovery and Reinvestment Act of 2009 (Pub. L. No. 111-5) (the "HITECH Act"), any associated regulations and the federal regulations published at 45 CFR parts 160 and 164 (sometimes collectively referred to as "HIPAA"). The Agency is a "Covered Entity" as that term is defined in HIPAA, and the parties to the underlying Agreement are entering into this Addendum to establish the responsibilities of both parties regarding HIPAA-covered information and to bring the underlying Agreement into compliance with HIPAA.

Whereas it is desirable, in order to further the continued efficient operations of Agency to disclose to its Associate certain information which may contain confidential individually identifiable health information (hereafter, Protected Health Information or PHI); and

Whereas, it is the desire of both parties that the confidentiality of the PHI disclosed hereunder be maintained and treated in accordance with all applicable laws relating to confidentiality, including the Privacy and Security Rules, the HITECH Act and its associated regulations, and the parties do agree to at all times treat the PHI and interpret this Addendum consistent with that desire.

NOW THEREFORE: the parties agree that in consideration of the mutual promises herein, in the Agreement, and of the exchange of PHI hereunder that:

- Definitions. Terms used, but not otherwise defined, in this Addendum shall have the same meaning as those terms in the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.
  - a. Agency Procurement Officer shall mean the appropriate Agency individual listed at: <a href="http://www.state.wv.us/admin/purchase/vrc/agencyli.html">http://www.state.wv.us/admin/purchase/vrc/agencyli.html</a>.
  - b. Agent shall mean those person(s) who are agent(s) of the Business Associate, in accordance with the Federal common law of agency, as referenced in 45 CFR § 160.402(c).
  - c. Breach shall mean the acquisition, access, use or disclosure of protected health information which compromises the security or privacy of such information, except as excluded in the definition of Breach in 45 CFR § 164.402.
  - d. Business Associate shall have the meaning given to such term in 45 CFR § 160.103.
  - e. HITECH Act shall mean the Health Information Technology for Economic and Clinical Health Act. Public Law No. 111-05. 111<sup>th</sup> Congress (2009).

- f. Privacy Rule means the Standards for Privacy of Individually Identifiable Health Information found at 45 CFR Parts 160 and 164.
- 9. Protected Health Information or PHI shall have the meaning given to such term in 45 CFR § 160.103, limited to the information created or received by Associate from or on behalf of Agency.
- h. Security incident means any known successful or unsuccessful attempt by an authorized or unauthorized individual to inappropriately use, disclose, modify, access, or destroy any information or interference with system operations in an information system.
- Security Rule means the Security Standards for the Protection of Electronic Protected Health Information found at 45 CFR Parts 160 and 164.
- j. Subcontractor means a person to whom a business associate delegates a function, activity, or service, other than in the capacity of a member of the workforce of such business associate.

#### 2. Permitted Uses and Disclosures.

- a. PHI Described. This means PHI created, received, maintained or transmitted on behalf of the Agency by the Associate. This PHI is governed by this Addendum and is limited to the minimum necessary, to complete the tasks or to provide the services associated with the terms of the original Agreement, and is described in Appendix A.
- b. Purposes. Except as otherwise limited in this Addendum, Associate may use or disclose the PHI on behalf of, or to provide services to, Agency for the purposes necessary to complete the tasks, or provide the services, associated with, and required by the terms of the original Agreement, or as required by law, if such use or disclosure of the PHI would not violate the Privacy or Security Rules or applicable state law if done by Agency or Associate, or violate the minimum necessary and related Privacy and Security policies and procedures of the Agency. The Associate is directly liable under HIPAA for impermissible uses and disclosures of the PHI it handles on behalf of Agency.
- c. Further Uses and Disclosures. Except as otherwise limited in this Addendum, the Associate may disclose PHI to third parties for the purpose of its own proper management and administration, or as required by law, provided that (I) the disclosure is required by law, or (ii) the Associate has obtained from the third party reasonable assurances that the PHI will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the third party by the Associate; and, (Iii) an agreement to notify the Associate and Agency of any instances of which it (the third party) is aware in which the confidentiality of the information has been breached. To the extent practical, the information should be in a limited data set or the minimum necessary information pursuant to 45 CFR § 164.502, or take other measures as necessary to satisfy the Agency's obligations under 45 CFR § 164.502.

### 3. Obligations of Associate.

- a. Stated Purposes Only. The PHI may not be used by the Associate for any purpose other than as stated in this Addendum or as required or permitted by law.
- Limited Disclosure. The PHI-is-confidential and will not be disclosed by the Associate other than as stated in this Addendum or as required or permitted by law. Associate is prohibited from directly or indirectly receiving any remuneration in exchange for an individual's PHI unless Agency gives written approval and the individual provides a valid authorization. Associate will refrain from marketing activities that would violate HIPAA, including specifically Section 13406 of the HITECH Act. Associate will report to Agency any use or disclosure of the PHI, including any Security Incident not provided for by this Agreement of which it becomes aware.
- c. Safeguards. The Associate will use appropriate safeguards, and comply with Subpart C of 45 CFR Part 164 with respect to electronic protected health information, to prevent use or disclosure of the PHI, except as provided for in this Addendum. This shall include, but not be limited to:
  - Limitation of the groups of its workforce and agents, to whom the PHI is disclosed to those reasonably required to accomplish the purposes stated in this Addendum, and the use and disclosure of the minimum PHI necessary or a Limited Data Set;
  - Appropriate notification and training of its workforce and agents in order to protect the PHI from unauthorized use and disclosure;
  - Maintenance of a comprehensive, reasonable and appropriate written PHI privacy and security program that includes administrative, technical and physical safeguards appropriate to the size, nature, scope and complexity of the Associate's operations, in compliance with the Security Rule;
  - iv. In accordance with 45 CFR §§ 164.502(e)(1)(ii) and 164.308(b)(2), if applicable, ensure that any subcontractors that create, receive, maintain, or transmit protected health information on behalf of the business associate agree to the same restrictions, conditions, and requirements that apply to the business associate with respect to such information.
- d. Compliance With Law. The Associate will not use or disclose the PHI in a manner in violation of existing law and specifically not in violation of laws relating to confidentiality of PHI, including but not limited to, the Privacy and Security Rules.
- e. **Mitigation.** Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Associate of a use or disclosure of the PHI by Associate in violation of the requirements of this Addendum, and report its mitigation activity back to the Agency.

- f. Support of Individual Rights.
  - i. Access to PHI. Associate shall make the PHI maintained by Associate or its agents or subcontractors in Designated Record Sets available to Agency for inspection and copying, and in electronic format, if requested, within ten (10) days of a request by Agency to enable Agency to fulfill its obligations under the Privacy-Rule, including, but not limited to, 45 CFR § 164.524 and consistent with Section 13405 of the HITECH Act.
  - II. Amendment of PHI. Within ten (10) days of receipt of a request from Agency for an amendment of the PHI or a record about an individual contained in a Designated Record Set, Associate or its agents or subcontractors shall make such PHI available to Agency for amendment and incorporate any such amendment to enable Agency to fulfill its obligations under the Privacy Rule, including, but not limited to, 45 CFR § 164.526.
  - Accounting Rights. Within ten (10) days of notice of a request for an accounting of disclosures of the PHI, Associate and its agents or subcontractors shall make available to Agency the documentation required to provide an accounting of disclosures to enable Agency to fulfill its obligations under the Privacy Rule, including, but not limited to, 45 CFR §164.528 and consistent with Section 13405 of the HITECH Act. Associate agrees to document disclosures of the PHI and information related to such disclosures as would be required for Agency to respond to a request by an individual for an accounting of disclosures of PHI in accordance with 45 CFR § 164.528. This should include a process that allows for an accounting to be collected and maintained by Associate and its agents or subcontractors for at least six (6) years from the date of disclosure, or longer if required by state law. At a minimum, such documentation shall include:
    - the date of disclosure;
    - the name of the entity or person who received the PHI, and if known, the address of the entity or person:
    - a brief description of the PHI disclosed; and
    - a brief statement of purposes of the disclosure that reasonably informs the individual of the basis for the disclosure, or a copy of the individual's authorization, or a copy of the written request for disclosure.
  - Iv. Request for Restriction. Under the direction of the Agency, abide by any individual's request to restrict the disclosure of PHI, consistent with the requirements of Section 13405 of the HITECH Act and 45 CFR § 164.522, when the Agency determines to do so (except as required by law) and if the disclosure is to a health plan for payment or health care operations and it pertains to a health care item or service for which the health care provider was paid in full "out-of-pocket."
  - v. Immediate Discontinuance of Use or Disclosure. The Associate will immediately discontinue use or disclosure of Agency PHI pertaining to any Individual when so requested by Agency. This includes, but is not limited to, cases in which an individual has withdrawn or modified an authorization to use or disclose PHI.

- Retention of PHI. Notwithstanding section 4.a. of this Addendum, Associate and its subcontractors or agents shall retain all PHI pursuant to state and federal law and shall continue to maintain the PHI required under Section 3.f. of this Addendum for a period of six (6) years after termination of the Agreement, or longer if required under state law.
- h. Agent's, Subcontractor's Compliance. The Associate shall notify the Agency of all subcontracts and agreements relating to the Agreement, where the subcontractor or agent receives PHI as described in section 2.a. of this Addendum. Such notification shall occur within 30 (thirty) calendar days of the execution of the subcontract and shall be delivered to the Agency Procurement Officer. The Associate will ensure that any of its subcontractors, to whom it provides any of the PHI it receives hereunder, or to whom it provides any PHI which the Associate creates or receives on behalf of the Agency, agree to the restrictions and conditions which apply to the Associate hereunder. The Agency may request copies of downstream subcontracts and agreements to determine whether all restrictions, terms and conditions have been flowed down. Failure to ensure that downstream contracts, subcontracts and agreements contain the required restrictions, terms and conditions may result in termination of the Agreement.
- J. Federal and Agency Access. The Associate shall make its internal practices, books, and records relating to the use and disclosure of PHI, as well as the PHI, received from, or created or received by the Associate on behalf of the Agency available to the U.S. Secretary of Health and Human Services consistent with 45 CFR § 164.504. The Associate shall also make these records available to Agency, or Agency's contractor, for periodic audit of Associate's compliance with the Privacy and Security Rules. Upon Agency's request, the Associate shall provide proof of compliance with HIPAA and HITECH data privacy/protection guidelines, certification of a secure network and other assurance relative to compliance with the Privacy and Security Rules. This section shall also apply to Associate's subcontractors, if any.
- k. Security. The Associate shall take all steps necessary to ensure the continuous security of all PHI and data systems containing PHI. In addition, compliance with 74 FR 19006 Guidance Specifying the Technologies and Methodologies That Render PHI Unusable, Unreadable, or Indecipherable to Unauthorized Individuals for Purposes of the Breach Notification Requirements under Section 13402 of Title XIII is required, to the extent practicable. If Associate chooses not to adopt such methodologies as defined in 74 FR 19006 to secure the PHI governed by this Addendum, it must submit such written rationale, including its Security Risk Analysis, to the Agency Procurement Officer for review prior to the execution of the Addendum. This review may take up to ten (10) days.
- I. Notification of Breach. During the term of this Addendum, the Associate shall notify the Agency and, unless otherwise directed by the Agency in writing, the WV Office of Technology immediately by e-mail or web form upon the discovery of any Breach of unsecured PHI; or within 24 hours by e-mail or web form of any suspected Security Incident, intrusion or unauthorized use or disclosure of PHI in violation of this Agreement and this Addendum, or potential loss of confidential data affecting this Agreement. Notification shall be provided to the Agency Procurement Officer at <a href="https://www.state.wv.us/admin/purchase/vrc/agencyli.htm">www.state.wv.us/admin/purchase/vrc/agencyli.htm</a> and

unless otherwise directed by the Agency in writing, the Office of Technology at <a href="mailto:incident@wv.gov">incident@wv.gov</a> or <a href="https://apps.wv.gov/ot/ir/Default.aspx">https://apps.wv.gov/ot/ir/Default.aspx</a>.

The Associate shall immediately investigate such Security Incident, Breach, or unauthorized use or disclosure of PHI or confidential data. Within 72 hours of the discovery, the Associate shall notify the Agency Procurement Officer, and, unless—otherwise-directed-by-the-Agency-in-writing, the Office of Technology of: (a) Date of discovery; (b) What data elements were involved and the extent of the data involved in the Breach; (c) A description of the unauthorized persons known or reasonably believed to have improperly used or disclosed PHI or confidential data; (d) A description of where the PHI or confidential data is believed to have been improperly transmitted, sent, or utilized; (e) A description of the probable causes of the improper use or disclosure; and (f) Whether any federal or state laws requiring individual notifications of Breaches are triggered.

Agency will coordinate with Associate to determine additional specific actions that will be required of the Associate for mitigation of the Breach, which may include notification to the Individual or other authorities.

All associated costs shall be borne by the Associate. This may include, but not be limited to costs associated with notifying affected individuals.

If the Associate enters into a subcontract relating to the Agreement where the subcontractor or agent receives PHI as described in section 2.a. of this Addendum, all such subcontracts or downstream agreements shall contain the same incident notification requirements as contained herein, with reporting directly to the Agency Procurement Officer. Failure to include such requirement in any subcontract or agreement may result in the Agency's termination of the Agreement.

m. Assistance in Litigation or Administrative Proceedings. The Associate shall make itself and any subcontractors, workforce or agents assisting Associate in the performance of its obligations under this Agreement, available to the Agency at no cost to the Agency to testify as witnesses, or otherwise, in the event of litigation or administrative proceedings being commenced against the Agency, its officers or employees based upon claimed violations of HIPAA, the HIPAA regulations or other laws relating to security and privacy, which involves inaction or actions by the Associate, except where Associate or its subcontractor, workforce or agent is a named as an adverse party.

### 4. Addendum Administration.

- a. Term. This Addendum shall terminate on termination of the underlying Agreement or on the date the Agency terminates for cause as authorized in paragraph (c) of this Section, whichever is sooner.
- b. Duties at Termination. Upon any termination of the underlying Agreement, the Associate shall return or destroy, at the Agency's option, all PHI received from, or created or received by the Associate on behalf of the Agency that the Associate still maintains in any form—and retain no copies of such PHI or, if such return or destruction is not feasible, the Associate shall extend the protections of this Addendum to the PHI and limit further uses and disclosures to the purposes that make the return or destruction of the PHI infeasible. This shall also apply to all agents and subcontractors of Associate. The duty of the Associate and its agents

- and subcontractors to assist the Agency with any HIPAA required accounting of disclosures survives the termination of the underlying Agreement.
- c. Termination for Cause. Associate authorizes termination of this Agreement by Agency, if Agency determines Associate has violated a material term of the Agreement. Agency may, at its sole discretion, allow Associate a reasonable period of time to cure the material breach before termination.
- d. Judicial or Administrative Proceedings. The Agency may terminate this Agreement if the Associate is found guilty of a criminal violation of HIPAA. The Agency may terminate this Agreement if a finding or stipulation that the Associate has violated any standard or requirement of HIPAA/HITECH, or other security or privacy laws is made in any administrative or civil proceeding in which the Associate is a party or has been joined. Associate shall be subject to prosecution by the Department of Justice for violations of HIPAA/HITECH and shall be responsible for any and all costs associated with prosecution.
- e. Survival. The respective rights and obligations of Associate under this Addendum shall survive the termination of the underlying Agreement.

