

## Onco Diagnostic Services, Inc.

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10401 Old Georgetown Road, Suite 408  
Bethesda, Maryland 20814  
Telephone (301) 530-5511  
Fax No. (301) 564-5748

October 28, 2009

Department of Administration  
Purchasing Division  
Building 15  
2019 Washington Street, East  
Charleston, WV 25305-0130

Subject: RFQ# MCH10037

Dear Sir:

Onco Diagnostic Services Inc. is an independent woman owned laboratory located in Bethesda, Maryland. Our Pathologists, Cytopathologists and Dermatopathologists are Board Certified in Anatomical, Clinical Pathology, Cytopathology and Dermatopathology, with additional expertise in GI Pathology and Pediatric Pathology. All Cytotechnologists are ASCP certified and are enrolled in the required Proficiency Testing Programs. Our entire professional staff exceeds the established minimum standards for continuing education. We have earned an outstanding reputation with our clients providing accurate interpretation of test results and quality of service. This quality of service makes your patients our No. 1 priority.

Onco Diagnostic Services Inc. performs all laboratory testing utilizing state of the art technologies. We perform high risk HPV DNA screening offered by Cervista, a Hologic Women's Health Company. This highly reliable screening test offers 100% detection of CIN III+ and 99.1% negative predictive value for CIN II+, with no cross-reactivity with common low risk HPV types, plus a substantial reduction of quantity not sufficient (QNS) results. An internal control to assess both sample cellularity and contamination is used, thus providing more specificity and sensitivity. With Cervista HPV DNA, Onco Diagnostic performs the only FDA approved genotyping test for HPV 16/18 from a single thin prep vial.

Thank you for the opportunity to participate with RFQ# MCH 10037 in providing Cytology Services for the Office of Maternal, Child & Family Health, Family Planning Program and Breast & Cervical Cancer Screening Program for the State of West Virginia.

Sincerely,



Nancy Rogowski  
President

Enclosures

aa

**REQUEST FOR QUOTATION**

**CYTOLOGY SERVICES**

**For: The Office of Maternal  
Child & Family Health  
Family Planning Program  
Breast & Cervical Cancer Program**

**RFQ NUMBER – MCH10037**

**FOR:**

**DEPARTMENT OF ADMINISTRATION  
PURCHASING DIVISION  
BUILDING 15  
2019 WASHINGTON STREET, EAST  
CHARLESTON, WV 25305-0130**

**BIDDER NAME:**

**ONCO DIAGNOSTIC SERVICES, INC.  
10401 OLD GEORGETOWN ROAD  
SUITE 408  
BETHESDA, MD 20814  
(301) 530-5511  
(301) 564-5748 FAX**

ONCO DIAGNOSTIC SERVICES, INC.  
 10401 OLD GEORGETOWN RD, # 408  
 BETHESDA, MD 20814

COST SHEET FOR MCH10037

Item #	Apprx. Annual Usage QUANTITY	DESCRIPTION	UNIT PRICE	TOTAL COST
1	50,000	CYTOLOGY SERVICES-LIQUID BASED PAP TEST	\$14.50	\$ 870,000
2	2,800	HPV/DNA TESTING (HIGH-RISK ONLY)	\$35.00	98,000
3	2,600	CYTOLOGY SERVICES LIQUID BASED PAP TEST (PRIVATE PAY BY PROGRAM ELIGIBLE CLIENT)	\$14.50	37,700
		<b>TOTAL COST</b>		<b>\$1,005,700</b>

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

*Nancy Roggenbush* President 10/28/09



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

### Request for Quotation

RFQ NUMBER: MCH10037

PAGE: 1

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

RFQ COPY  
TYPE NAME/ADDRESS HERE

ONCO DIAGNOSTIC SERVICES, INC  
10401 OLD GEORGETOWN RD, # 408  
BETHESDA, MD 20814

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

DATE PRINTED	TERMS OF SALE	SHIP VIA	FOB	FREIGHT TERMS
09/22/2009				

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

LINE	QUANTITY	UOP	CAT NO	ITEM NUMBER	UNIT PRICE	AMOUNT
0001	1	JB		948-21	\$14.50	\$ 870,000
<p>OPEN- END BLANKET CONTRACT</p> <p>CYTOLOGY SERVICES - LIQUID BASED PAP TEST</p> <p>OPEN END CONTRACT</p> <p>BLANKET OPEN- END CONTRACT FOR CYTOLOGY SERVICES FOR THE OFFICE OF MATERNAL, CHILD &amp; FAMILY HEALTH, FAMILY PLANNING PROGRAM AND BREAST &amp; CERVICAL CANCER SCREENING PROGRAM PER THE ATTACHED SPECIFICATIONS.</p> <p>THE VENDOR WILL PROVIDE CYTOLOGY SERVICES TO INCLUDE: SPECIMEN ACCESSION, SPECIMEN PROCESSING, HRHPV TESTING, PROVISION OF CYTOTECHNOLOGIST, PATHOLOGIST(S) COVERAGE, SPECIMEN EVALUATION, RECORD KEEPING, AND QUALITY ASSURANCE ACTIVITIES AND REPORTS. ALL QUOTATIONS MUST MEET THE MANDATORY REQUIREMENTS OF THIS RFQ AS DESCRIBED IN THE ATTACHED SPECIFICATIONS.</p> <p>EXHIBIT 3</p>						

RECEIVED

2009 NOV 12 A 10: 22

PURCHASING DIVISION  
STATE OF WV

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE: *Pancy Rogowski* TELEPHONE: 301 530 5511 DATE: 10/28/09  
 TITLE: *President* FEIN: 56 237 2362 ADDRESS CHANGES TO BE NOTED ABOVE

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



State of West Virginia  
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 Purchasing Division  
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**MCH10037**

PAGE  
**2**

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**304-558-0067**

PROPERTY

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PROPERTY

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LINE	QUANTITY	UOP	QAT NO	ITEM NUMBER	UNIT PRICE	AMOUNT
<p><b>LIFE OF CONTRACT:</b> THIS CONTRACT BECOMES EFFECTIVE ON NOVEMBER 15, 2009 AND EXTENDS FOR A PERIOD OF ONE (1) YEAR OR UNTIL SUCH "REASONABLE TIME" THEREAFTER AS IS NECESSARY TO OBTAIN A NEW CONTRACT OR RENEW THE ORIGINAL CONTRACT. THE "REASONABLE TIME" PERIOD SHALL NOT EXCEED TWELVE (12) MONTHS. DURING THIS "REASONABLE TIME" THE VENDOR MAY TERMINATE THIS CONTRACT FOR ANY REASON UPON GIVING THE DIRECTOR OF PURCHASING 30 DAYS WRITTEN NOTICE.</p> <p><b>UNLESS SPECIFIC PROVISIONS ARE STIPULATED ELSEWHERE IN THIS CONTRACT DOCUMENT THE TERMS, CONDITIONS AND PRICING SET HEREIN ARE FIRM FOR THE LIFE OF THE CONTRACT.</b></p> <p><b>RENEWAL:</b> THIS CONTRACT MAY BE RENEWED UPON THE MUTUAL WRITTEN CONSENT OF THE SPENDING UNIT AND VENDOR, SUBMITTED TO THE DIRECTOR OF PURCHASING THIRTY (30) DAYS PRIOR TO THE EXPIRATION DATE. SUCH RENEWAL SHALL BE IN ACCORDANCE WITH THE TERMS AND CONDITIONS OF THE ORIGINAL CONTRACT AND SHALL BE LIMITED TO TWO (2) ONE (1) YEAR PERIODS.</p> <p><b>CANCELLATION:</b> THE DIRECTOR OF PURCHASING RESERVES THE RIGHT TO CANCEL THIS CONTRACT IMMEDIATELY UPON WRITTEN NOTICE TO THE VENDOR IF THE COMMODITIES AND/OR SERVICES SUPPLIED ARE OF AN INFERIOR QUALITY OR DO NOT CONFORM TO THE SPECIFICATIONS OF THE BID AND CONTRACT HEREIN.</p> <p><b>OPEN MARKET CLAUSE:</b> THE DIRECTOR OF PURCHASING MAY AUTHORIZE A SPENDING UNIT TO PURCHASE ON THE OPEN MARKET, WITHOUT THE FILING OF A REQUISITION OR COST ESTIMATE, ITEMS SPECIFIED ON THIS CONTRACT FOR IMMEDIATE DELIVERY IN EMERGENCIES DUE TO UNFORESEEN CAUSES (INCLUDING BUT NOT LIMITED TO DELAYS IN TRANSPORTATION OR AN UNANTICIPATED INCREASE IN THE VOLUME O</p>						

SIGNATURE: <i>Theresa Rogge</i>		TELEPHONE: 301 530 5511	DATE: 10/28/09
TITLE: <i>President</i>	FEDV: 562372362	ADDRESS CHANGES TO BE NOTED ABOVE	

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



State of West Virginia  
 Department of Administration  
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**Request for  
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RFQ NUMBER:  
**MCH10037**

PAGE:  
**3**

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

RFQ COPY

TYPE NAME/ADDRESS HERE

ONCO DIAGNOSTIC SERVICES, INC.  
 10401 OLD GEORGETOWN RD, # 408  
 BETHESDA, MD 20814

RFQ COPY

HEALTH AND HUMAN RESOURCES  
 BPH - MCH WAREHOUSE

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

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

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

LINE	QUANTITY	UOP	CAT NO	ITEM NUMBER	UNIT PRICE	AMOUNT
<p>WORK.)</p> <p>QUANTITIES: QUANTITIES LISTED IN THE REQUISITION ARE APPROXIMATIONS ONLY, BASED ON ESTIMATES SUPPLIED BY THE STATE SPENDING UNIT. IT IS UNDERSTOOD AND AGREED THAT THE CONTRACT SHALL COVER THE QUANTITIES ACTUALLY ORDERED FOR DELIVERY DURING THE TERM OF THE CONTRACT, WHETHER MORE OR LESS THAN THE QUANTITIES SHOWN.</p> <p>ORDERING PROCEDURE: SPENDING UNIT(S) SHALL ISSUE A WRITTEN STATE CONTRACT ORDER (FORM NUMBER WV-39) TO THE VENDOR FOR COMMODITIES COVERED BY THIS CONTRACT. THE ORIGINAL COPY OF THE WV-39 SHALL BE MAILED TO THE VENDOR AS AUTHORIZATION FOR SHIPMENT, A SECOND COPY MAILED TO THE PURCHASING DIVISION, AND A THIRD COPY RETAINED BY THE SPENDING UNIT.</p> <p>BANKRUPTCY: IN THE EVENT THE VENDOR/CONTRACTOR FILES FOR BANKRUPTCY PROTECTION, THIS CONTRACT IS AUTOMATICALLY NULL AND VOID, AND IS TERMINATED WITHOUT FURTHER ORDER.</p> <p>THE TERMS AND CONDITIONS CONTAINED IN THIS CONTRACT SHALL SUPERSEDE ANY AND ALL SUBSEQUENT TERMS AND CONDITIONS WHICH MAY APPEAR ON ANY ATTACHED PRINTED DOCUMENTS SUCH AS PRICE LISTS, ORDER FORMS, SALES AGREEMENTS OR MAINTENANCE AGREEMENTS, INCLUDING ANY ELECTRONIC MEDIUM SUCH AS CD-ROM.</p> <p>REV. 04/11/2001.</p> <p>INQUIRIES:                  WRITTEN QUESTIONS SHALL BE ACCEPTED THROUGH CLOSE OF BUSINESS ON 10/6/2009. QUESTIONS MAY BE SENT VIA USPS, FAX, COURIER, OR E-MAIL. IN ORDER TO ASSURE</p>						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE <i>Nancy Roguski</i>	TELEPHONE 301 530 5511	DATE 10/28/09
TITLE <i>President</i>	FAX 56 237 2362	ADDRESS CHANGES TO BE NOTED ABOVE

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**Request for Quotation**

REQ NUMBER
MCH10037

PAGE
4

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304-558-0067

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 10401 OLD GEORGETOWN RD, # 408  
 BETHESDA, MD 20814