### 5. General Provisions/Ownership of PHI.

- a. Retention of Ownership. Ownership of the PHI resides with the Agency and is to be returned on demand or destroyed at the Agency's option, at any time, and subject to the restrictions found within section 4.b. above.
- b. Secondary PHI. Any data or PHI generated from the PHI disclosed hereunder which would permit identification of an individual must be held confidential and is also the property of Agency.
- Electronic Transmission. Except as permitted by law or this Addendum, the PHI or any data generated from the PHI which would permit identification of an individual must not be transmitted to another party by electronic or other means for additional uses or disclosures not authorized by this Addendum or to another contractor, or allied agency, or affiliate without prior written approval of Agency.
- d. No Sales. Reports or data containing the PHI may not be sold without Agency's or the affected individual's written consent.
- e. No Third-Party Beneficiaries. Nothing express or implied in this Addendum is intended to confer, nor shall anything herein confer, upon any person other than Agency, Associate and their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever.
- f. Interpretation. The provisions of this Addendum shall prevail over any provisions in the Agreement that may conflict or appear inconsistent with any provisions in this Addendum. The interpretation of this Addendum shall be made under the laws of the state of West Virginia.
- g. Amendment. The parties agree that to the extent necessary to comply with applicable law they will agree to further amend this Addendum.
- h. Additional Terms and Conditions. Additional discretionary terms may be included in the release order or change order process.

AGREED:	Marlborough Holdings LLC
Name of Agency:	Marlborough Holdings LLC aba Pennsylvania Cytology Services Name of Associate: Robert H. Swedarsky, MD
Signature:	Signature
Title:	Title: Medical Director
Date:	Date: 8-30-2013
Form - WVBAA-012004 Amended 06.26.2013	

APPROVED AS TO FORM THIS 20 17

Retrick Morrisey
Attorney General

#### Appendix A

(To be completed by the Agency's Procurement Officer prior to the execution of the Addendum, and shall be made a part of the Addendum. PHI not identified prior to execution of the Addendum may only be added by amending Appendix A and the Addendum, via Change Order.)

Name of Associate:	Office of Maternal, Child and Family Health				
	*				
Name of Agency:	Family Planning Program/Breast & Cervical Cancer Screening Program				
Describe the PHI (do not include any <u>actual</u> PHI). If not applicable, please indicate the same.					
v	<u>.</u>				
Patient information	,				
Choice of billing					
Type of test ordered					
Specimen source					
Number of specimens	•				
Patient history .					



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

Pennsylvania Cytology Services

Solicitation

NUMBER MCH14020 PAGE

ADDRESS CORRESPONDENCE TO ATTENTION OF

OBERTA WAGNER 04-558-0067

HEALTH AND HUMAN RESOURCES

BPH - MCH WAREHOUSE 900 BULLITT STREET

CHARLESTON, WV

25301

304-558-3417

NENDOR Suite 1700 Parkway Bldg. Monroeville PA 15146

RFQ COPY

TYPE NAME/ADDRESS HERE

339 Old Haymaker Kd.

DATE PRINTED 08/23/2013

09/04/2013 BID OPENING TIME 1:30PM BID OPENING DATE: QUANTITY UOP CAT. ITEM NUMBER UNIT PRICE

			Y			
		A	.DDENDUM NO	. 1		
i i	ADDENDUM IS	SSUED:				
	. TO PROVIDE		SES TO VEN		ESTIONS	*
	SHOULD BE FAILURE TO	SIGNED SIGN A	ACKNOWL AND RETURN ND RETURN OF YOUR BI	ED WITH Y MAY RESUI		T
	*****	**** EN	D OF ADDEN	DUM NO. 3	********	***
	$\gamma$					
SIGNATURE	Bers A Si	u	$\rightarrow$	TELEPHONE 41	2-373-8300	DATE 8-30-2013
Medical	Director FE	N 20-021	07816			ANGES TO BE NOTED ABOVE

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



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

#### Solicitation

NUMBER MCH14020 PAGE

ADDRESS CORRESPONDENCE TO ATTENTION OF:

ROBERTA WAGNER 304-558-0067

HEALTH AND HUMAN RESOURCES BPH - MCH WAREHOUSE

900 BULLITT STREET CHARLESTON, WV

25301 304-558-3417

RFQ COPY
TYPE NAME/ADDRESS HERE
Pennsylvania Cytology Services
339 Old Haymaker Rd.
Suite 1700 Parkway Bldg.
Monroeville PA 15146

DATE PRINTED

08/23/2013

BID OPENING DATE:

09/04/2013 BID OPENING TIME 1:30PM QUANTITY AMOUNT LINE UOP ITEM NUMBER UNIT PRICE 0001 JВ 948-21 7 CYTOLOGY SERVICES - LIQUID BASED PAP TEST 0002 ĖΑ 948-21 2,700 HPV/DNA TESTING (HIGH-RISK ONLY) 0003 EA 948-21 2,600 CYTOLOGY SERVICES - LIQUID BASED PAP TEST (PRIVATE) THIS IS THE END OF REQ MCH14 \$\phi 20 \*\*\*\*\* TOTAL: SIGNATURE 412-373-8300 ADDRESS CHANGES TO BE NOTED ABOVE

#### SOLICITATION NUMBER: MCH14020 Addendum Number: 1

The purpose of this addendum is to modify the solicitation identified as ("Solicitation") to reflect the change(s) identified and described below.

#### Applicable Addendum Category:

[ ]	Modify bid opening date and time
[ ]	Modify specifications of product or service being sought
[ 🗸 ]	Attachment of vendor questions and responses
[ ]	Attachment of pre-bid sign-in sheet
[ ]	Correction of error
[/]	Other

#### Description of Modification to Solicitation:

- 1. To provide responses to vendors' questions.
- 2. To provide Addendum Acknowledgement.

Additional Documentation: Documentation related to this Addendum (if any) has been included herewith as Attachment A and is specifically incorporated herein by reference.

#### **Terms and Conditions:**

- 1. All provisions of the Solicitation and other addenda not modified herein shall remain in full force and effect.
- 2. Vendor should acknowledge receipt of all addenda issued for this Solicitation by completing an Addendum Acknowledgment, a copy of which is included herewith. Failure to acknowledge addenda may result in bid disqualification. The addendum acknowledgement should be submitted with the bid to expedite document processing.

### ATTACHMENT A

#### MCH14020

#### ADDENDUM #1

#### **VENDOR QUESTION #1:**

**Subparagraph 2.1.** Does the definition of "Contract Services" include cytology services for the Family Planning Program or "FPP"?

#### RESPONSE:

FPP is the Family Planning Program. It is listed in the Purpose and Scope, Family Planning Program (FPP).

#### **VENDOR QUESTION #2:**

Mandatory Requirements, Specimen Processing, Evaluation and Reporting, Subparagraphs 4.1.1.1., 4.1.1.8 and Exhibit A, Pricing. Please clarify the requirement for the Vendor to use only the single specimen ThinPrep Liquid Medium/Monolayer System for processing and reporting Pap and HPV specimens

#### RESPONSE:

Federal specifications for both Programs require one liquid-based testing methodology for both pap and HPV testing. If bidding using and alternate testing method/product, the vendor must provide literature to prove it is equal.

#### **VENDOR QUESTION #3:**

What is the State's requirement with respect to FDA approval for follow up HPV reflex testing?

#### RESPONSE:

Federal specifications for both Programs require FDA-approved testing methodology.

#### **VENDOR QUESTION #4:**

Paragraph 5, Contract Award. The contract is to be awarded to the Vendor meeting the required specifications for the lowest overall total cost. In the event the requirement under the RFQ is not solely ThinPrep Liquid Medium/Monolayer system for processing and reporting Pap and HPV specimens, please explain the evaluation criteria to be used to determine "or equal" for an alternate testing system under the required specifications.

#### RESPONSE:

Federal specifications for both Programs require one liquid-based testing methodology for both Pap and HPV testing. The testing method/product must have evidence it is equal to ThinPrep Liquid Medium/Monolayer System. If bidding using and alternate testing method/product, the vendor must provide literature to prove it is equal.

#### **VENDOR QUESTION #5:**

Mandatory Requirements Subparagraph 4.1.1.2. Does this requirement mean that the Vendor must include space for these specified data fields on its cytology requisition form for the State to pre-populate?

#### RESPONSE:

The cytology requisition form needs to remain the same as it is now.

#### **VENDOR QUESTION #6:**

Mandatory Requirements Subparagraph 4.1.1.3. Please clarify the time requirement for processing and reporting Pap and HPV results under MCH14020.

#### RESPONSE:

The time frame for reporting Pap test results is "in a period not to exceed ten (10) calendar days" of receipt of the specimen. HPV test results "in a period not to exceed ten (10) calendar days of receipt of the pap result".

#### **VENDOR OUESTION #7:**

Mandatory Requirements Subparagraph 4.1.1.7, Slide retention. Please explain the rationale for requiring retention of "positive slides for twenty (20) years", exceeding the regulatory requirements specified in CLIA '88 guidelines. See, CLIA '88 at 42 CFR 493.1105 (as amended 10/01/2012) Standard: Retention Requirements, which states in pertinent part, "... (7) Slide, block and tissue retention (i) Slides. (A) Retain cytology slide preparations for at least 5 years from the date of examination...." See also, CAP guidelines (rev. Mar 2010), Retention of Laboratory Records and Materials. In addition, a 20 year retention policy is not mandated for hospitals in the State.

#### RESPONSE:

Slide retention is standard for slides with abnormal results.

#### **VENDOR QUESTION #8:**

Mandatory Requirements Subparagraph 4.1.1.7, Slide retention. In the event the State's requirement for slide retention exceeds CLIA '88 and includes a separate retention standard for "positive slides", please define what the State means by the term "positive".

#### RESPONSE:

"Positive" means slides with an abnormal cytology result.

#### **VENDOR QUESTION #9:**

General Terms and Conditions, Required Documents Paragraph 8, Worker's Compensation Insurance. Please verify that out of state Vendors are able to meet this requirement with the applicable insurance certificate(s) for the state(s) in which it is located.

#### RESPONSE:

The vendor must provide proof of Worker's Compensation if the Vendor would need to go onsite.

#### **VENDOR QUESTION #10:**

General Terms and Conditions, Required Documents Paragraph 8, Insurance. Please clarify the insurance requirement as to type (professional liability/malpractice?), and please explain the requirement to "list the state as certificate holder" under such a professional liability/malpractice policy.

#### RESPONSE:

The type of insurance is professional liability. The successful vendor shall furnish proof of insurance prior to contract award and shall list the state as a certificate holder.

#### **VENDOR QUESTION #11:**

General Terms and Conditions, Paragraph 44, Purchasing Card Acceptance. Does the state intend to use the purchasing card for services provided under the contract?

#### RESPONSE:

The purchasing card can only be used for purchases that do not exceed \$2,500.

#### I. INTRODUCTION

Marlborough Holdings, LLC, d/b/a Pennsylvania Cytology Services ("PCS") is an independent physician-owned laboratory specializing in GYN Cytology for the past thirty four years. PCS offers its clients cytology services that include both Conventional and Monolayer/Liquid based Pap testing and HPV/DNA testing. In response to RFQ MCH14020 ("RFQ" or "MCH14020"), PCS will utilize the FDA approved Hologic ThinPrep Pap Test methodology for monolayer/liquid based Pap smears ("ThinPrep"). The methodology utilized for HPV/DNA High Risk Assay System is the FDA approved Qiagen (aka Digene) Hybrid Capture II System approved for use with ThinPrep Pap transport media PreservCyt. ThinPrep is the only liquid cytology system that has been approved by the FDA for testing with the same sample using the Digene Hybrid Capture II reflex HPV/DNA test. PCS offers both the Pap and HPV/DNA testing in-house.

#### II. QUALIFICATIONS AND EXPERIENCE

- A. PCS exceeds CLIA '88 qualifications and laboratory requirements necessary to meet the requirements of MCH 14020 (RFQ Section 4.1.3.3). In addition to CLIA accreditation (No. 39D0656968), PCS is accredited by the College of American Pathologists ("CAP") (No. 41911-01). PCS is also licensed by the State of Pennsylvania (No. 331) and has been designated an American Society of Cytopathology Laboratory. Tabs 3.1.-3.3.
- B. PCS' staff also exceeds CLIA '88 qualifications. PCS' services are provided by two 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 (License No. 18130), Alabama, Pennsylvania, Florida, Ohio and Maryland. Tab 3.4. Our staff of 11 cytotechnologists, including the on site cytology general supervisor, Ms. Sharon Copley, BS, CT (ASCP)<sup>CM</sup>, are certified by the American Society of Clinical Pathologists ("ASCP"). More than half of these cytotechnologists have greater than 10 years of experience. An organizational chart and job descriptions are included herein in Tab 3.5, and resumes for key personnel have also been included in Tab 3.6.
- C. Pennsylvania Cytology Services has been performing Monolayer/Liquid Based ThinPrep Pap test analysis for the past seventeen years, and has the full capability to process, interpret and timely report the number of Pap and HPV/DNA Reflex testing cases required by the RFQ. PCS has extensive successful experience providing similar cytology services as the incumbent contractor for the State of West Virginia, and for Family Planning Councils, hospitals and other State Departments of Health, currently including the State of Alabama (*see*, References herein). In addition, PCS provided Monolayer/Liquid Based ThinPrep Pap test cytology services to large national laboratories such as SmithKline Beecham Clinical Laboratories, Quest Diagnostics, Inc.

and Labcorp Inc. for processing case back logs (approximately 650 specimens per day) in a timely manner.

#### III. MANDATORY REQUIREMENTS - TECHNICAL SOLUTION

#### A. Scope of Service

1. In response to RFQ MCH14020, PCS will utilize the FDA approved Hologic ThinPrep Pap Test methodology for monolayer/liquid based Pap smears. The methodology utilized for HPV/DNA High Risk Assay System is the FDA approved Qiagen (aka Digene) Hybrid Capture II System. The ThinPrep Pap test is the only technology currently FDA approved and available for both Pap and HPV/DNA Reflex Testing directly from the same vial using the Digene Hybrid Capture II System with ThinPrep Pap transport media PreservCyt.

The CAP has stated in pertinent part, "... [B]ecause of the high volume of tests performed and the significance of the results for cancer risk and high cost interventions, well-validated tests with known operating characteristics are vital to maintain the robust nature of the tests' prediction of risk. ... FDA-approval indicates that the performance characteristics of these tests are well validated and, therefore, predictive for the indications of excluding risk of high-grade cervical dysplasia or carcinoma (screening), and the triage of equivocal cervical cytology tests." The only three FDA approved tests for hrHPV/DNA detection are: (1) Oiagen Hybrid Capture II assay; (2) Hologic/Third Wave Cervista HR assay; and (3) Hologic/ThirdWave Cervista HPV 16/18 assay which detects only hrHPV types 16 and 18. These tests are only FDA approved for use with the ThinPrep Pap test media (PreservCyt). In contrast, use of these tests with transport media other than ThinPrep PreservCyt requires the laboratory to perform appropriate selfvalidation studies as per the regulations of CLIA '88. However, even with selfvalidation, use of approved HPV/DNA methods (Qiagen or Hologic) with different non-FDA approved transport media (e.g., BD SurePath) is considered a non-FDA approved off-label methodology. See, Human Papillomavirus DNA Testing (HPV), CAP POET Report, December 17, 2010.