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 25301 304-558-3417

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09/22/2009				

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

LINE	QUANTITY	UOP	CAF NO	ITEM NUMBER	UNIT PRICE	AMOUNT
<p>NO VENDOR RECEIVES AN UNFAIR ADVANTAGE, NO SUBSTANTIVE QUESTIONS WILL BE ANSWERED ORALLY. IF POSSIBLE, E-MAIL QUESTIONS ARE PREFERRED. ADDRESS INQUIRIES TO:</p> <p>ROBERTA WAGNER                  DEPARTMENT OF ADMINISTRATION                  PURCHASING DIVISION                  2019 WASHINGTON STREET, EAST                  CHARLESTON, WV 25311                  FAX: 304-558-4115                  E-MAIL: RWAGNER@WVADMIN.GOV</p> <p>EXHIBIT 4</p> <p>LOCAL GOVERNMENT BODIES: UNLESS THE VENDOR INDICATES IN THE BID HIS REFUSAL TO EXTEND THE PRICES, TERMS, AND CONDITIONS OF THE BID TO COUNTY, SCHOOL, MUNICIPAL AND OTHER LOCAL GOVERNMENT BODIES, THE BID SHALL EXTEND TO POLITICAL SUBDIVISIONS OF THE STATE OF WEST VIRGINIA. IF THE VENDOR DOES NOT WISH TO EXTEND THE PRICES, TERMS, AND CONDITIONS OF THE BID TO ALL POLITICAL SUBDIVISIONS OF THE STATE, THE VENDOR MUST CLEARLY INDICATE SUCH REFUSAL IN HIS BID. SUCH REFUSAL SHALL NOT PREJUDICE THE AWARD OF THIS CONTRACT IN ANY MANNER.</p> <p>REV. 3/88                  PURCHASING CARD ACCEPTANCE: THE STATE OF WEST VIRGINIA CURRENTLY UTILIZES A VISA PURCHASING CARD PROGRAM WHICH IS ISSUED THROUGH A BANK. THE SUCCESSFUL VENDOR MUST ACCEPT THE STATE OF WEST VIRGINIA VISA PURCHASING CARD FOR PAYMENT OF ALL ORDERS PLACED BY ANY STATE AGENCY AS A CONDITION OF AWARD.</p>						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS			
SIGNATURE <i>Nancy Reynolds</i>	TELEPHONE 301 530 5511	DATE 10/28/09	
TITLE <i>President</i>	FERN 562372362	ADDRESS CHANGES TO BE NOTED ABOVE	

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### Request for Quotation

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PAGE  
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ADDRESS (CORRESPONDENCE TO ATTENTION OF)  
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304-558-0067

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HEALTH AND HUMAN RESOURCES  
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09/22/2009				

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

LINE	QUANTITY	UOP	CAT NO	ITEM NUMBER	UNIT PRICE	AMOUNT
NOTICE						
A SIGNED BID MUST BE SUBMITTED TO:						
DEPARTMENT OF ADMINISTRATION PURCHASING DIVISION BUILDING 15 2019 WASHINGTON STREET, EAST CHARLESTON, WV 25305-0130						
PLEASE NOTE: A CONVENIENCE COPY WOULD BE APPRECIATED.						
THE BID SHOULD CONTAIN THIS INFORMATION ON THE FACE OF THE ENVELOPE OR THE BID MAY NOT BE CONSIDERED:						
SEALED BID						
BUYER:-----RW/FILE 22-----						
RFQ. NO.:-----MCH10037-----						
BID OPENING DATE:---10/22/2009---						
BID OPENING TIME:---1:30 PM---						
PLEASE PROVIDE A FAX NUMBER IN CASE IT IS NECESSARY TO CONTACT YOU REGARDING YOUR BID:						
-----301-564-5748-----						
CONTACT PERSON (PLEASE PRINT CLEARLY): Nancy Rogowski						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS		
SIGNATURE <i>Nancy Rogowski</i> President	TELEPHONE 301-530-5511	DATE 10/28/09
FAX 562372362	ADDRESS CHANGES TO BE NOTED ABOVE	

WHEN RESPONDING TO RFQ, 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

**Request for  
 Quotation**

RFQ NUMBER:  
**MCH10037**

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

RFQ COPY

TYPE NAME/ADDRESS HERE

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 BETHESDA, MD 20814

RFQ COPY

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

DATE PRINTED	TERMS OF SALE	SHIP VIA	POB	FREIGHT TERMS
09/22/2009				

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

LINE	QUANTITY	UOF	QTY NO.	ITEM NUMBER	UNIT PRICE	AMOUNT
0002	2,800	EA		948-21	\$35.00	\$ 98,000
HPV/DNA TESTING (HIGH-RISK ONLY)						
0003	2,600	EA		948-21	\$14.50	\$ 37,700
CYTOLOGY SERVICES - LIQUID BASED PAP TEST (PRIVATE						
PAY BY PROGRAM ELIGIBLE CLIENT)						
AWARD WILL BE MADE TO THE VENDOR WITH THE LOWEST OVER-ALL COST WHO MEETS SPECIFICATIONS.						
VENDOR MUST SUBMIT AN ORIGINAL ITEMIZED INVOICE FOR EACH ORDER. PAYMENT WILL BE MADE IN ARREARS AFTER RECEIPT OF EACH COMPLETED ORDER. ORDERS WILL BE PLACED ON AN AS NEEDED BASIS.						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS:

SIGNATURE: *Nancy Roguski* TELEPHONE: **301 530 5511** DATE: **10/28/09**

TITLE: *President* FEIN: **56 237 2362** ADDRESS CHANGES TO BE NOTED ABOVE

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



State of West Virginia  
Department of Administration  
Purchasing Division  
2019 Washington Street East  
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### Request for Quotation

RFQ NUMBER	PAGE
MCH10037	7

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

RFQ COPY  
TYPE NAME/ADDRESS HERE

VENDOR

ONCO DIAGNOSTIC SERVICES, INC  
10401 OLD GEORGETOWN RD, # 408  
BETHESDA, MD 20814

VENDOR

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

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

LINE	QUANTITY	UOF	CAT. NO.	ITEM NUMBER	UNIT PRICE	AMOUNT
***** THIS IS THE END OF RFQ MCH10037 ***** TOTAL:						\$1,005,700

SEE REVERSE SIDE FOR TERMS AND CONDITIONS			
SIGNATURE <i>Nancy Roguski</i> President	TELEPHONE 301-530-5511	DATE 10/28/09	
TITLE President	FBN 562372362	ADDRESS CHANGES TO BE NOTED ABOVE	

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COST SHEET FOR MCH10037

Item #	Apprx. Annual Usage QUANTITY	DESCRIPTION	UNIT PRICE	TOTAL COST
1	60,000	CYTOLOGY SERVICES-LIQUID BASED PAP TEST	\$14.50	\$ 870,000
2	2,800	HPV/DNA TESTING (HIGH-RISK ONLY)	\$35.00	98,000
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TOTAL COST				\$1,005,700

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

*Nancy Ryznar* President 10/28/09

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

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## Part 1 PURPOSE

### 1.1 PURPOSE

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

### 1.2 BACKGROUND

Within the West Virginia Department of Health and Human Resources (WVDHHR), Bureau for Public Health, the Office of Maternal, Child and Family Health (OMCFH) offers preventive health care and screening services through a community-based network of health care providers throughout the State. The Family Planning Program (FPP) provides comprehensive reproductive health care, medical services, counseling and education, contraceptive methods, and laboratory services, including cytology screening. Family Planning Program services are offered through a statewide network of 150 participating provider agencies

The Breast and Cervical Cancer Screening Program (BCCSP) provides early detection, screening, and referral services for breast and cervical cancers which include a pelvic examination, Pap test collection, clinical breast examination, patient education and referrals for mammography and other appropriate diagnostic and treatment services. These services are offered through a network of 185 participating provider agencies, most of which are also providers of the Family Planning Program

## Part 2 CONTRACTUAL SERVICES

### 2.1 REQUIRED SERVICES

The vendor will provide cytology services for approximately 60,000 Pap tests per year to include: specimen accession, specimen processing, hrHPV testing, provision of cytotechnologists, pathologist(s) coverage, specimen evaluation, record keeping, and quality assurance activities and reports.

#### Specimen Processing, Evaluation, and Reporting:

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

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

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- B. The vendor will require that the following minimum information be submitted with the specimen:
1. Clinic code number
  2. Patient social security number
  3. Patient name
  4. Clinic visit date (date specimen collected)
  5. Date of Birth
  7. Specimen type
  8. Date of previous Pap test
  9. Class of previous Pap test
  10. Name and address of program provider
- C. The vendor will examine, interpret, and report results on all Pap tests submitted by the FPP and BCCSP Program providers not to exceed ten (10) calendar days from the date the specimens are received by the vendor. For specimens requiring HPV testing, the vendor will examine, interpret and report results not to exceed ten (10) calendar days from the date the specimens are received by the vendor
- D. The vendor will be responsible for strictly adhering to reporting specimen test results, using the 2001 Bethesda System, including specimen adequacy, general categorization, interpretation and results. Results will be reported to the ordering physician/clinic at the address supplied by the Program provider.
- E. The vendor assumes all responsibility and liability for reading and processing of all Pap tests
- F. The vendor must have written criteria for rejection of specimens and for categorizing specimens as unsatisfactory
- G. The vendor must retain negative and unsatisfactory slides for five (5) years and positive slides for twenty (20) years

Data Requirements:

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

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

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- I The vendor agrees to supply the FPP, BCCSP and all participating Program providers with on-line access to test results via a website, including HPV results. To the extent consistent with applicable laws and regulations, the parties hereto shall maintain patient test records in confidence and comply with privacy, patient access and confidentiality provisions
- J The vendor must respond to all requests for statistical information or data within five (5) working days

Quality Assurance:

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

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

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- R. The vendor must have documentation including acknowledgment of receipt, when slides from the programs are loaned to special programs such as the College of American Pathologists Interlaboratory Comparison Program in Cervical Vaginal Cytology.
- S. The vendor must show documentation of a maintenance schedule for equipment and microscopes and implement said schedule
- T. The vendor must show documentation of and perform at least an annual review of all procedures in the cytology section by current laboratory director or designee
- U. The vendor must show documentation for continuing education for the staff cytotechnologist(s).
- V. Vendor must have been in business and maintained a business license to perform cytology services for a minimum of five (5) years.

## 2.2 ADMINISTRATIVE AND OPERATIONAL REQUIREMENTS

1. The vendor shall designate a project administrator. The vendor's project administrator shall report to the FPP and BCCSP program directors regarding all matters related to cytology services.
2. The vendor must meet all requirements within the specification. By signing the bid, the vendor is agreeing to meet these requirements.
3. The vendor shall comply with all applicable provisions of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, 110 Stat. 1936 (HIPAA) and regulations promulgated thereunder (HIPAA Regulations), if applicable

## PART 3 GENERAL TERMS AND CONDITIONS

### 3.1 REJECTION OF QUOTATION/BIDS

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

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

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**3.2 SUBCONTRACTS PROHIBITED**

The successful vendor will be solely responsible for all work performed under the contract. The vendor shall not enter into written or oral subcontracts for performance of work under the contract without written permission of the agency.

**3.3 COMPLIANCE WITH LAW AND REGULATIONS**

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

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

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

**3.4 RECORD RETENTION AND CONFIDENTIALITY**

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

**3.5 TERMINATION OF THE CONTRACT**

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

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

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

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

**3.6 INVOICE AND PAYMENTS**

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

ONCO DIAGNOSTIC SERVICES, INC.  
10401 OLD GEORGETOWN RD, # 408  
BETHESDA, MD 20814

COST SHEET FOR MCH10037

Item #	Apprx. Annual Usage QUANTITY	DESCRIPTION	UNIT PRICE	TOTAL COST
1	60,000	CYTOLOGY SERVICES-LIQUID BASED PAP TEST	\$14.50	\$ 870,000
2	2,800	HPV/DNA TESTING (HIGH-RISK ONLY)	\$35.00	98,000
3	2,600	CYTOLOGY SERVICES LIQUID BASED PAP TEST (PRIVATE PAY BY PROGRAM ELIGIBLE CLIENT)	\$14.50	37,700
		TOTAL COST		\$1,005,700

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

*Tracy Reynolds*  
President

RFQ No MC H10037STATE OF WEST VIRGINIA  
Purchasing Division**PURCHASING AFFIDAVIT****VENDOR OWING A DEBT TO THE STATE:**

*West Virginia Code* §5A-3-10a provides that: No contract or renewal of any contract may be awarded by the state or any of its political subdivisions to any vendor or prospective vendor when the vendor or prospective vendor or a related party to the vendor or prospective vendor is a debtor and the debt owed is an amount greater than one thousand dollars in the aggregate

**PUBLIC IMPROVEMENT CONTRACTS & DRUG-FREE WORKPLACE ACT:**

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

**ANTITRUST:**

In submitting a bid to any agency for the state of West Virginia, the bidder offers and agrees that if the bid is accepted the bidder will convey, sell, assign or transfer to the state of West Virginia all rights, title and interest in and to all causes of action it may now or hereafter acquire under the antitrust laws of the United States and the state of West Virginia for price fixing and/or unreasonable restraints of trade relating to the particular commodities or services purchased or acquired by the state of West Virginia. Such assignment shall be made and become effective at the time the purchasing agency tenders the initial payment to the bidder.