Off-label HPV/DNA testing methodology using a SurePath specimen has produced inconclusive data. One widely reported study of off-label testing showed that 2 of 3 tested samples from patients with cervical cancer yielded false negative results. Some authors have suggested that the chemicals used in the off-label, non FDA approved system, cause significant HPV/DNA degredation and fixation (Austin, M.A. and Zhao, C. Observations From Pap Litigation Consultations. Pathology Case Reviews, March/April 2011; 16(2): p. 73-82). Studies have also found that additional assessments are needed on the reliability of invasive cervical cancer detection when widely used hrHPV tests, not approved by the FDA, and classified as "laboratory developed tests" are used. See, Zaibo Li, R. Marshall Austin, Ming Guo, and Chengquan Zhao (2012), Screening Test Results Associated With Cancer Diagnoses in 287 Women With Cervical Squamous Cell

Carcinoma. Archives of Pathology & Laboratory Medicine: December 2012, Vol. 136, No. 12, pp. 1533-1540. Citing, among other articles, Anekella B, Dryga SA, Moskowitz KA, et.al., Stability of Integrated HPV16 DNA in Various Sample Transport Media. *J Mol Diagn*. 2007; 9(5): 679–680, wherein results found that performance for preservation and maintenance of samples with different transport media currently being used produce varied results. For HPV/DNA testing, BD SurePath transport media has shown "pronounced" degradation after one day at room temperature and 4 deg. C storage, and significant degradation at -20 deg. C. Finally, it should also be noted that the ASCUS/LSIL Triage Study (ALTS Trial) upon which the ASCCP (American Society for Colposcopy and Cervical Pathology) guidelines are based, was run exclusively using the ThinPrep Pap test; only the ThinPrep Pap Test has FDA approval for HPV/DNA reflex and Chlamydia/Gonorrhea testing out of the same PreservCyt vial; and the Army's Cervical Cancer Screening Project was based on ThinPrep data, and now uses the ThinPrep Pap Test exclusively.

Under the requirement regarding FDA approved reflex HPV/DNA testing as set forth in Addendum No. 1, MCH14020, Vendor Question 3, a vendor offering the SurePath liquid based methodology versus ThinPrep, will either provide less optimal non-FDA off-label HPV/DNA reflex testing utilizing a single specimen; or for FDA approved HPV/DNA reflex testing, a SurePath laboratory must: (a) provide for every patient a distinct and separate FDA approved HPV/DNA specimen container to be used for HPV/DNA Reflex testing; or (b) the laboratory must perform a formal validation study that compares their off-label use to an approved FDA system or method for reflex HPV/DNA. If the Vendor has not performed the appropriate validation studies, a two-vial kit is required. This necessitates additional handling and record keeping on the part of the State's health care provider over the FDA approved ThinPrep single sample methodology. Alternatively, rather than utilize a two vial kit, the State would be required to call patients back to the clinic for follow up HPV/DNA testing once Pap test results are reported. This would result in an inconvenient, costly, time consuming and medically less than optimal solution.

Based on the foregoing, PCS submits that: (1) use of the ThinPrep Pap test with an FDA approved HPV/DNA test assures single specimen integrity with well validated performance characteristics, and (2) the ThinPrep and SurePath liquid based methodologies should not be considered equivalent for follow-up HPV/DNA Reflex testing.

#### B. Specimen Processing, Evaluation and Reporting

1. PCS provides all necessary supplies to include mailers, requisition forms, specimen containers, cervical scrapers, and endocervical brushes to accomplish the testing required by the RFQ. In order to prepare the specimen containers for mailing, clinics will request the necessary supplies from PCS. PCS provides requisition forms containing all of the requested data to be submitted with the specimen using the assigned

clinic account number. Our requisition format contains easy-to-complete sections for the required information. Tab 4.1. PCS accepts the provided mailers from each clinic using first class mail service. PCS will receive, register, bar code specimen, analyze and maintain specimens from the West Virginia clinics, ensuring that proper handling, identification and the required clinical information is included with each specimen. PCS follows CLIA/CAP mandated procedures that are incorporated in the PCS Standard Operating Procedures Manual ("SOP") to avoid mislabeling/mistaken entry of specimens, which includes the necessary recordkeeping and labeling guidelines.

As demonstrated in Section III.D. herein, PCS also has a continuous quality improvement program in accordance with CAP guidelines to assure good laboratory practice in all areas.

- 2. In accordance with the RFQ, PCS will initiate laboratory analysis, analyze specimens and test results will be available for liquid based Pap tests, and when appropriate HPV/DNA reflex testing, within 10 (ten) calendar days from receipt of specimen. HPV/DNA results will be available within 10 (ten) calendar days of receipt of the Pap result. For tests results that require special attention, PCS immediately notifies the appropriate clinic through its online reporting service or other means necessarily appropriate to the situation. PCS can provide results that need immediate attention on any other mutually agreed basis with the clinic(s). PCS routinely provides this service for its clients and routinely reports results in these timeframes. PCS has a past performance reputation of producing timely results.
- 3. As required by MCH14020 Section 4.1.1.4, PCS reports Pap specimens utilizing Bethesda terminology, and abides by the approved standard for processing cervical specimens as recommended by CLIA '88. PCS consistently meets or exceeds CLIA standards. In addition, the PCS SOP includes general criteria for determining what makes a specimen unsatisfactory or abnormal. These guidelines follow medically accepted parameters established by the CAP, Bethesda Reporting System, and good medical practice. However, PCS employs a combination of these recognized standards with the substantial experience of its staff to determine when a specimen produces unsatisfactory or abnormal results. All unsatisfactory and abnormal specimens/cases are reviewed by one of our Board Certified Pathologists prior to reporting.
- 4. PCS' retention policy is included in the SOP. Cytology slides are kept 5 years, and reports can be generated for 10 years. However, PCS has the capability to retain "positive" slides for 20 years, if required. PCS's record keeping system allows for timely access to and retrieval of information as required by RFQ Sections 4.1.2.3 (5 working days from request) and 4.1.3.6. (same day as request). To assure West Virginia of PCS' reporting standards, included in this Proposal are sample reports at Tabs 4.2. and 4.3. With respect to the security of patient information, reporting and records maintenance, PCS complies with the Health Insurance Portability and Accountability Act ("HIPAA").

5. PCS provides a monthly summary of cytology findings by clinical site and/or program as requested. The data will be submitted by the 15<sup>th</sup> of the each month following that in which the testing took place. See, Tab 4.3 for current sample monthly report. 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: (1) Total Pap specimens for the month; (2) Negative for intraepithelial lesion or malignancy; (3) Unsatisfactory; (4) Inflammation, no epithelial cell abnormalities; (5) Organisms; (6) Reactive cellular changes; (7) Other (endometrials in patient over 40 years old); (8) Atypical squamous cells; (9) Atypical glandular cells; (10) Squamous Intraepithelial lesion – low grade; (11) Squamous Intraepithelial lesion – high grade; (12) Squamous carcinoma; (13) Adenocarcinoma; and (14) Other neoplasm.

#### C. Data Requirements

In accordance with RFQ Section 4.1.2, PCS will provide program specific and clinic site access to our online reporting system for all test results and reports for each clinic site. Moreover, as stated in Section III.B.4., PCS complies with HIPAA with respect to the security of patient information, reporting and records maintenance.

#### D. Quality Control And Assurance

- 1. Overview. As a CLIA/CAP accredited laboratory, PCS currently meets stringent quality assurance requirements, to include those set forth in RFQ Section 4.1.3. PCS also maintains a continuous quality improvement program in accordance with CAP guidelines. PCS stresses a high quality laboratory result for each and every specimen. Thus, PCS maintains internal and external quality assurance and quality control measures consistent with or exceeding CLIA '88.
- 2. Reporting. The PCS Medical Director reviews the content and format of computer-generated reports. The clinical significance of this review is that patient safety is enhanced through the assurance that the reports generated by the PCS computer system are accurate and readable.
- 3. Staff. All PCS Pathologists are Board Certified, and the Medical Director is also subspecialty Board Certified in Cytopathology. All the pathologists have extensive experience in GYN pathology. All PCS cytotechnologists are ASCP certified, and most have over 10 years experience. During the interview process and prior to employment with PCS, all cytotechnologists are given an entrance exam, consisting of patient Pap smear slides from our archives.
- 4. PCS selects analytical methods that are in agreement with national processing trends and performs testing with good laboratory practice. As outlined in Section III A.

above, PCS strongly recommends ThinPrep specimens. It is the only FDA approved method for high-risk HPV testing directly from the Pap specimen vial.

#### E. Additional Quality Assurance Programs at PCS

- 1. Our personnel are held to the highest level of professionalism. Supervision and division of work have always been a high priority, the goal to keep our personnel challenged while maintaining the highest quality work. We hold an open-door communication philosophy, to ensure that all have input into Best Practices policies. PCS employs an active case review program, where any cytology staff member can request case review by another staff member. PCS believes that its team approach to cytology results in a more accurate and clinically relevant result; all cytology cases with a follow-up biopsy are reviewed in light of the biopsy finding, and are used for continuing education of cytology personnel.
- 2. PCS goes an extra step in doing the mandated 10% QC from CLIA '88. A supervisory-level cytotechnologist is chosen each day to pull the random cases and any case with a history of a previous abnormal report is QC'd. Our current QC rate is 15 to 20%.
- 3. Statistics are kept on each cytotechnologist, and are analyzed monthly to compare each to the laboratory as a whole. Quarterly performance evaluations are done on each cytotechnologist on several statistical parameters.
- 4. PCS participates in the ASCP Check Sample program, the CAP interlaboratory program, and required proficiency programs. PCS also encourages laboratory personnel to attend other continuing education opportunities, and our staff cytotechnologists do participate in regular continuing education programs. See, e.g., Tab 3.7.
- 5. PCS maintains a Standard Operations Manual that is updated regularly, and has a continuous quality improvement program in accordance with CAP guidelines. In addition, PCS maintains the required equipment maintenance schedules and documentation that will be available upon request.

#### IV. ADMINISTRATIVE & OPERATIONAL REQUIREMENTS

- **A. General** PCS is the current West Virginia provider of the services solicited under this RFO. However, to the extent required, upon award of the contract:
- 1. PCS will contact administrative personnel in West Virginia to obtain lists of personnel, clinic sites, and programs active at each site.

- 2. For any clinic or office not currently served by PCS, PCS will contact such clinic/office to obtain approximate volumes of tests per site, along with which providers and which programs are active at each site.
- 3. For any clinic not currently served by PCS, PCS will, within 2 weeks, or 2 weeks prior to contract date, send out welcome kits with start-up information and supplies to each clinic along with assigning account numbers to each site/program/clinician. These will be used to mine data for the reports requested in MCH14020. The sites will then review instructions included with the supplies, and contact Lisa Ritchey at 1-800-344-1026 or by email at <a href="mailto:lisaritchey@pacytology.com">lisaritchey@pacytology.com</a> with any questions.
- 4. West Virginia clinical staff involved in providing services under MCH14020, generally, are already educated as to collection procedures. However, PCS offers phone or on-site consultations, education and training as necessary. PCS welcomes on site monitoring by representatives of the Programs, and agrees to: onsite visits to PCS by representatives of FPP and BCCSP and/or designated cytotechnologist in accordance with RFQ Section 4.1.3.1; review of materials in accordance with Section 4.1.3.2.; and on site attendance at meetings as requested by FPP or BCCSP.
- 5. Once performance begins the schedule is cyclical. Clinics send specimens to PCS. PCS will then accession, process, stain and coverslip specimens. Specimens will be screened by ASCP-certified cytotechnologists, who will refer cases to the pathologist when necessary. Reports (including HPV/DNA if requested/necessary) will be provided and can be accessed through the PCS online reporting system.
  - 6. The sites/clinics request additional supplies when necessary.

#### **B.** Customer Service

- 1. PCS business hours are Monday through Friday between 8AM and 4:30PM. Laboratory staff members are available for consultation at any time during normal business hours. PCS customer service can be contacted as follows: Telephone: 1-800-344-1026; 1-412-373-8300; Fax: 1-412-373-7027.
- 2. Lisa Ritchey is assigned as both project administrator/primary contract manager and customer service representative. Ms. Ritchey can be reached by telephone: 1-800-344-1026; 1-412-373-8300; Fax: 1-412-373-7027; or <a href="lisaritchey@pacytology.com">lisaritchey@pacytology.com</a>. All customer service representatives answering the phones are capable of handling the vast majority of issues, or they will transfer the inquiry to the appropriate technical representative.

#### V. PAST PERFORMANCE

PCS has successfully fulfilled other contracts with the same requirements and volume of tests as MCH14020, including the current West Virginia Contract MCH10037. Pennsylvania Cytology Services has extensive experience over the past 34 years working with Family Planning Councils, State Departments of Health and large National Laboratories. MCH14020 is consistent with our daily mission.

PCS has performed liquid based monolayer Pap smear (ThinPrep Pap test) for the past seventeen years. In addition, to State health departments and hospital systems, SmithKline Beecham Clinical Laboratories, Quest Diagnostics, Inc. and Labcorp Inc. all have contracted with Pennsylvania Cytology Services to do their back log of ThinPrep Pap tests – some 650 specimens per day. Quest Diagnostics, Inc. routinely audited our laboratory on site with a team of four senior cytotechnologists and a quality assurance supervisor. These quality assurance meetings lasted three to four days. At the conclusion of these visits a summation conference was held with much praise for Pennsylvania Cytology Services finding no deficiencies. This experience managing a large volume of Pap smears for National Laboratories positioned us to provide a professional and dependable service for the state of West Virginia over the last 4 years, and in the future under a new contract.

References for projects completed within the last 24 months with volume of work, bid specifications and requirements similar to MCH14020 are:

West Virginia Dept. of Health and Human Resources Bureau for Public Health Office of Maternal, Child and Family Health 350 Capitol Street, Room 427 Charleston, WV 25301-3714

Contact: GeorgeAnn Grubb, MPH, BCCSP Director

Telephone: 1-304-558-7180

Contact: Tisha Reed, FPP Director

Telephone: 1-304-558-7181

Alabama Department of Public Health RSA Tower 201 Monroe Street, Suite 1381 Montgomery, AL 36104 Contact: Laurie Stout, RN, Director of Clinical Services

Telephone: 1-334-206-2905

Indiana Hospital 835 Hospital Road Indiana, PA 15701-0788 Contact: Kelly Yoder, Laboratory Director Telephone: 1-724-357-7165

DuBois Medical Center 100 Hospital Avenue P.O. Box 447 Dubois, PA 15801 Contact: Nancy Stephens, DRMC Laboratory Telephone: 1-814-375-3238

#### VI. PRICING

Our prices for Pap and HPV/DNA testing are included herein on Exhibit A, Pricing Page, as required by the RFQ. Tab 5

#### VII. OTHER PERTINENT INFORMATION

Upon notification that PCS is the apparent successful offeror, proof of insurance in compliance with the RFQ General Terms and Conditions, Required Documents Paragraph 8, Insurance, will be provided.

## 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

06/28/2013

**EXPIRATION DATE** 

06/27/2015

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.