I certify that this bid is made without prior understanding, agreement, or connection with any corporation, firm, limited liability company, partnership or person or entity submitting a bid for the same materials, supplies, equipment or services and is in all respects fair and without collusion or fraud. I further certify that I am authorized to sign the certification on behalf of the bidder on this bid.

**LICENSING:**

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

**CONFIDENTIALITY:**

The vendor agrees that he or she will not disclose to anyone, directly or indirectly, any such personally identifiable information or other confidential information gained from the agency, unless the individual who is the subject of the information consents to the disclosure in writing or the disclosure is made pursuant to the agency's policies, procedures and rules. Vendor further agrees to comply with the Confidentiality Policies and Information Security Accountability Requirements, set forth in <http://www.state.wv.us/admin/purchase/privacy/noticeConfidentiality.pdf>

Under penalty of law for false swearing (*West Virginia Code* §61-5-3), it is hereby certified that the vendor affirms and acknowledges the information in this affidavit and is in compliance with the requirements as stated.

Vendor's Name: Onco Diagnostic Services Inc.  
 Authorized Signature: [Signature] Date: 10/28/09

Rev 09/08

State of West Virginia

N/A

16

VENDOR PREFERENCE CERTIFICATE

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

N/A

- 1. Application is made for 2.5% resident vendor preference for the reason checked:
  - Bidder is an individual resident vendor and has resided continuously in West Virginia for four (4) years immediately preceding the date of this certification; or,
  - Bidder is a partnership, association or corporation resident vendor and has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; or 80% of the ownership interest of Bidder is held by another individual, partnership, association or corporation resident vendor who has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; or,
  - Bidder is a nonresident vendor which has an affiliate or subsidiary which employs a minimum of one hundred state residents and which has maintained its headquarters or principal place of business within West Virginia continuously for the four (4) years immediately preceding the date of this certification; or,
- 2. Application is made for 2.5% resident vendor preference for the reason checked:
  - Bidder is a resident vendor who certifies that, during the life of the contract, on average at least 75% of the employees working on the project being bid are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; or,
- 3. Application is made for 2.5% resident vendor preference for the reason checked:
  - Bidder is a nonresident vendor employing a minimum of one hundred state residents or is a nonresident vendor with an affiliate or subsidiary which maintains its headquarters or principal place of business within West Virginia employing a minimum of one hundred state residents who certifies that, during the life of the contract, on average at least 75% of the employees or Bidder's affiliate's or subsidiary's employees are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; or,
- 4. Application is made for 5% resident vendor preference for the reason checked:
  - Bidder meets either the requirement of both subdivisions (1) and (2) or subdivision (1) and (3) as stated above; or,
- 5. Application is made for 3.5% resident vendor preference who is a veteran for the reason checked:
  - Bidder is an individual resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard and has resided in West Virginia continuously for the four years immediately preceding the date on which the bid is submitted; or,
- 6. Application is made for 3.5% resident vendor preference who is a veteran for the reason checked:
  - Bidder is a resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard, if, for purposes of producing or distributing the commodities or completing the project which is the subject of the vendor's bid and continuously over the entire term of the project, on average at least seventy-five percent of the vendor's employees are residents of West Virginia who have resided in the state continuously for the two immediately preceding years.

Bidder understands if the Secretary of Revenue determines that a Bidder receiving preference has failed to continue to meet the requirements for such preference, the Secretary may order the Director of Purchasing to: (a) reject the bid; or (b) assess a penalty against such Bidder in an amount not to exceed 5% of the bid amount and that such penalty will be paid to the contracting agency or deducted from any unpaid balance on the contract or purchase order.

By submission of this certificate, Bidder agrees to disclose any reasonably requested information to the Purchasing Division and authorizes the Department of Revenue to disclose to the Director of Purchasing appropriate information verifying that Bidder has paid the required business taxes, provided that such information does not contain the amounts of taxes paid nor any other information deemed by the Tax Commissioner to be confidential.

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

Bidder: Cisco Diagnostic Services, Inc. Signed: Nancy Loggins  
 Date: 10/28/09 Title: President

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

N/A



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

### Request for Quotation

RFQ NUMBER  
MCH10037

PAGE  
1

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

RFQ COPY

TYPE NAME/ADDRESS HERE

ONCO DIAGNOSTIC SERVICES, INC.  
10401 OLD GEORGETOWN RD, # 408  
BETHESDA, MD 20814

RFQ COPY

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

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

LINE	QUANTITY	U/P	UNIT PRICE	AMOUNT
<p>ADDENDUM NO. 1</p> <p>1. QUESTIONS AND ANSWERS ARE ATTACHED.</p> <p>2. ADDENDUM ACKNOWLEDGEMENT IS ATTACHED. THIS DOCUMENT SHOULD BE SIGNED AND RETURNED WITH YOUR BID. FAILURE TO SIGN AND RETURN MAY RESULT IN DISQUALIFICATION OF YOUR BID.</p> <p>EXHIBIT 10</p> <p>REQUISITION NO.: MCH10037</p> <p>ADDENDUM ACKNOWLEDGEMENT</p> <p>I HEREBY ACKNOWLEDGE RECEIPT OF THE FOLLOWING CHECKED ADDENDUM(S) AND HAVE MADE THE NECESSARY REVISIONS TO M PROPOSAL, PLANS AND/OR SPECIFICATION, ETC.</p> <p>ADDENDUM NO.'S:</p> <p>NO. 1 ..... ✓</p> <p>NO. 2 ..... ✓</p> <p>NO. 3 .....</p> <p>NO. 4 .....</p> <p>NO. 5 .....</p> <p>I UNDERSTAND THAT FAILURE TO CONFIRM THE RECEIPT OF THE ADDENDUM(S) MAY BE CAUSE FOR REJECTION OF BIDS.</p> <p>VENDOR MUST CLEARLY UNDERSTAND THAT ANY VERBAL</p>				

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE <i>Nancy Rogan</i>	TELEPHONE 301 530 5511	DATE 10/28/09
TITLE <i>President</i>	FBN 562372362	ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO RFQ, 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

**Request for  
 Quotation**

RFQ NUMBER  
**MCH10037**

PAGE  
**2**

ADDRESS/CORRESPONDENCE/ATTENTION OF  
**ROBERTA WAGNER  
 304-558-0067**

RFQ COPY

TYPE NAME/ADDRESS HERE

Onco Diagnostic Services Inc.  
 10401 Old Georgetown Road  
 Suite 408  
 Bethesda MD 20814

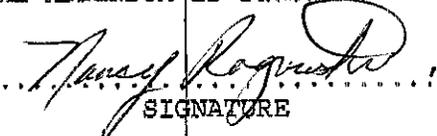
RFQ COPY

HEALTH AND HUMAN RESOURCES  
 BPH - MCH WAREHOUSE

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

DATE PRINTED	TERMS OF SALE	SHIP VIA	FOB	FREIGHT TERMS
10/08/2009				

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

LINE	QUANTITY	UOP	CAT NO	ITEM NUMBER	UNIT PRICE	AMOUNT
<p>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.</p> <p style="text-align: right;">                       ..... President                      SIGNATURE                      Onco Diagnostic Services Inc.                      COMPANY                      .October 28, 2009.....                      DATE                 </p> <p>NOTE: THIS ADDENDUM ACKNOWLEDGEMENT SHOULD BE SUBMITTED WITH THE BID.</p> <p>REV. 09/21/2009</p> <p style="text-align: center;">END OF ADDENDUM NO. 1</p>						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS		
SIGNATURE <i>Nancy Rogstad, President</i>	TELEPHONE 301-530-5511	DATE 10/28/09
TITLE President	FEBN 562372362	ADDRESS CHANGES TO BE NOTED ABOVE

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

WV-39 (Rev. 01/01/07)

**STATE OF WEST VIRGINIA  
PURCHASE CONTINUATION SHEET**

Page _____ of _____ Pages		Requisition/P.O. No.: MCH10037
File:	Acct. No.:	
Spending Unit: WVDHHR/OMCFH/FPP		

Vendor: \_\_\_\_\_ P.O. Date: \_\_\_\_\_

Item No.	Quantity	Description	Unit Price	Amount
1.		<p><b>QUESTION:</b></p> <p>ON PAGE 6 OF THE RFQ MCH10037 LISTS 2,800 TEST FOR HPV/DNA TESTING AND 2,600 LIQUID BASED PAP TESTS AND BUT THE COST SHEET FOR MCH10037 LIST BOTH OF THOSE AND ALSO LIST 60,000 ADDITIONAL LIQUID BASED PAPS. COULD YOU CLARIFY THE NUMBER OF TESTS IN THIS CONTRACT AND IF THE 60,000 TESTS ARE OF THE CONTRACT WHERE DO WE ENTER A PRICE ON THOSE IN THE RFQ.</p> <p><b>ANSWER:</b></p> <p>60,000 PAP TEST ARE FOR BCCSP AND FPP CLIENTS. OUT OF THOSE TESTS, WE ESTIMATE 2,800 WILL ALSO NEED HPV TEST. WE ALSO ESTIMATE 2,600 PROGRAM ELIGIBLE CLIENTS WILL NOT BE ELIGIBLE FOR BCCSP AND FPP TO PAY FOR A TEST (TEST ARE TO BE COMPLETED EVERY OTHER YEAR, BUT SOME CLIENTS FEEL MORE COMFORTABLE HAVING A TEST YEARLY) AND WILL ELECT TO PAY FOR A TEST OUT OF POCKET. CURRENT CONTRACT ALLOWS CLIENTS TO PAY FOR THE LIQUID-BASED PAP TESTS AT THE SAME RATE AS THE PROGRAM PAYS.</p>		
2		<p><b>QUESTION:</b></p> <p>WHAT IS THE RATIONALE FOR PROHIBITING SUB-CONTRACTING?</p> <p><b>ANSWER:</b></p> <p>THE SUCCESSFUL VENDOR WILL BE SOLELY RESPONSIBLE FOR ALL WORK PERFORMED ON THE CONTACT AS WE WOULD HAVE NO KNOWLEDGE OF THE SUBCONTRACTORS EXPERIENCE AND/OR QUALIFICATIONS AND IF FDA APPROVED TO PERFORM THESE SERVICES.</p>		
3.		<p><b>QUESTION:</b></p> <p>WHAT ARE THE REQUIREMENTS FOR A VENDOR TO ACQUIRE WRITTEN PERMISSION TO USE SUB-CONTRACTORS?</p> <p><b>ANSWER:</b></p> <p>SELECTED VENDOR MUST REQUEST IN WRITING AND APPROVAL MUST BE GIVEN BY WEST VIRGINIA DEPARTMENT OF ADMINISTRATION PURCHASING DIVISION BEFORE ANY CHANGES CAN BE MADE TO THE AWARDED CONTRACT.</p>		

WV-38 (Rev. 01/01/07)

STATE OF WEST VIRGINIA  
PURCHASE CONTINUATION SHEET

Page _____ of _____ Pages	Requisition/P.O. No.: MCH10037
File:	Acct. No.:
Spending Unit: WVDHHR/OMCFH/FPP	