CIVIS

Judith a Yest

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

41 Certs2\_052913

VIROLOGY (140)

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:

LAB CERTIFICATION (CODE) EFFECTIVE DATE

10/18/2010

HISTOPATHOLOGY (610) 10/27/2005

CYTOLOGY (630) 06/16/2003

A THE STATE OF THE

OF TRAIN A TORONG FMENT TO SERVICE

LAB CERTIFICATION (CODE)

EFFECTIVE DATE



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.

# 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

**AUTHORIZED CATEGORIES:** 

Name and Director of Laboratory:

PENNSYLVANIA CYTOLOGY SERVICES ROBERT SWEDARSKY, MD 339 OLD HAYMAKER ROAD PARKWAY BUILDING SUITE 1700 MONROEVILLE, PA 15146 EXFOLIATIVE CYTOLOGY TISSUE PATHOLOGY VIROLOGY HPV

Owner:

ROBERT H SWEDARSKY MD

Issued: August 15, 2013

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

DATE EXPIRES: August 15, 2014

Michael Wolf

Michael Wolf Secretary of Health

DISPLAY THIS CERTIFICATE PROMINENTLY



LAP#: 4191101 AU-ID: 1190340 July 17, 2012

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

Dear Dr. Swedarsky:

The College of American Pathologists is pleased to advise you that the medical laboratory you direct, Pennsylvania Cytology Services Cytology Laboratory, in Monroeville, Pennsylvania, has 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:

- Promptly notify the CAP Office whenever the laboratory finds itself the subject of an investigation or inspection by a state or federal agency, or of adverse media attention related to laboratory performance;
- Have a written policy and procedure for investigating complaints that is incorporated into the Laboratory Quality Management Plan;
- 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;
- Effectively participate annually in a CAP-accepted proficiency testing program;
- Notify the CAP Office of changes in location, ownership, or directorship of the laboratory. Accreditation
  does not automatically survive these changes. Documentation, including a copy of the new director's
  curriculum vitae and an organizational chart, will be requested for evaluation of the laboratory's accreditation
  status;
- Notify the CAP Office when there is a change in the laboratory's test menu, prior to beginning testing;
- Submit a completed Self-Inspection 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 you are providing. Please remember CAP accreditation is not a substitute for continuous in-depth monitoring by the laboratory and its personnel to maintain a safe and properly functioning laboratory. We look forward to working with you in the future and commend your achievement of the "gold standard" of laboratory accreditation.

Sincerely,

Ronald B. Lepoff, MD

Chair, Accreditation Committee

cc: Frank R. Rudy, MD, Chair, Commission on Laboratory Accreditation

Jagjit Singh, MD



# 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 accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to June 25, 2014 to maintain accreditation.

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

Frank & Rudy

Chair, Commission on Laboratory Accreditation

Stanley & bottom mo

President, College of American Pathologists

#### WEST VIRGINIA BOARD OF MEDICINE

LICENSE NO.

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 7/1/2013 TO 6/30/2015

ROBERT C. KNITTLE, Executive Director

Commonwealth of Pennsylvania Department of State

Bureau of Professional and Occupational Affairs PO Box 2649 Harrisburg PA 17105-2649

License Type

Medical Physician and Surgeon

ROBERT HUTCHER SWEDARSKY

License Number

License Status Active

**Initial License Date** 08/05/1983

**Expiration Date** 12/31/2014

AMERICAN A RESIDENCE ALTERATION OF THIS DOCUMENT IS A CRIME

Control No. 1061705

1061705



## DEPARTMENT OF HEALTH AND MENTAL HYGIENE

LICENSE OR CERTIFICATION

MARYLAND BOARD OF PHYSICIANS

CERTIFIES THAT IS AN AUTHORIZED

ROBERT HUTCHER SWEDARSKY PHYSICIAN AND SURGEON

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

09/30/2013

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

AC# 4792746

#### STATE OF FLORIDA DEPARTMENT OF HEALTH DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
01/26/2012		381884

The MEDICAL DOCTOR

named below has met all requirements of the laws and rules of the state of Florida.

Expiration Date: JANUARY 31, 2014 ROBERT HUTCHER SWEDARSKY

Rick Scott GOVERNOR

H. Frank Farmer, Jr., M.D., Ph.D., F.A.C.P. STATE SURGEON GENERAL

DISPLAY IF REQUIRED BY LAW

ALABAMA MEDICAL LICENSURE COMMISSION P.O. BOX 887 **MONTGOMERY, ALABAMA 36101-0887** 

#### CERTIFICATE OF REGISTRATION 2013

This is to certify that annual registration has been made and license to practice medicine in the State of Alabama has been granted for the year ending December 31, 2013

License # Date Issued: 06/26/2007 Amount Paid: \$300.00 Receipt #927632

Robert H. Swedarsky MD

amos E. West, m D CHAIRMAN



# MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE OFFICE OF HEALTH CARE QUALITY

SPRING GROVE CENTER
BLAND BRYANT BUILDING
55 WADE AVENUE
CATONSVILLE, MD 21228-4663

#### MEDICAL LABORATORY PERMIT

NUMBER: 1243 EFFECTIVE PERIOD: 07/01/2012 - 06/30/2014

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

MARLBOROUGH HOLDINGS LLC DBA PENNSYLVANIA CYTOLOGY SERVICES
339 Old Haymaker Rd Ste 1700
MONROEVILLE, PA 15146

Director: Dr ROBERT SWEDARSKY
Owner: ROBERT H. SWEDARSKY

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

Molecular Biology:

HPV

Pathology:

Cytology - GYN, Cytology - Non-GYN, Diagnosis/Interpretation, Histopathology, Prepare, process and stain

nany B. Brimm

CONTROL: 49670

Director

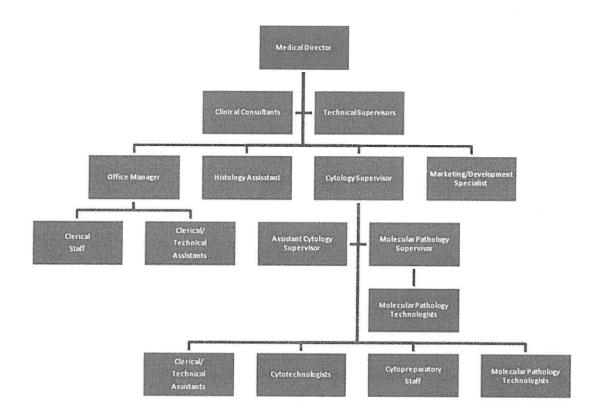
Falsification of a license shall subject the perpetrator to criminal prosecution and the impostition of civil fines.

Page 1 of 4

Section: Lab Systems, Personnel

Subject: Organizational Charts and Descriptions

Author: S.E.Copley



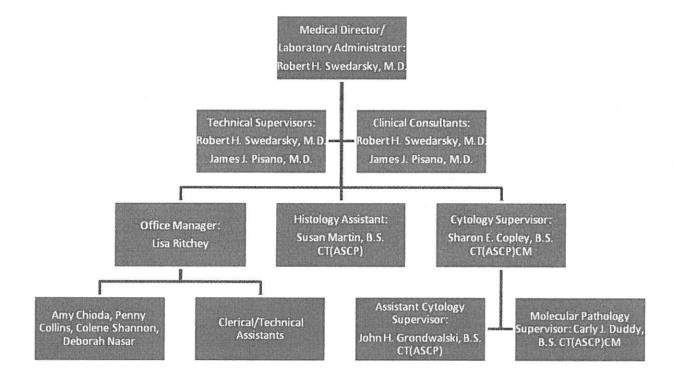
Page 2 of 4

Section: Lab Systems, Personnel

Subject: Organizational Charts and Descriptions

Author: S.E.Copley

#### Managerial Organizational Chart with Personnel Designations



Section: Lab Systems, Personnel

Subject: Organizational Charts and Descriptions

Author: S.E.Copley

#### Principle

Descriptions of the various job titles and general responsibilities.

#### Clinical Significance

Ensure patient safety by delineating general responsibilities.

#### Descriptions

#### 1. General Administration

- 1.1. Laboratory Administrator: The Laboratory Administrator is the chief administrative officer of Pennsylvania Cytology Services. Ensures that the philosophy of the Medical Director is followed by all laboratory personnel and is responsible for the fiscal solvency of the laboratory. Presents our service capabilities to hospitals, clinics and physicians in a detailed, medically accurate presentation. Serves as an account administrator, providing direct in-person communication between the clinicians and the laboratory. Channels questions, reports or concerns to the appropriate technical and professional personnel, and follows up with the clinician to assure the inquiry was handled promptly, accurately, and to their complete satisfaction.
- 1.2. Office Manager: Responsible for the day-to-day accounting practices of Pennsylvania Cytology Services, and oversees the clerical staff.
- 1.3.Marketing/Development Specialist: Responsible for website, clinician relations, new and existing business opportunities.
- 1.4. Clerical Staff: Responsible for accurate accessioning, computer log-in, and printing of final reports. Answers the phone, promptly handling clinician and patient billing questions. Other routine office duties are included, along with technical assistance as needed.
- 1.5. Clerical/Technical Assistants: Responsible for routine clerical and technical support tasks as assigned by the Office Manager or Cytology Supervisor.

#### 2. Technical Administration

- 2.1. Medical Director: A board-certified cytopathologist, responsible for the overall management of the laboratory. Ensures that the Technical Supervisors and Cytotechnologists work as a team to communicate relevant cytologic findings with clarity and precision to the clinicians. Oversees programs of quality assurance, continuing education of laboratory professionals, and proficiency testing.
- 2.2. Technical Supervisor: Pathologists, board-certified in anatomical and clinical pathology. Some are also board certified with a subspecialty in cytopathology. Responsible for reviewing and final results for all non-gynecologic cases and those gynecologic samples determined to be reactive changes or above by the Cytotechnologists.
- 2.3. Clinical Consultants: All Technical Supervisors act as Clinical Consultants, answering clinician questions regarding results.

**CONFIDENTIAL**: approved for internal use only

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Page 3 of 4

valua Cytology Services Folicy/ Frocedure #2

Section: Lab Systems, Personnel

Subject: Organizational Charts and Descriptions

Author: S.E.Copley

- 2.4. Cytology Supervisor: A registered cytotechnologist. Closely monitors the daily workload of each Cytotechnologist, assigns a senior Cytotechnologist to rescreen a minimum of 10% of the pap smears interpreted to be negative on initial examination, reviews some cases in the atypical category prior to referral to the Technical Supervisor, and performs selected responsibilities delegated by the Medical Director or Laboratory Administrator.
- 2.5. Assistant Cytology Supervisor: A registered cytotechnologist. Acting supervisor in the absence of the Cytology Supervisor. Performs all duties of a Cytotechnologist, along with selected responsibilities delegated by the Cytology Supervisor, the Medical Director or Laboratory Administrator.
- 2.6. Histology Assistant: Prepares and processes the biopsy specimens in preparation for staining, imbedding, and mounting.
- 2.7. Molecular Pathology Supervisor: Responsible for all activities having to do with the molecular pathology department, including running tests, training other personnel within molecular pathology, tracking inventory for use in molecular pathology.
- 2.8. Cytotechnologist: A registered cytotechnologist. Makes the initial interpretation of pap smears under the supervision of the Cytology Supervisor and under the direction of the Medical Director. Senior Cytotechnologists (cytotechnologists with more than 3 years experience) may also rescreen the 10% negative quality control cases. May be trained within the molecular pathology department or as a histology assistant.
- 2.8. Cytopreparatory Technician: Responsible for preparing slides from liquid media, staining and coverslipping. Other duties may include filing slides, sending supplies to clients, and clerical assistance as needed.
- 2.9. Clerical/Technical Assistants: Responsible for routine clerical and technical support tasks as assigned by the Office Manager or Cytology Supervisor.

#### References:

- 1. CLIA '88. Federal Register Vol.68, No. 16. CFR 493, January 24, 2003.
- 2. Berte, Lucia. <u>Developing Performance Standards for Hospital Personnel</u>. ASCP Press, Chicago, 1989.
- 3. Troil, J. H., ed., ASCT Cytopathology Quality Assurance Guide Vol. 1, 1992.
- 4. Sharkey, Francis, M.D. <u>College of American Pathologists Laboratory Accreditation</u>
  Manual. Oct., 2005 Ed.

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#### CURRICULUM VITAE

## ROBERT H. SWEDARSKY, M.D. Pathologist

#### Personal

Home Address:



Date of Birth:

May 31, 1946

Citizenship:

USA

**Marital Status:** 

Married, four children

#### Education:

Georgetown University, College of Arts and Sciences, Washington, D.C. Bachelor of Science, June 1968 Master of Science, June 1970

Georgetown University School of Medicine, 1970-1974 Doctor of Medicine, May 18, 1974 Honors - Merck Award

Walter Reed US Army Medical Center, Washington, D.C. Department of Pathology Residency in Anatomic and Clinical Pathology June 1974 - June 1978

#### **Board Certification:**

American Board of Pathology, Certification in Anatomic and Clinical Pathology, 1978 American Board of Pathology, Added Qualification in Cytopathology, 1998 US Air Force, Command and General Staff College, Diplomate, 1991

#### **Professional Experience**

January 2004 – Present CEO and Medical Director – Marlborough Holdings dba Pennsylvania Cytology Services

January 2002-October 2002

Interim Director, Department of Pathology Monongalia General Hospital

1979 - 1983

Pathologist & Director of Cytopathology Service Monongalia General Hospital 1200 J.D. Anderson Drive Morgantown, WV 26505
Consulting Pathologist and Laboratory Director Podiatry Hospital of Pittsburgh 215 South Negely Avenue Pittsburgh, PA 15206
Laboratory Director, Divine (Mercy) Providence Hospital 1004 Arch Street Pittsburgh, PA 15212
Associate Pathologist, St. Margaret Memorial Hospital Pittsburgh, PA 15215
Staff Pathologist, IMA, US Air Force Reserves USAF Medical Center Wright-Patterson Air Force Base, OH
Chief of Clinical Pathology, Assistant Chief of Pathology Brooke Army Medical Center, Ft. Sam Houston, TX (1980 - 1983) Medical Director, Microbiology (1979 - 1983) Staff Anatomic Pathologist (1978 - 1983) Lieutenant Colonel, US Army Medical Corps (separated from active service August 1983)
Colonel, US Air Force Reserve (inactive since 1993)
Consulting Pathologist, State Chest Hospital San Antonio, TX

Deputy Medical Examiner, Bexar County, TX

#### Academic Appointments

University of Texas at San Antonio Health Center; Clinical Assistant Professor of Pathology 1978 - 1983

University of Pittsburgh School of Medicine, Clinical Assistant Professor of Pathology 1983 - 1995

West Virginia University School of Medicine, Clinical Assistant Professor of Pathology 1995 - Present

#### **Professional Affiliations**

College of American Pathologists, Fellow, 1979 - Present

American Society of Clinical Pathologists, 1979- Present

#### Licensure

Active:

Pennsylvania, West Virginia, Florida

Inactive:

Ohio, Texas, Washington, D.C.

(Page 1 of 5)



Business Address: Pennsylvania Cytology Services
Suite 1700 Parkway Building
339 Old Haymaker Road
Monroeville, PA 15146
412-373-8300
412-373-7027 (Fax)

LICENSURE AND CERTIFICATION

Passed the American Society of Clinical Pathologists Board Of Registry Examination for Cytotechnology, August, 1982.

Licensed in the State of Maryland.

Successfully completed the proficiency test administered by the State of Maryland, which is approved by the Health Care Financing Administration in accordance with the Clinical Laboratory Improvement Act of 1988.