Vendor: \_\_\_\_\_ P.O. Date: \_\_\_\_\_

Item No.	Quantity	Description	Unit Price	Amount
4.		<p>QUESTION:</p> <p>THE RFQ AT PART 2.1 PARA. N REQUIRES PATHOLOGIST AS DIRECTOR (TECHNICAL SUPERVISOR). DO YOU INTEND TO CONSIDER THE PATHOLOGIST'S EXPERIENCE AND QUALIFICATIONS BEYOND THIS MINIMUM? IF SO, HOW, IF NOT WHY NOT?</p> <p>ANSWER:</p> <p>CLIA-88 QUALIFIED PATHOLOGIST IS THE REQUIREMENT OF FPP AND BCCSP FEDERAL AGENCIES.</p>		
5.		<p>QUESTION:</p> <p>THE RFQ AT PART 2.1 PARA V REQUIRES ONLY THAT THE VENDOR MUST HAVE BEEN IN BUSINESS TO PERFORM CYTOLOGY SERVICES FOR A MINIMUM OF FIVE YEARS. DO YOU INTEND TO CONSIDER THE PAST PERFORMANCE RECORD OF A VENDOR WITH RESPECT TO CYTOLOGY SERVICES DURING THAT PERIOD? IF SO, WHAT EVALUATION CRITERIA WILL BE EMPLOYED, AND HOW WILL THEY BE APPLIED UNDER THIS RFQ? IF NOT, WHY NOT?</p> <p>ANSWER:</p> <p>THIS REQUIREMENT IS TO ENSURE THE BUSINESS IS AN ESTABLISHED CYTOLOGY VENDOR.</p>		
6.		<p>QUESTION:</p> <p>THE RFQ DOES NOT REQUIRE FDA APPROVED HPV TESTING. HOW DO YOU INTEND TO EVALUATE QUALITY ASSURANCE FOR A NON-FDA APPROVED METHODOLOGY?</p> <p>ANSWER:</p> <p>ALL TESTING CONDUCTED BY FPP, BCCSP OR IT'S VENDORS MUST BE FDA APPROVED.</p>		

MCH10037 Addendum #1

Response to vendor questions:

**7. Question:** My question is in regard to amendment V under quality assurance. This amendment states that the vendor must have been in business and maintained a business license to perform cytology for five years; with that in lies my inquiry. My company, West Virginia Laboratory Services (WVLS), recently purchased and took over operations for American Cytopathology Services (ACS). ACS has been practicing cytology since 1997 and has worked with the state in years past conducting cytology until 2006. WVLS operates at the same location as ACS and still maintains the state of the art equipment and operations standards as ACS. WVLS also maintains all the documentation of ACS and the work that it had performed in the past with both the state and private practices. In June of this year (2009) ACS was taken over by a group of new owners and a decision was made to change the name of the company. Recently, my company applied for a vendor number under WVLS even though ACS's is still active until February. Here in lies my question. Due to the fact that American Cytopathology Services now operates under West Virginia Laboratory Services, and West Virginia Laboratory Services is the new name of the business, will this affect the chances of my company being considered for the contract due to amendment V? The company has been operational for over twelve years and I hope that a recent change in name, which means a new business licenses, will not dismiss my company from putting a bid on this upcoming contract.

**Response:** The specifications state the vendor must have been in business and maintained a business license to perform cytology for a minimum of five years. The vendor placing the bid, must have been in business and maintained a business license to perform cytology for five years. If WVLS does not show evidence of a business license that identifies WVLS as having the license for the minimum of five years, they will not be considered as having met the specification.



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

### Request for Quotation

RFQ NUMBER  
**MCH10037**

PAGE  
**1**

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

RFQ COPY  
TYPE NAME/ADDRESS HERE

ONCO DIAGNOSTIC SERVICES, INC.  
10401 OLD GEORGETOWN RD, # 408  
BETHESDA, MD 20814

HEALTH AND HUMAN RESOURCES  
BPH - MCH WAREHOUSE

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

DATE PRINTED <b>10/15/2009</b>	TERMS OF SALE	SHIP VIA	FOB	FREIGHT TERMS
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BID OPENING DATE: <b>10/30/2009</b>	BID OPENING TIME <b>01:30PM</b>
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LINE	QUANTITY	UNIT	CA NO	ITEM NUMBER	UNIT PRICE	AMOUNT
<p>ADDENDUM NO. 2</p> <p>1. TO MOVE BID OPENING DATE FROM 10/22/9 TO 10/30/9.</p> <p>2. ADDENDUM ACKNOWLEDGEMENT IS ATTACHED. THIS DOCUMENT SHOULD BE SIGNED AND RETURNED WITH YOUR BID. FAILURE TO SIGN AND RETURN MAY RESULT IN DISQUALIFICATION OF YOUR BID.</p> <p>EXHIBIT 10</p> <p>REQUISITION NO.: MCH10037</p> <p>ADDENDUM ACKNOWLEDGEMENT</p> <p>I HEREBY ACKNOWLEDGE RECEIPT OF THE FOLLOWING CHECKED ADDENDUM(S) AND HAVE MADE THE NECESSARY REVISIONS TO MY PROPOSAL, PLANS AND/OR SPECIFICATION, ETC.</p> <p>ADDENDUM NO.'S:</p> <p>NO. 1 ..... ✓</p> <p>NO. 2 ..... ✓</p> <p>NO. 3 .....</p> <p>NO. 4 .....</p> <p>NO. 5 .....</p> <p>I UNDERSTAND THAT FAILURE TO CONFIRM THE RECEIPT OF THE ADDENDUM(S) MAY BE CAUSE FOR REJECTION OF BIDS.</p>						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS		
SIGNATURE <i>Nancy Rogowski</i>	TELEPHONE <b>301 530 5511</b>	DATE <b>10/28/09</b>
TITLE <i>President</i>	FAX <b>56 237 2362</b>	ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO RFQ, 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

### Request for Quotation

RFQ NUMBER  
MCH10037

PAGE  
2

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

RFQ COPY

TYPE NAME/ADDRESS HERE

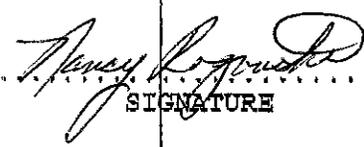
ONCO DIAGNOSTIC SERVICES, INC  
10401 OLD GEORGETOWN RD, # 408  
BETHESDA, MD 20814

HEALTH AND HUMAN RESOURCES  
BPH - MCH WAREHOUSE

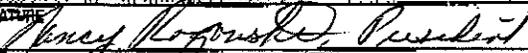
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25301 304-558-3417