#### EDUCATION

May, 1982: Bachelor of science degree awarded (Magna Cum Laude) from Marshall University, Huntington, WV.

May, 1982: Certificate of Graduation awarded from Cabell Huntington Hospital School of Cytotechnology.

#### Coursework

Biology of plants Principles of chemistry I Identification of elements Human biology I Principles of chemistry II Quantitative aspects of chemistry College algebra Human biology II Organic chemistry I General physics Histology Cellular physiology Genetics Animal parasitology General bacteriology General physiology Principles of organic evolution Vertebrate embryology

Cytology of gastrointestinal tract Cytology seminar Advanced methods in cytology Cytological methodology Elementary cytology Gynecologic cytology Cytology of the respiratory tract Cytology of body cavities Cytology of the urinary tract Cytology of the breast Additional Coursework

(page 2 of 5)

English composition honors

General psychology

Fundamentals of speech communication

Classical mythology

Science fiction

Plane trigonometry

Introductory sociology

Folklore

First aid

Abnormal psychology

Calculus I

#### Graduate Coursework

Cellular and molecular biology

Psychopharmacology

#### **Continuing Education**

1997, December: PAPNET retraining.

1997, November: Developing Performance Standards; Florida Excell, Inc.

1997, October: CLIA / OSHA Compliance program, Lab Consulting Services,

Pittsburgh, PA.

1997, June: LAP/CAP Inspector Training, Pittsburgh, PA.

1997, June: Gynecologic Cytology Update, PA Department of Health, Bureau of

Laboratories.

1997, June: PAPNET Challenge CED-2

1997, May: Cytology Standardization Conference, Smith-Kline Beecham Clinical

Laboratories, Vancouver, British Colombia.

1997, May: ASCP 1996 Check Sample Program Cytopathology II.

1997, April: Supervisory Management, Community College of Allegheny County.

1996, December: PAPNET Challenge CED 1.

1996, June: CAP Conference XXX: Liability and Quality Issues in Cervicovaginal Cytology,

Seattle, Washington.

1996, May: Cytology Standardization Conference, Smith-Kline Beecham Clinical

Laboratories, Memphis, Tennessée.

1996, March: ASCP 1994 Check Sample Program.

1996, March: ASCP 1995 Check Sample Program.

1996, February: ASCP 1994 Tech Sample Program.

1996, February: ASCP 1993 Check Sample Program.

1996, January: ASCP 1993 Tech Sample Program.

1995, November: PAPNET training and Certification, Neuromedical Systems, Suffern, NY.

1995, May: Cytology Standardization Conference, Smith-Kline Beecham Clinical

Laboratories, San Antonio, TX.

1995, May: CAP Interlaboratory Comparison Program.

1995, March: CAP Interlaboratory Comparison Program.

1995, January: CAP Interlaboratory Comparison Program.

1994, December: CAP Interlaboratory Comparison Program.

1994, October: CAP Interlaboratory Comparison Program.

1994, June: ASCP Teleconference: Inflammatory and Preneoplastic Lesions of the uterine

1994, June: CAP Interlaboratory Comparison Program.

1994, February: ASC Cytoteleconference: Diagnostic Problems in Gynecologic Cytology.

1994, January: CAP Interlaboratory Comparison Program.

### Sharon E. Copley, B.S. CT(ASCP)

### **Continuing Education (continued)**

(page 3 of 5)

- 1993, December: CAP Interlaboratory Comparison Program.
- 1993, October: ASCP 1991 Tech Sample Program.
- 1993, September: CAP Interlaboratory Comparison Program.
- 1993, August: Basic Supervision, University of Pittsburgh.
- 1993, July: CAP Interlaboratory Comparison Program.
- 1993, June: ASCP 1992 Check Sample Program.
- 1993, May: ASCP 1990 Tech Sample Program.
- 1993, April: CAP Interlaboratory Comparison Program,
- 1993, March: ASCP Spring Meeting; Adenocarcinoma of the Female Genital Tract, Chicago, IL.
- 1993, March: ASCP Spring Meeting; Look-Alikes in Gynecologic Cytology, Chicago, IL.
- 1993, March: CAP Spring Meeting; PAP: State of the Art in Cytopathology.
- 1993, March: The More Effective Supervisor; Dun and Bradstreet Seminars, Pittsburgh, PA.
- 1992, December: CAP Interlaboratory Comparison Program.
- 1992, December: ASC Cytoteleconference; Cervical cytology Pre-screening Devices.
- 1992, December: ASCP 1990 Check Sample Program.
- 1992, October: CAP Interlaboratory Comparison Program.
- 1992. August: CAP Interlaboratory Comparison Program.
- 1992, April: American Society for Cytotechnology Spring Meeting, Indianapolis, IN.
- 1992, February: ASC Cytoteleconference: Repair- a Ubiquitous Phenomenon.
- 1992, January: ASC Cytoteleconference: Cytopathology of HPV of the Lower Genital Tract.
- 1991, July: ASC Cytoteleconference: Chlamydia Trachomatis in Cervical Smears.
- 1991, April: 1991 Bethesda System Workshop, National Cancer Institute, Bethesda, MD.
- 1991, March: ASC Cytoteleconference: Problems in Gynecologic Cytology.
- 1990, December: ASC Cytoteleconference: Non-neoplastic entities in Gynecologic Specimens.
- 1990, August: ASC Cytoteleconference: Diagnostic Problems in the Cytopathology of Peritoneal, Pleural, and Pericardial Effusions.
- 1990. July: ASC Cytoteleconference: The Cytology of Direct Endometrial Samples.
- 1990, June: ASC Cytoteleconference: Hepatocellular VS Metastatic Carcinomas.
- 1990, June: Gynecologic Cytology Update: Practical application of the Bethesda System and Impact of Regulatory Changes; National Laboratory Training Network, Lionville, PA.
- 1990, April: ASC Cytoteleconference: Cyto-histological correlation of transitional cell neoplasms.
- 1990, April: American Society for Cytotechnology Annual Meeting, Indianapolis, IN.
- 1990, April: Cytology Workshop: Gynecologic Cytology: Differential Diagnoses and the Bethesda System, ASCT Annual Meeting, Indianapolis, IN.
- 1990, March: ASC Cytoteleconference: Fine Needle Aspiration Cytology in Primary Bone Neoplasm.
- 1990, February: ASC Cytoteleconference: The Cytologic Faces of Adenocarcinoma.
- 1990, January: ASCP 1988 Check Sample Program.
- 1990, January: ASCP 1989 Tech Sample Program.
- 1989, December: ASC Cytoteleconference: Applications of flow cytometry to diagnostic cytology.
- 1989, August: Self-Assessment Workshop in Gynecologic Cytology; Dayton, OH.
- 1989, January: ASC Cytoteleconference: Microinvasive Cervical Carcinoma.
- 1988\_July: ASC Cytoteleconference: Early Endocervical Glandular Neoplasia.
- 1987, April: Ohio Society of Cytology Annual Seminar, Cleveland, OH.
- 1986, November: ASC Cytoteleconference: Accommodating Changing Diagnoses and Classification Systems in Gynecologic Cytology.
- 1985, August: ASC Cytoteleconference: Differential Diagnosis of Small Cells in Cervicovaginal Smears.
- 1985, May: ASC Cytoteleconference: Pitfalls in Breast Aspiration Cytology.

### Sharon E. Copley, B.S. CT(ASCP)

**Continuing Education (continued)** 

(page 4 of 5)

1985, April: ASC Cytoteleconference: The Cytology of Repair: A Ubiquitous Phenomenon. 1984, May: Endometrial Cytopathology and Aspiration Biopsy Cytology, Magee-Women's

Hospital, Pittsburgh, PA.

1984, April: Ohio Society of Cytology Annual Seminar: Cytopathology of the Urinary Tract and Sexually Transmitted Diseases; Richfield, OH.

1983, April: Aspiration Cytology Conference; Charleston, WV.

1982, April: Buckeye Society of Cytology Seminar: Fine Needle Aspirations and Repair/Regeneration.

### Honors, Awards, Achievements

Member, Gamma Beta Phi, Service Honor Society.

Member, Alpha Epsilon Delta, Premedical Honor Society.

Dean's List during entire undergraduate coursework.

### EMPLOYMENT

1988-Present

Supervisor, Pennsylvania Cytology Services

Duties Include:

Testing, hiring, orientation and training new employees.

Implementation and maintenance of extensive quality assurance program.

Implementation and maintenance of comprehensive safety program.

Supervision of daily workload throughput.

Recordkeeping of daily workload, including cytologic results of all work completed.

Review of abnormal cases prior to review by the pathologist.

Analysis of daily, weekly, monthly, semiannual and annual statistics.

Remain current on all pertinent cytologic literature.

Inspect other cytology laboratories when requested by the CAP.

Complete and record retrospective reviews.

Review, record, and analyze quality control data.

Implement remedial action for cytotechnologists when warranted.

Counsel staff as to work problems and personal problems as they relate to the workplace.

Analyze PAPNET digitized images using NSI computer module.

Screen and report results on various gynecologic cases.

Use computers to recall and review historical data on cytology cases.

Interact with pathologists for sign-out of abnormal cases.

Review of any eases requested by a cytotechnologist.

Interact with clinicians to aid in clarifications of reports or methodology.

1997-Present

Book Reviewer, Glencoe/McGraw-Hill.

Duties Include:

Creation of documents that correlate text books with legislated outcomes.

Review and revision of previously created correlations.

1983-1988

Staff Cytotechnologist, Pennsylvania Cytology Services.

Duties Included:

Screen and render results on normal and abnormal gynecologic cytology smears.

Interact with pathologists for sign-out of abnormal cases.

Interact with clinicians to aid in clarifications of reports or methodology.

Screen and render results on quality control cases when requested.

Curriculum Vitae

### Sharon E. Copley, B.S. CT(ASCP)

**EMPLOYMENT** (continued)

(page 5 of 5)

1982-1983

Staff Cytotechnologist, John Marshall Medical Services, Huntington, WV. Duties Included:

Screen and render preliminary results on gynecologic and nongynecologic specimens.

PROFESSIONAL ASSOCIATIONS

American Society of Clinical Pathologists- Registrant, 1982- present.

American Society of Clinical Pathologists- Associate Member, 1897- present.

American Society for Cytotechnology- Member, 1988- present.

Ohio Society of Cytology- Member, 1987- present.

Buckeye Society of Cytology-Member, 1982-1987.

### INTERESTS, ACTIVITIES, COMMUNITY SERVICE

Teacher, CCD classes, St. Mary's Catholic Church, Export, PA. Advancement Chairman, Cub Scout Pack 206, Murrysville, PA. Vice-President, Holiday East Collector's Club, Pittsburgh, PA. Student, Contraguerro's Martial Arts, Murrysville, PA.

### JOHN H. GRONDWALSKI



#### **EDUCATION**

UNITED STATES PATENT AND TRADEMARK OFFICE – registered patent attorney, admitted to practice December 1991.

PENNSYLVANIA BAR - admitted to practice June 1992.

UNIVERSITY OF PITTSBURGH SCHOOL OF LAW/UNIVERSITY OF PITTSBURGH SCHOOL OF BUSINESS; Pittsburgh, Pennsylvania. Joint J.D./M.B.A. Program. J.D. and M.B.A. conferred December 1991. Cumulative Grade Average: B/B+.

UNIVERSITY OF PITTSBURGH SCHOOL OF CYTOTECHNOLOGY; Pittsburgh, Pennsylvania. Laboratory Specialty Degree in Cytotechnology, June 1983.

PENNSYLVANIA STATE UNIVERSITY; University Park, Pennsylvania. B.S. in Biology May 1981. HONORS AND ACTIVITIES: Dean's List Fall 1980, Dean's List Spring, 1981; Member Penn State Biology Society/Nominated for College of Science Senior Prize.

### **EXPERIENCE**

CLERK FOR JUDGE DONALD E. ZIEGLER: FEDERAL DISTRICT COURT, WESTERN DISTRICT OF PENNSYLVANIA: PITTSBURGH, PENNSYLVANIA. JUNE – OCTOBER 1990.

Drafted Opinions and Orders. Reviewed Motions from Plaintiff's and Defendant's attorneys. Researched topic of Collegiality for Judge Ziegler's speech at a Judicial Conference. Observed settlement conference. Observed civil and criminal trials.

SUMMER CLINIC: PENNSYLVANIA DEPARTMENT OF ENVIRONMENTAL RESOURCES.
LITIGATION DEPARTMENT; EAST LIBERTY, PENNSYLVANIA.
JULY-AUGUST, 1989.

Examined answers to interrogatories and drafted a Motion to Compel Answers in regard to case appeal. Determined ownership of leaking oil and gas wells. Researched and drafted a memo concerning ownership of public roadways.

### JOHN H. GRONDWALSKI PAGE 2

### PRESENT EMPLOYMENT

ASSISTANT SUPERVISOR: PENNSYLVANIA CYTOLOGY SERVICES, MOROEVILLE, PENNSYLVANIA. JANUARY 1998 – PRESENT.

Act as Safety and OSHA Compliance Officer. Schedule employees. Interview potential employees and train new hires. Calculate payroll. Act as liaison between technologists and pathologists, and between laboratory and clients. Screen microscopic slides for carcinoma cells. Screen quality control slides.

### PREVIOUS EMPLOYMENT

<u>CYTOTECHNOLOGIST</u>: PENNSYLVANIA CYTOLOGY SERVICES, MONROEVILLE, PENNSYLVANIA. JUNE 1991 – PRESENT.

Screen microscope slides for carcinoma cells. Screen quality control slides. Act as supervisor in permanent supervisor's absence. Act as a liaison between technologists and pathologists and between the laboratory and clients.

<u>CYTOTECHNOLOGIST</u>: UPMC/MCKEESPORT HOSPITAL, MCKEESPORT, PENNSYLVANIA. AUGUST 1983-1988.

Prepared and screened microscope slides for carcinoma cells. Prepared specimens. Ordered laboratory supplies. Assisted in all duties involved with maintaining the laboratory.

### PROFESSIONAL ASSOCIATIONS

- ALLEGHENY COUNTY BAR ASSOCIATION admitted 1992.
- AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS Certification received 1983.

REFERENCES AVAILABLE UPON REQUEST

# UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE

Center for Continuing Education in the Health Sciences

# GRIBGIE OF MINISTER

Sharon E Copley (Enter Your Name)

Attended the Continuing Medical Education Activity, Course #3922

# Cervical Cancer Screening: State of the Art in 2013

Friday/Saturday, April 19-20, 2013 ♦ Conference Center Auditorium, Zero Level ♦ Magee-Women's Hospital of UPMC, Pittsburgh PA

University of Pittsburgh School of Medicine is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians

University of Pittsburgh School of Medicine designates this live activity for a maximum of 9.75 AMA PRA Category 1 Credit(s)™ Physicians should claim only the credit commensurate with the extent of their participation in the activity

Other Healthcare Professionals are awarded .9 Continuing Education Units (CEU's), which are equivalent to 9.7 Contact Hours

For your official credit transcript, please access the CCEHS website at http://ccehs.upmc.edu and follow the link to the Credit Transcript screen

Please allow six (6) – eight (8) weeks post-course for processing





USA

Course #	Title	Date Taken	Location	Description	Credit Hours
	Sub Total	2012		CMLE	2.00
CSCY1106	The Cytology of Squamous Cell Carcinoma Variants . Check Sample Cytopathology 1106-CME/CMLE	03/14/2013		ý	1.00 CME/CMLE
CSCY1107	Ultrasound-Guided Fine-Needle Aspiration of Parathyroid Lesions. Check Sample Cytopathology 1107-CME/CMLE	03/14/2013			1.00 CME/CMLE
CSCY1104	Small Cell Neoplasms of the Salivary Glands: Adenoid Cystic Carcinoma. Check Sample Cytopathology 1104-CME/CMLE	03/14/2013			1.00 CME/CMLE
CSCY1105	Pulmonary Neuroendocrine Tumors: A Review of Clinicopathologic and Cytologic Features . Check Sample Cytopathology 1105-CME/CMLE	03/14/2013			1.00 CME/CMLE
CSCY1109	Mutational Analysis: An Adjunct to Cytologic Interpretation of Carcinomas of Pulmonary Origin. Check Sample Cytopathology 1109-CME/CMLE	03/14/2013			1.00 CME/CMLE
CSCY1111	KRAS Testing: Role, Methods and Sampling, and Cytopreparatory Issues. Check Sample Cytopathology 1111-CME/CMLE	03/14/2013			1.00 CME/CMLE
CSCY1110	Immunocytochemistry: Specimen Preparation Techniques, Technical Limitations, and the Use of Appropriate Controls. Check Sample Cytopathology 1110-CME/CMLE	03/14/2013			1.00 CME/CMLE
CSCY1101	Fine-Needle Aspiration Cytologic Features of Metastatic Uterine Malignancies. Check Sample Cytopathology 1101-CME/CMLE	03/14/2013			1.00 CME/CMLE
CSCY1112	Epithelioid Gastrointestinal Stromal Tumor: Fine-Needle Aspiration Diagnosis and Pitfalls. Check Sample Cytopathology 1112-CME/CMLE	03/14/2013			1.00 CME/CMLE
CSCY1102	Cytomorphologic Changes on FNA Biopsy of Thyroid Nodules in Patients Treated With Radioactive Iodine. Check Sample Cytopathology 1102-CME/CMLE	03/14/2013			1.00 CME/CMLE

The ASCP certifies that the named individual has participated in the educational activities at the locations and dates indicated above, and if a physician is awarded the indicated number of CME Category 1 credits(s) toward the AMA Physician's Recognition Award.

American Society for Clinical Pathology 33 West Monroe, Suite 1600 Chicago, IL 60603

Accredited by the Accreditation Council for Continuing Medical Education California CE Registration No. 0010



**ASCP ID:** 03476117

USA

Course #	Title	Date Taken	Location	Description	Credit Hours
CSCY1108	Cytologic and Molecular Diagnostic Testing of Malignant Melanoma. Check Sample Cytopathology 1108-CME/CMLE	03/14/2013			1.00 CME/CMLE
CSCY1103	BRAF Testing in Routine Thyroid Cytology Practice. Check Sample Cytopathology 1103-CME/CMLE	03/14/2013			1.00 CME/CMLE
	Sub Total	2013		CME/CMLE	12.00
	Grand Total			CME/CMLE	99.00

The ASCP certifies that the named individual has participated in the educational activities at the locations and dates indicated above, and if a physician is awarded the indicated number of CME Category 1 credits(s) toward the AMA Physician's Recognition Award.

American Society for Clinical Pathology 33 West Monroe, Suite 1600 Chicago, IL 60603 Accredited by the Accreditation Council for Continuing Medical Education California CE Registration No. 0010

### PENNSYLVANIA CYTOLOGY SERVICES

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

## **CLIENT ACCOUNT NUMBER(S)**

Welcome to Pennsylvania Cytology Services! We look forward to working with you. Below you will find your client account number(s) for each program (FPP, BCCSP, PP{private pay}). If you were not issued an account number for a particular program and need one please contact our office and we can set one up. It's imperative that you place the correct client account number on the requisition.

FPP
(Family Planning Program)
BCCSP
(Breast and Cervical Cancer Screening Program)
PP
(Private Pay Patients)

If you have any questions please feel free to contact our office or send an email to  $\underline{\sf lisaritchey@pacytology.com}$  .

# THE FOLLOWING INFORMATION WILL HELP YOU COMPLETE OUR CYTOLOGY REQUISITION

Sample copy of cytology requisition is enclosed. Items that need completed have been underlined in bold.

- Include your 3-digit doctor account number on every requisition and any correspondence you send to us.
- Complete the patient information in the top portion of our requisition. Patient ID# - this is optional, if you put something in this field (chart #, etc.) we will print on the final report, otherwise patient ID# will not print on final.
- Choice of billing does not need to be completed due to the fact that each program (FPP, BCCSP, PP {private pay}) has their own account number, but you MUST have the correct 3-digit account number or the wrong program will get billed.
- GYN Cytology portion please mark appropriate box for test ordered. According to WV Algorithm: age 20 and under only receive a ThinPrep Pap test and age 21 and over receive ThinPrep Pap test with HPV reflex if result is ASCUS.
- Mark SOURCE of specimen.
- Patient History please complete all that apply, including the LMP and age.

# TRANSPORT/TRACKING LOG We strongly recommend the use of the transport/tracking log

- Please indicate the patient name and date of service of all specimens enclosed in box and put the total specimens at the bottom of the page and complete the contact information in case we need to call your office about the specimens.
- FAX COMPLETED SHEET TO 412-373-7027 AND ENCLOSE A COPY OF TRANSPORT/TRACKING LOG IN THE BOX.

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## PREPARING A THINPREP PAP TEST FOR SHIPMENT

- Be sure the patient name is on the vial and the name on the vial and requisition match completely, please no variations in the name (nickname, etc.)
- SECURELY CLOSE THE LID ENSURE THE BLACK TORQUE LINE ON THE LID GOES PAST THE TORQUE LINE ON THE VIAL.
- Place the vials in slots in cardboard vial holder (holds up to 10 specimens), place the vial holder and vials in the plastic bag – include one of the absorbent sheets.
- Expel all the air from the plastic bag. Seal plastic bag with zipper lock.
   Place another absorbent pad in the bottom of the prepaid mailing box.
- Place the plastic bag containing the vials into the prepaid mailing box.
- Include the corresponding requisitions in the box.
- Complete and fax the Transport/Tracking Log to 412-373-7027 and enclose a copy in the box with the specimens and requisitions.
- Ensure the box is securely closed also secure with tape.

Should you need additional supplies you can include a supply order form in the mailer or fax the request slip to 412-373-7027.

Should you have any questions please feel free to call us at 1-800-344-1026 or send an email to lisaritchey@pacytology.com

# SPECIMEN PACKING LIST AND TRANSPORT/TRACKING LOG

# PLEASE COMPLETE AND FAX TO: 412-373-7027 PRIOR TO SHIPPING AND

### INCLUDE THIS PACKING LIST IN THE SHIPPING BOX

Account #	Practice Name	Date shipped
Please list below	the patient names of speci	mens enclosed in box:
Patient Name		Date of service
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2		
7		
TOTAL SPECIME	ENS ENCLOSED:	
Name of person	completing this form in c	ase we need to contact you:
Name		Direct telephone #

## PENNSYLVANIA CYTOLOGY SERVICES

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

# INTERNET ACCESS INFORMATION (If you do not have internet access, please contact our office ASAP so we can set up paper reporting for you)

Website to access patient results:

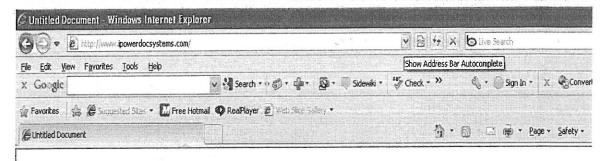
www.ipowerdocsystems.com

Click Internet Based iPowerdoc picture on the left side of the screen and a login screen will pop up.

User name:	-
Password: _	

- Once logged in you will see a page that lists all the new reports available to view/print this is the Results for Review section.
- If you'd like to print all the reports displayed click the print all button. If you'd like to view/print one just click on that patient to view and print from the report screen.
- When you are finished viewing or printing these reports simply click Flag Results as Reviewed in top right of screen and the reports will be archived.
- To search for an archived report click "Results Inquiry" along left side of screen.
- Enter the Start Date (Collection) and fill in your method of searching (name, dob, ss, etc.) and click find. The system defaults to a 10 day search which means it will search 10 days prior to and including the collection date you entered. If a report exists it will be displayed on the list below and you can click on the patient to view and then print the report.
- To logout, click the LOGOUT button above Pennsylvania Cytology Services.

If you have any questions please feel free to contact our office or send an email to: <a href="mailto:lisaritchey@pacytology.com">lisaritchey@pacytology.com</a> .

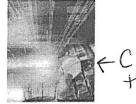


QUALITY SOFTWARE SYSTEMS,



Lab Info Systems For The Independent Clinical Laboratory

Providing Custom Laboratory Information Systems EXCEEDING CUSTOMER EXPECTATIONS



Click on this picture



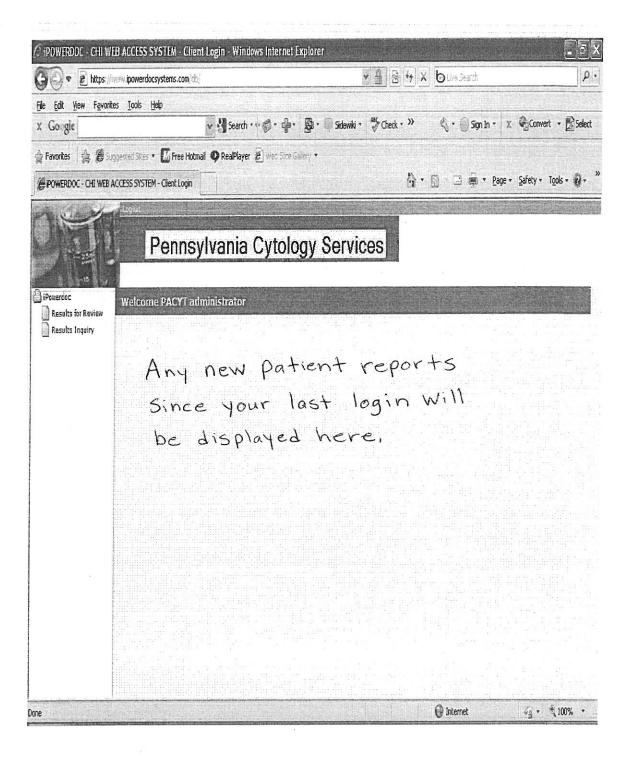


Safe Med. Data

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Section: Analytic Phase

Subject: Cervicovaginal Cytology Method of Reporting

Author: S.E.Copley

### **Principle**

A consistent method of reporting findings is essential for assuring patient safety through quality results.

### Clinical Significance

The clinician depends on consistent reporting to aid determining proper patient care.

### Specimen Type

All Cervicovaginal Papanicolaou specimens, both conventional and liquid-based.

### Procedure

- 1. General outline of report.
  - 1.1. Specimen Adequacy (two possible categories):
    - \*Satisfactory for evaluation... (with description of endocervical component and any other quality indicators, e.g., blood, inflammation).
    - \*Unsatisfactory for evaluation... (with description of reason. This will not have a general categorization).
  - 1.2. General Categorization six possible categories):
    - \*Negative for intraepithelial cell lesion or malignancy.
    - \*Inflammation, no epithelial cell abnormality.
    - \*Epithelial cell abnormality.
    - \*Other, no epithelial cell abnormality
    - \*Other (non-gyn)
    - \*See Remarks
  - 1.3. Description. (Many possible categories. The following is a sampling.)
    - \*Negative for intraepithelial cell lesion or malignancy. (Includes infections, reactive changes.)
    - \*No squamous epithelial cell abnormality
    - \*The following are used with epithelial cell abnormality:
      - \*ASC-US
      - \*ASC-H
      - \*LSIL
      - \*HSIL
      - \*Squamous cell carcinoma
      - \*Adenocarcinoma
      - \*Atypical glandular cells. (Further description of the origin (endocervical or endometrial) and severity given if further subclassification is possible).
    - \*Other (Used if interpretation does not fit in other categories.)
  - 1.4. Remarks (These may include comments on history, further clarification of results, or recommendations.)

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Section: Analytic Phase

Subject: Cervicovaginal Cytology Method of Reporting

Author: S.E.Copley

2. Cytology Method of Reporting

2.1. Specimen Adequacy [The quality indicators and unsatisfactory cases have explanations for these designations (see 2.1.4.)].

2.1.1. Satisfactory

Indicates the specimen is an adequate sample which can be interpreted without qualifications based on sampling or preparation. If the presence of endocervical cells is noted on a postmenopausal patient without a cervix, it is usually because squamous metaplastic cells cannot always be discerned from atrophic epithelium. An accurate history will usually help with this determination.

2.1.2. Satisfactory with qualifiers

Indicates the specimen may provide useful information; however, interpretation may be compromised.

2.1.3. Unsatisfactory

Indicates the specimen was processed and examined but is unreliable for the detection of cervical epithelial abnormalities.

- 2.1.4. Quality indicators
  - 2.1.4.1. Scant cellularity: There are too few cells on the slide for an adequate evaluation.
  - 2.1.4.2. Air drying: Indicates the cells have been air-dried, either after being smeared on the slide or *in situ*.
  - 2.1.4.3. Inflammation or blood obscuring cells: An abundance of white blood cells or red blood cells cover and obscure cellular detail.
  - 2.1.4.4. Cytolysis: Destruction of cytoplasm. Cellular debris makes evaluation difficult.
  - 2.1.4.5. No endocervical components: Indicates that none of the following elements is present in a premenopausal woman who has a uterine cervix:
    - a) endocervical cells
    - b) endocervical mucus
    - c) squamous metaplastic cells

If insufficient patient history is given, it is assumed the patient is premenopausal with cervix intact.

- 2.1.4.6. Thick: Indicates that portions of the smear are too thick for proper evaluation. In liquid-based cases, this may occur if the cells cling together in large groups. This can sometimes be avoided by immediately swirling the collection device in the vial, not letting it rest there before agitation.
- 2.1.4.7. Lack of age or menstrual status: Each of these is important to the interpretation of the Pap test. By omitting this information, the results could be compromised.

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Section: Analytic Phase

Subject: Cervicovaginal Cytology Method of Reporting

Author: S.E.Copley

- 2.1.4.8. Endocervical cells only/ sparse squamous component: An optimal Pap test should contain both endocervical and squamous cells.
- 2.2. General categorization
  - 2.2.1. Negative for epithelial cell lesion or malignancy: For triage as "negative." See description for any further findings.
  - 2.2.2. Epithelial cell abnormality: See description.
  - 2.2.3. Other: See description (non-gyn).
  - 2.2.4. Other: No epithelial cell abnormalities.
  - 2.2.5. See Remarks (used when the changes noted do not fit into other categories).
- 2.3. Description (Negative for intraepithelial cell lesion or malignancy):
  - 2.3.1. Organisms:
    - 2.3.1.1. Fungi consistent with candida (yeast): The spores and/or hyphae of a fungus, usually <u>Candida albicans</u>, which may cause vaginal itching if present in large quantities.
    - 2.3.1.2. Shift in vaginal flora suggestive of bacterial vaginosis: "Clue cells" present with coccobacilli; may be indicative of but not diagnostic for bacterial vaginosis.
    - 2.3.1.3. Bacteria consistent with actinomyces: Group of organisms sometimes classified as bacteria rather than fungi. May be observed in the female genital tract with the use of intrauterine contraceptive devices and are known human pathogens.
    - 2.3.1.4. Trichomonas vaginalis: Trichomonas is a pear-shaped protozoan sometimes associated with marked inflammatory changes. It may be unclear to the cytotechnologist whether or not these changes are directly due to trichomoniasis. The patient should be treated and a follow-up smear taken. If trichomonas is not present in the second smear, but the changes persist, then there may be an underlying atypical condition.
    - 2.3.1.5. Herpes virus changes present: The presence of the virus within the nuclei of the cells is pathognomonic for Herpes Simplex
  - 2.3.2. Reactive cellular changes associated with:
    - 2.3.2.1. Inflammation: Manifestations of inflammation exhibited in squamous cells.
    - 2.3.2.2. Radiation: Morphologic changes associated with radiation therapy.
    - 2.3.2.3. IUD: Cellular changes associated with the use of intrauterine contraceptive devices.
    - 2.3.2.4. Repair: Cellular changes associated with reparative processes.

Section: Analytic Phase

Subject: Cervicovaginal Cytology Method of Reporting

Author: S.E.Copley

- 2.3.2.5. Atrophy with inflammation (atrophic vaginitis): This is usually seen in post-menopausal patients who have an inflammatory condition.
- 2.3.3. Other; No epithelial cell abnormalities: A category for cases in which there are no morphological abnormalities per se; however, the findings may indicate the woman is at some increased risk.
  - 2.3.3.1. Glandular cells post-hysterectomy: The origin of these cells is uncertain. Possible sources include residual cervix, vaginal endometriosis, mesonephric duct remnants, vaginal adenosis, intravaginal prolapse of fallopian tube rectovaginal fistula, and columnar cell metaplasia of the atrophic vaginal epithelium. An accurate history, including whether the patient has a residual cervix, will aid in interpretation of these cells.
  - 2.3.3.2. Endometrial cell in a post-menopausal woman: These may be significant for an endometrial hyperplastic or neoplastic condition.
  - 2.3.3.3. Endometrial cells in a woman 40+ years of age: may indicate an increased risk for endometrial carcinoma. The clinician must take patient history into consideration when determining proper follow-up for these cases.
  - 2.3.3.4. Small glandular cells present, may be of endometrial origin: the cells do not appear to be atypical, but differentiating between these cells and a well differentiated glandular carcinoma can be impossible cytologically.
- 2.3.4. Epithelial cell abnormalities:
  - 2.3.4.1. Atypical squamous cell of undetermined significance (ASC-US): Cellular abnormalities that are more marked than those attributable to reactive changes, but that quantitatively or qualitatively fall short of a squamous intraepithelial lesion (SIL). Because the cellular changes in the ASCUS category may reflect an exuberant benign change or a potentially serious lesion, which cannot be unequivocally classified, they are interpreted as being of undetermined significance. Also includes cells with some abnormalities suggestive but not diagnostic of HPV.
  - 2.3.4.2. Atypical squamous cells, repair: These are changes associated with repair which are also atypical. Current literature suggests these patients are at higher risk of harboring a high-grade lesion.
  - 2.3.4.3. Atypical squamous cells, cannot exclude HSIL (ASC-H): Cases that show atypical immature cells. Thick fragments of cells with obscured nuclei, or small atypical cells

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Pennsylvania Cytology Services Policy/ Procedure # 5.1.5.

Section: Analytic Phase

Subject: Cervicovaginal Cytology Method of Reporting

Author: S.E.Copley

showing nuclear enlargement or irregularity. Current literature suggests that 24-94% of ASC-H cases show CIN 2-3 on biopsy.

2.3.4.4. Squamous intraepithelial lesion (SIL):

Low grade (LSIL) – mild dysplasia, CIN 1, with or without HPV infection.

High grade (HSIL) – Moderate dysplasia through CIS; CIN 2-3.

- 2.3.4.5. Squamous cell carcinoma: Presence of cells characteristic of invasive squamous cell carcinoma.
- 2.3.4.6. Atypical endocervical cells or atypical endometrial cells: endocervical and endometrial cells are subcategories of glandular cells. The Bethesda System states that it is helpful to the clinician to further sub-classify atypical glandular cells into endocervical or endometrial cells, whenever possible.
- 2.3.4.7. Atypical glandular cells of undetermined significance: Cells showing either endometrial or endocervical differentiation displaying nuclear atypia that exceeds obvious reactive or reparative changes but lacks unequivocal features of invasive adenocarcinoma. Appropriate clinical follow-up is indicated.
- 2.3.4.8. Adenocarcinoma: Cells characteristic of adenocarcinoma. Sometimes endometrial or endocervical origin can be suggested.
- 2.3.4.9. Malignant cells present, site undetermined: Malignant cells are present on the slide, but the site of origin cannot be specified. These may be gynecologic in origin, or may be metastatic. The clinician must take patient history into consideration when determining follow-up for these patients.
- 2.4. Remarks: These are other conditions, findings, and recommendations that may be of clinical use, depending on the clinician's practice protocols. Some are self-explanatory, but there are a few that may need further clarification:
  - 2.4.1. Drying artifact noted: This is similar to the drying artifact noted in the adequacy qualifiers, but is not extensive enough to note under the adequacy qualifiers.
  - 2.4.2. Excessive blood is present: Again, more blood than expected is noted, but it does not obscure cellular detail.
  - 2.4.3. Moderate/marked/acute inflammation: More than the expected amount of inflammation is present, but it falls short of obscuring a significant amount of the cellular material.

Section: Analytic Phase

Subject: Cervicovaginal Cytology Method of Reporting

Author: S.E.Copley

2.4.4. Immediately agitating the collection device in the vial may result in an improved specimen. Allowing the sampling instrument to rest in the vial before agitating may result in the cellular material forming aggregates, which may result in a specimen that is too thick, or one that is scanty (if aggregates cling to the device).

2.4.5. Cases that are run through the TPIS will have a remark to that effect, specifying whether it was also manually reviewed by a cytotechnologist, pathologist, or both.

- 2.5. Hormonal Evaluation: This is done upon the request of the clinician, in the form of a maturation index or a general evaluation of the overall epithelial maturation. The physician may then evaluate and interpret the findings with the age and last menstrual period (LMP) of the patient. The hormonal evaluation is inaccurate in the presence of trichomonas, candida, or an inflammatory process. Special care is required when taking these smears; sampling should be done from the lateral vaginal walls.
- 3. Amended Reports: It is sometimes necessary to amend a cytology report, due to quality assurance reviews, conversations with the clinician, or additional patient history not originally received. All amended reports are required by CLIA law to include why the report was amended, and to indicate what the original report stated that was changed.

### Procedural Notes

The 2001 Bethesda system for reporting results of cervical/vaginal cytology is now widely accepted. We at Pennsylvania Cytology Services feel that the use of the Bethesda System 2001 will result in improved patient management. To assist us in this goal, we request that clinicians provide us with all pertinent clinical information on each patient. It is especially important to note whether or not the patient has risk factors for cervical or endometrial cancer. Risk factors for cervical cancer include early age at first sexual intercourse, multiple sexual partners, history of sexually transmitted diseases including human papilloma virus, cigarette smoking, and possibly use of birth control pills. Risk factors for endometrial cancer include obesity, diabetes mellitus, infertility, and the use of Tamoxifen. Evidence of erosion, lesion, or abnormal bleeding is also very important. Inclusion of any pertinent information will result in a more accurate report.

Because the Pap smear is an interpretive test which relies on the ability of the clinician to obtain well-preserved cells, the accuracy of this test varies from 70-90% in the literature. A single Pap smear should not be relied upon to rule out cancerous and pre-cancerous lesions of the uterine cervix. Visible lesions should be biopsied. Repeat Pap smear testing, preferably on an annual basis, is recommended to detect cervical lesions.

Individual laboratories vary somewhat in their use of the Bethesda System. In order that our clinicians may better understand our terminology, and in turn benefit the patient, we have compiled this list of terms with explanations. On the back of each requisition, we have printed suggestions on how to obtain a cervical or vaginal smear.

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Section: Analytic Phase

Subject: Cervicovaginal Cytology Method of Reporting

Author: S.E.Copley

### References

- 1. Solomon, Diane. "Terminology and Management Guidelines for Abnormal Cervical Cytology." American Society of Cytology, Teleconference Syllabus; May 28, 2002.
- 2. Solomon, D., et al. "The 2001 Bethesda System: Terminology for Reporting Results of Cervical Cytology." JAMA 2002:287:2114-2119.
- 3. Wright, T.C., et al. "2001 Consensus Guidelines for the Management of Women with Cervical Cytological Abnormalities." JAMA 2002: 287: 2120-2129.
- 4. CLSI. <u>Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline Third Edition</u>. CLSI Document GP15-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2008.

# PENNSYLVANIA CYTOLOGY SERVICES

SUITE 1700 PARKWAY BUILDING ,339 OLD HAYMAKER ROAD, MONROEVILLE, PA 15146
Phone: 412-373-8300 Fax: 412-373-7027

College of American Pathologists Accredited Laboratory #41911-01 , Pennsylvania Laboratory #331

CLIA #39D0656968 Laboratory Director: Robert H. Swedarsky, MD

NAME:	ACCOUNT #		
SSN:	2 12 12 12 12 13 13 13 13 13 13 13 13 13 13 13 13 13	*	
PATIENT ID:			
DOB:			
3	PHYSICIAN:		

LAB #2013047938 LIQUID BASED PAP TEST (THINPREP)

COLLECTED: 08/19/2013

RECEIVED: 08/22/2013 REPORTED: 08/26/2013

SOURCE: VAGINAL

SAMPLING DEVICE:

BRUSH SPATULA

PATIENT HISTORY:

PREVIOUS LAB #2012058605

LMP: 1999 HYST

PREVIOUS SMEAR DATE: 8-23-12 HYSTERECTOMY: SEE LMP GIVEN

CYTOPATHOLOGY REPORT

THE BETHESDA REPORTING SYSTEM

SPECIMEN ADEQUACY:

SATISFACTORY FOR EVALUATION, POST-HYSTERECTOMY.

GENERAL CATEGORIZATION:

NEGATIVE FOR INTRAEPITHELIAL LESION OR MALIGNANCY.

DESCRIPTION:

NEGATIVE FOR INTRAEPITHELIAL LESION OR MALIGNANCY.

CERVICAL CYTOLOGY IS A SCREENING TEST WITH LIMITED SENSITIVITY AND AN IRREDUCIBLE FALSE NEGATIVE RATE. REGULAR SCREENING IS CRITICAL FOR CANCER PREVENTION. PAP TESTS ARE DESIGNED FOR THE DETECTION OF SQUAMOUS CELL CARCINOMA AND ITS PRECURSORS, NOT ADENOCARCINOMAS OR OTHER CANCERS.

CYTOTECHNOLOGIST: CJD

# PENNSYLVANIA CYTOLOGY SERVICES

# SUITE 1700 PARKWAY BUILDING ,339 OLD HAYMAKER ROAD, MONROEVILLE, PA 15146 Phone: 412-373-8300 Fax: 412-373-7027

College of American Pathologists Accredited Laboratory #41911-01, Pennsylvania Laboratory #331

CLIA #39 D0656968 Laboratory Director: Robert H. Swedarsky, MD

NAME:		ACCOUNT #	500 S 500 O 500 C 5 1 1 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
SSN:				
DOB:				
			4	
		PHYSICIAN:		

LAB #2013048447 LIQUID BASED PAP TEST (THINPREP)

COLLECTED: 08/22/2013

RECEIVED: 08/26/2013

REPORTED: 08/28/2013

SOURCE:

CONDITIONS:

CERVICAL

IUD

ENDOCERVICAL

SAMPLING DEVICE:

BRUSH

SPATULA

PATIENT HISTORY:

PREVIOUS LAB #2012010651
PREVIOUS SMEAR DATE: 2-1-12

REASON FOR REPEAT SMEAR: NEGATIVE PAP NO ENDOCERVICAL COMPONENT

ADDITIONAL HISTORY/PHYSICIAN NOTES: IUD MIRENA

CYTOPATHOLOGY REPORT

THE BETHESDA REPORTING SYSTEM

SPECIMEN ADEQUACY:

SATISFACTORY FOR EVALUATION, ENDOCERVICAL/TRANSFORMATION

ZONE COMPONENT PRESENT.

GENERAL CATEGORIZATION:

EPITHELIAL CELL ABNORMALITY (SEE DESCRIPTION) .

DESCRIPTION:

FUNGI CONSISTENT WITH CANDIDA (YEAST).

HIGH GRADE SQUAMOUS INTRAEPITHELIAL LESION: MODERATE DYSPLASIA/SEVERE DYSPLASIA/CARCINOMA IN SITU (CIN 2-3).

(ICD-9 CODE: 795.04)

REMARKS:

CLINICAL CORRELATION AND FOLLOW-UP AS APPROPRIATE.

CANNOT EXCLUDE A MORE SEVERE LESION.

CERVICAL CYTOLOGY IS A SCREENING TEST WITH LIMITED SENSITIVITY AND AN IRREDUCIBLE FALSE NEGATIVE RATE. REGULAR SCREENING IS CRITICAL FOR CANCER PREVENTION. PAP TESTS ARE DESIGNED FOR THE DETECTION OF SQUAMOUS CELL CARCINOMA AND ITS PRECURSORS, NOT ADENOCARCINOMAS OR OTHER CANCERS.

CYTOTECHNOLOGIST: DGB

ROBERT H SWEDARSKY, MD LABORATORY DIRECTOR

ELECTRONIC SIGNATURE

MY ELECTRONIC SIGNATURE IS ATTESTATION THAT I HAVE PERSONALLY REVIEWED THE SUBMITTED MATERIAL(S) AND THE FINAL RESULT REFLECTS THAT EVALUATION.

# Pennsylvania Cytology Services

SUITE 1700 PARKWAY BUILDING ,339 OLD HAYMAKER ROAD, MONROEVILLE, PA 15146
Phone: 412-373-8300 Fax: 412-373-7027

College of American Pathologists Accredited Laboratory #41911-01, Pennsylvania Laboratory #331

CLIA #39D0656968 Laboratory Director: Robert H. Swedarsky, MD

NAME:

SSN:

PATIENT ID:

DOB:

PHYSICIAN:

ACCOUNT #

LAB #2013045456 LIQUID BASED PAP TEST (THINPREP)

COLLECTED: 08/06/2013

RECEIVED: 08/09/2013 REPORTED: 08/16/2013

SOURCE:

CERVICAL

ENDOCERVICAL

SAMPLING DEVICE:

BRUSH

SPATULA

PATIENT HISTORY:

LMP: MIRENA

CYTOPATHOLOGY REPORT

THE BETHESDA REPORTING SYSTEM

HPV REPORT TO FOLLOW

SPECIMEN ADEQUACY:

SATISFACTORY FOR EVALUATION, ENDOCERVICAL/TRANSFORMATION

ZONE COMPONENT PRESENT.

GENERAL CATEGORIZATION:

EPITHELIAL CELL ABNORMALITY (SEE DESCRIPTION).

DESCRIPTION:

ATYPICAL SQUAMOUS CELLS OF UNDETERMINED SIGNIFICANCE

(ASC-US). (ICD-9 CODE: 795.01)

REMARKS:

CLINICAL CORRELATION AND FOLLOW-UP AS APPROPRIATE.

EVALUATION OF THE ABNORMALITY IS LIMITED DUE TO SCARCITY OF

ATYPICAL CELLS.

CERVICAL CYTOLOGY IS A SCREENING TEST WITH LIMITED SENSITIVITY AND AN IRREDUCIBLE FALSE NEGATIVE RATE. REGULAR SCREENING IS CRITICAL FOR CANCER PREVENTION. PAP TESTS ARE DESIGNED FOR THE DETECTION OF SQUAMOUS CELL CARCINOMA AND ITS PRECURSORS, NOT ADENOCARCINOMAS OR OTHER CANCERS.

CYTOTECHNOLOGIST: CJD

ROBERT H SWEDARSKY, MD LABORATORY DIRECTOR

ELECTRONIC SIGNATURE

MY ELECTRONIC SIGNATURE IS ATTESTATION THAT I HAVE PERSONALLY REVIEWED THE SUBMITTED MATERIAL(S) AND THE FINAL RESULT REFLECTS THAT EVALUATION.

# Pennsylvania Cytology Services

# SUITE 1700 PARKWAY BUILDING ,339 OLD HAYMAKER ROAD, MONROEVILLE, PA 15146 Phone: 412-373-8300 Fax: 412-373-7027

College of American Pathologists Accredited Laboratory #41911-01, Pennsylvania Laboratory #331

CLIA #39D0656968 Laboratory Director: Robert H. Swedarsky, MD

NAME:		ACCOUNT #	
SSN:			
PATIENT ID:			
DOB:	1		
e l			
		PHYSICIAN:	

LAB #2013045456

COLLECTED: 08/06/2013
RECEIVED: 08/09/2013
REPORTED: 08/20/2013

SOURCE: CERVICAL ENDOCERVICAL

SAMPLING DEVICE:

BRUSH SPATULA

PATIENT HISTORY: LMP: MIRENA

DIGENE HYBRID CAPTURE II HPV TEST

RESULTS:

HIGH RISK (HPV TYPES 16, 18, 31, 33 35, 39, 45, 51, 52, 56, 58 59, 68) POSITIVE

CYTOTECHNOLOGIST: SAJ

### SUMMARY OF CYTOLOGY FINDINGS

PAGE 1

PENNSYLVANIA CYTOLOGY SERVICES SUITE 1700 PARKWAY BUILDING 339 OLD HAYMAKER ROAD MONROEVILLE, PA 15146-1477

PHONE: 412-373-8300

CLIENT NUMBER:

PERIOD ENDING: 07/31/2013

DESCRIPTION: SQUAMOUS INTRA LESION - LOW TOTAL: 3

2013041548 ALMA 07/17/2013 2013039301 MELODY 06/17/2013 2013039302 WANTIKA 06/17/2013	LAB NUMBER	PATIENT	DATE	PATIENT	ID	HPV
	2013039301	MELODY	06/17/20	013		

DESCRIPTION: ATYPICAL SQUAMOUS CELLS

TOTAL:

LAB NUMBER	PATIENT	DATE	PATIENT ID	HPV
2013039303	JERLESA	06/19/2	2013	+
2013040451	KIMBERLY	07/10/2	:013	+
2013041547	NIESHA	07/17/2	:013	
2013039297	EMILY	06/26/2	:013	+

DESCRIPTION: NEGATIVE FOR INTRAEPITHELIAL LESION OR MALIGNANCY

TOTAL:

LAB NUMBER	PATIENT	DATE	PATIENT	ID HP	V
2013040447 2013040449 2013040450 2013040452 2013039300	CAND ALEXA AMANDA ELIZA DAWN	07/ 07/ BETH 07/ 06/	/08/2013 /08/2013 /10/2013 /10/2013 /13/2013		Q
*2013039298 2013040448	7.0		01/2013 08/2013		

PENNSYLVANIA CYTOLOGY SERVICES

CLIENT NUMBER:

PERIOD ENDING: 07/31/2013

DESCRIPTION: ORGANISMS TOTAL: 4

TOTAL:

PATIENT ID HPV
5/2013 4/2013
7/2013 5/2013 +
4

DESCRIPTION: REACTIVE CELLULAR CHANGES

TOTAL: 2

LAB NUMBER	PATIENT		DATE		PATIENT	ID	HPV
2013041545 2013039299		KEILA BRIANNA		07/17/20 07/03/20		·	

PENNSYLVANIA CYTOLOGY SERVICES

CLIENT NUMBER:

PERIOD ENDING: 07/31/2013

	MONTHL	Y TOTALS	SIX-MON	TH TOTALS
SQUAMOUS CARCINOMA	0	0.00 %	<b>-</b>	0.00.8
ADENOCARCINOMA	Ō	0.00 %	0	0.00 %
OTHER NEOPLASM TYPE	0	0.00 %	Ō	0.00 %
SQUAMOUS INTRA LESION - HIGH	0	0.00 % 0.00 % 0.00 % 0.00 % 15.00 % 20.00 % 35.00 % 20.00 %	0	0.00 %
ASC-H	0	0.00 %	1	0.91 %
SQUAMOUS INTRA LESION - LOW	3	15.00 %	6	5.45 %
ATYPICAL SQUAMOUS CELLS	4	20.00 %	19	17.27 %
ATYPICAL GLANDULAR CELLS	0	0.00 %	1	0.91 %
NEGATIVE FOR INTRAEPITHELIAL LESION OR M	7	35.00 %	39	35.45 %
ORGANISMS	4	20.00 %	25	22.73 %
REACTIVE CELLULAR CHANGES	2	10.00 %	17	15.45 %
OTHER	U	0.00 %	1	0.91 %
UNSATISFACTORY	0	0.00 %	0	0.00 %
NON-GYN	0	0.00 %	0	0.00 %
SATISFACTORY WITH QUALIFIERS	6	30.00 %	22	20.00 %
	20	100.00 %	110	100.00 %
ADEQUACY BREAKDOWN	(PERCEN	TAGES BASED	ON TOTA	ALS ABOVE)
SATISFACTORY FOR EVALUATION:				
POST-HYSTERECTOMY.	0	0.00 %	0	0.00 %
ENDOCERVICAL/TRANSFORMATION ZONE	19	0.00 % 95.00 %	102	92.73 %
COMPONENT PRESENT.				
ENDOCERVICAL/TRANSFORMATION ZONE COMPONENT ABSENT.	1	5.00 %	8	7.27 %
SCANT CELLULARITY.	1	5.00 %	1	0.91 %
CYTOLYSIS.	1	5.00 % 5.00 %	4	3.64 %
SEE REMARKS*.	1	5.00 %	4	3.64 %
LACK OF AGE OR MENSTRUAL STATUS.	1	5.00 %	4	3.64 %
PARTIALLY OBSCURING THICK AREAS.	1	5.00 %	2	1.82 %

### **EXHIBIT A**

PRICING PAGES FOR MCH14020						
ITEM #	APPROX. ANNUAL USAGE	DESCRIPTION	UNIT PRICE	EXTENDED COST		
1	60,000	THIN PREP LIQUID MEDIUM/MONOLAYER OR EQUAL (4.1.1.1)	\$ 12.85	\$771,000.00		
2	2,700	HPV/DNA TESTING (HIGH-RISK ONLY) THIN PREP LIQUID MEDIUM/MONOLAYER OR EQUAL (4.1.1.1)	\$ 28.00	\$ 75,600.00		
3	2,600	THIN PREP LIQUID MEDIUM/MONOLAYER OR EQUAL (PRIVATE PAY BY PROGRAM ELIGIBLE CLIENT) (4.1.1.1)	\$12.85	\$ 33,410.00		
	OVERALL TOTAL COST \$880,010.00					

THIS WILL BE AN OPEN END CONTRACT. QUANTITIES LISTED ARE ESTIMATES ONLY. ACTUAL NEEDS OF THE AGENCY WILL BE SUPPLIED, WHETHER THEY BE GREATER THAN OR LESS THAN ESTIMATES. ORDERS WILL BE PLACED ON AN AS-NEEDED BASIS.

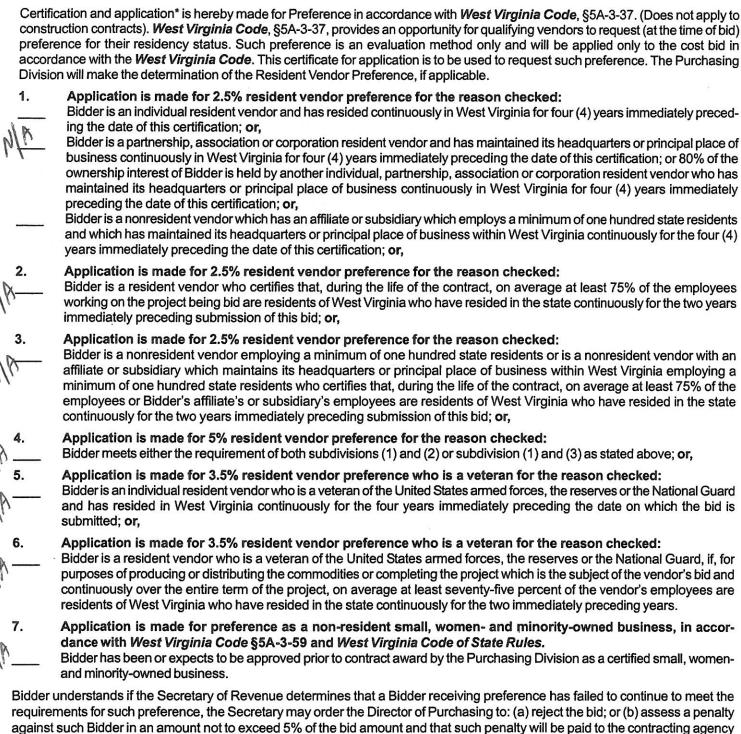
EVALUATION OF BIDS WILL BE BASED ON EXTENDED COST AND AWARD WILL BE MADE TO THE LOWEST OVERALL TOTAL COST WHICH MEETS SPECIFICATIONS.

VENDORNAME: Pennsylvania Cytology Services
ADDRESS: 339 Old Haymaker Rd. Ste, 1700
Monroeville PA 15146
FAX #: 412-373-7027
PHONE #: 412-373-8300 or 1-800-344-1026
E-MAIL ADDRESS: lisaritchey@pacytology.com
REMIT TO ADDRESS: 339 012 Haymaker Rd. Ste. 1700
Mogropville PA 15146
SIGNATURE. TO STORY THE PARTY OF THE PARTY O
DATE: 8-30-2013

## State of West Virginia

# **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



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

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: Off Our	4	
Date: 8-30-2013	Title: Medical Director		_

deemed by the Tax Commissioner to be confidential.

# STATE OF WEST VIRGINIA Purchasing Division

### **PURCHASING AFFIDAVIT**

**MANDATE:** Under W. Va. Code §5A-3-10a, 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: (1) the debt owed is an amount greater than one thousand dollars in the aggregate; or (2) the debtor is in employer default.

**EXCEPTION:** The prohibition listed above does not apply where a vendor has contested any tax administered pursuant to chapter eleven of the W. Va. 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.

#### **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.

"Employer default" means having an outstanding balance or liability to the old fund or to the uninsured employers' fund or being in policy default, as defined in W. Va. Code § 23-2c-2, failure to maintain mandatory workers' compensation coverage, or failure to fully meet its obligations as a workers' compensation self-insured employer. An employer is not in employer default if it has entered into a repayment agreement with the Insurance Commissioner and remains in compliance with the obligations under the repayment agreement.

"Related party" means a party, whether an individual, corporation, partnership, association, limited liability company or any other form or business association or other entity whatsoever, related to any vendor by blood, marriage, ownership or contract through which the party has a relationship of ownership or other interest with the vendor so that the party will actually or by effect receive or control a portion of the benefit, profit or other consideration from performance of a vendor contract with the party receiving an amount that meets or exceed five percent of the total contract amount.

AFFIRMATION: By signing this form, the vendor's authorized signer affirms and acknowledges under penalty of law for false swearing (*W. Va. Code* §61-5-3) that neither vendor nor any related party owe a debt as defined above and that neither vendor nor any related party are in employer default as defined above, unless the debt or employer default is permitted under the exception above.

### WITNESS THE FOLLOWING SIGNATURE:

NOTARY PUBLIC
STATE OF WEST VIRGINIA
LYNN M. WOLFE
1200 JD ANDERSON DRIVE
MORGANTOWN, WV 26505
My commission expires February 20. 2022

Vendor's Name: Marlborough Holdings, LLC, dba	Pennsylvania Cytology	Services
Authorized Signature: Kollesold Sun	Date:	81261293
State of West Virginia		
County of Monongalia, to-wit:		
Taken, subscribed, and sworn to before me this <u>Ale</u> day of	of August	, 20 <u>13</u> .
My Commission expires February 20, 2028	, 20	2 11 12 1
AFFIX SEAL HERE	NOTARY PUBLIC	M. Ufle
OFFICIAL SEAL		Purchasing Affidavjt (Revised 07/01/2012

### **CERTIFICATION AND SIGNATURE PAGE**

By signing below, I certify that I have reviewed this Solicitation in its entirety; understand the requirements, terms and conditions, and other information contained herein; that I am submitting this bid or proposal for review and consideration; that I am authorized by the bidder to execute this bid or any documents related thereto on bidder's behalf; that I am authorized to bind the bidder in a contractual relationship; and that to the best of my knowledge, the bidder has properly registered with any State agency that may require registration.

Marlborough H	ioldings LLC		
dba Pennsylvan	ia Cytology	Services	
(Company)	an Or	ı	
(Authorized Signature)		= -	
Robert H. Swe	darsky, MD	Medical	Director
(Representative Name, Title)			
412-373-8300			
1-800-344-1026	412-373-7	027	
(Phone Number)	(Fax Number)		
8-30-2013			
(Date)			

# ADDENDUM ACKNOWLEDGEMENT FORM SOLICITATION NO.: MCH14020

**Instructions:** Please acknowledge receipt of all addenda issued with this solicitation by completing this addendum acknowledgment form. Check the box next to each addendum received and sign below. Failure to acknowledge addenda may result in bid disqualification.

**Acknowledgment:** I hereby acknowledge receipt of the following addenda and have made the necessary revisions to my proposal, plans and/or specification, etc.

	100000000000000000000000000000000000000	American Strain Commence	Numbers Received:	-		
(Chec	k th	e bo	ox next to each addendum rec	eive	d)	
	[\	/	Addendum No. 1	[	]	Addendum No. 6
	[	]	Addendum No. 2	[	]	Addendum No. 7
	[	]	Addendum No. 3	[	]	Addendum No. 8
	[	]	Addendum No. 4	[	]	Addendum No. 9
	Γ	1	Addendum No. 5	ſ	]	Addendum No. 10

I understand that failure to confirm the receipt of addenda may be cause for rejection of this bid. I further understand that any verbal representation made or assumed to be made during any oral discussion held between Vendor's representatives and any state personnel is not binding. Only the information issued in writing and added to the specifications by an official addendum is binding.

Marlborough Holdings LLC

dba Pennsylvania Cytology Services

Company

Authorized Signature

8-30-2013

Date

NOTE: This addendum acknowledgement should be submitted with the bid to expedite document processing. Revised 6/8/2012