DATE PRINTED 10/15/2009	TERMS OF SALE	SHIP VIA	FOB	FREIGHT TERMS
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BID OPENING DATE: 10/30/2009 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT NO	ITEM NUMBER	UNIT PRICE	AMOUNT
<p>VENDOR MUST CLEARLY 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.</p> <p style="text-align: right;">             President            SIGNATURE            Onco Diagnostic Services Inc.            COMPANY            October 28, 2009            DATE         </p> <p>NOTE: THIS ADDENDUM ACKNOWLEDGEMENT SHOULD BE SUBMITTED WITH THE BID.</p> <p>REV. 09/21/2009</p> <p style="text-align: center;">END OF ADDENDUM NO. 2</p>						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE 	TELEPHONE 301-530-5511	DATE 10/28/09
TITLE President	FEN 562372362	ADDRESS CHANGES TO BE NOTED ABOVE

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

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

LABORATORY NAME AND ADDRESS  
  
ONCO DIAGNOSTIC SVCS INC  
10401 OLD GEORGETOWN RD #408  
BETHESDA, MD 20814

CLIA ID NUMBER  
21D0711736

EFFECTIVE DATE  
08/11/2009

LABORATORY DIRECTOR  
MICHAEL LEHMAN MD

EXPIRATION DATE  
08/10/2011

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

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



*Judith A. Yost*

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

47 cert2\_071809

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

<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
HISTOPATHOLOGY (610)	08/11/1993
ORAL PATHOLOGY (620)	11/06/2008
CYTOLOGY (630)	08/11/1993

<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
---------------------------------	-----------------------



FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT [WWW.CMS.HHS.GOV/CLIA](http://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.



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: 560      EFFECTIVE PERIOD: 07/01/2008 - 06/30/2010

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

**ONCO DIAGNOSTIC SVCS INC  
10401 OLD GEORGETOWN RD #206  
BETHESDA, MD 20814**

**Director: MICHAEL LEHMAN MD  
Owner: ONCO DIAGNOSTIC SERVICES, INC.**

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

**Microbiology:**

Bacteriology Test, Mycology Test, Virology Test

**Pathology:**

Cytology - GYN, Cytology - Non-GYN, Dermatopathology, Diagnosis/Interpretation, Fine Needle Aspirations,  
Histopathology, Oral Pathology, Prepare, process and stain

**CONTROL: 34712**

Director

*Falsification of a license shall subject the perpetrator to criminal prosecution and the imposition of civil fines*

# ONCO DIAGNOSTIC SERVICES, INC.

Cytopathology Laboratory

10401 Old Georgetown Road, Suite 408

Bethesda, MD 20814 (301) 530-5511 \* Fax (301) 564-5748

Accession No

## PATIENT INFORMATION (PLEASE PRINT)

Patient Last Name: \_\_\_\_\_ Patient First Name: \_\_\_\_\_ PID: \_\_\_\_\_  
Gender:  Male  Female DOB: \_\_\_\_ / \_\_\_\_ / \_\_\_\_ AGE: \_\_\_\_\_  
Patient Street Address: \_\_\_\_\_  
City / State / Zip \_\_\_\_\_

## BILLING INFORMATION

Bill To:  Client  Patient  Insurance  Physician Signature: \_\_\_\_\_ Diagnosis \_\_\_\_\_ ICD-9 Code \_\_\_\_\_  
NPI: \_\_\_\_\_  
Insurance Company: \_\_\_\_\_  
Ins. Address \_\_\_\_\_  
ID#: \_\_\_\_\_ GROUP#: \_\_\_\_\_

## CLINICAL HISTORY

PREVIOUS PAP SMEAR		
Date: _____	LMP Date _____	Menopausal <input type="checkbox"/>
Result: _____	Amenorrhea <input type="checkbox"/>	Post Menopausal <input type="checkbox"/>
	Abnormal Bleeding <input type="checkbox"/>	Post Menopausal Bleeding <input type="checkbox"/>
	Hormone Replacement Therapy <input type="checkbox"/>	Contraceptives _____
	Hysterectomy - Total <input type="checkbox"/>	IUD <input type="checkbox"/>
	Hysterectomy - Partial <input type="checkbox"/>	Medications _____
	Pregnant <input type="checkbox"/>	Radiation / Chemotherapy <input type="checkbox"/>
	Post Partum <input type="checkbox"/>	Other _____

## SPECIMEN INFORMATION

CYTOLOGY		TISSUE PATHOLOGY, GROSS & MIC	
COLLECTION DATE: ____ / ____ / ____		COLLECTION DATE: ____ / ____ / ____	
Source <input type="checkbox"/> CERVICAL <input type="checkbox"/> ENDOMETRIAL		Source: _____	
<input type="checkbox"/> VAGINAL <input type="checkbox"/> OTHER		a. _____ d. _____	
<input type="checkbox"/> ENDOCERVICAL		b. _____ e. _____	
<input type="checkbox"/> THIN PREP PAP TEST ONLY		c. _____ f. _____	
<input type="checkbox"/> THIN PREP +HPV Screening (Regardless of diagnosis)			
<input type="checkbox"/> THIN PREP +HPV+CHLAMYDIA+GONORRHEA			
<input type="checkbox"/> THIN PREP (Reflex to HPV when ASC-US)			
<input type="checkbox"/> THIN PREP +CHLAMYDIA / GONORRHEA			
<input type="checkbox"/> PAP SMEAR (Conventional Smear)			
<input type="checkbox"/> CHLAMYDIA / GONORRHEA (Amplified)			
<input type="checkbox"/> OTHER _____			
<input type="checkbox"/> OTHER _____			

CLINICAL IMPRESSION / INFORMATION:

All ThinPrep Pap tests are Imaged unless directed otherwise.

## FOR LABORATORY USE ONLY

CLASS INFLAM ORG BACTERIA COMMENT RECOMMEND SCREENER

MAT INDEX

## **Onco Diagnostic Services, Inc.**

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**10401 Old Georgetown Road, Suite 408  
Bethesda, Maryland 20814  
Telephone (301) 530-5511  
Fax No. (301)-564-5748**

### **Reporting of Test Results**

- A. Within Normal Limits
- B. Benign Cellular Changes
  - 1. Infection
  - 2. Reactive Cellular Changes Associated with:
- C. Epithelial Cell Abnormalities
  - 1. Atypical Squamous Cells of Undetermined Significance.
  - 2. Low-grade Squamous Intraepithelial Lesion (encompassing Human Papilloma Virus (HPV), mild dysplasia, cervical intraepithelial neoplasia, CIN I).
  - 3. High-grade Squamous Intraepithelial Lesion (encompassing moderate dysplasia, severe dysplasia, and carcinoma in situ CIN II and CIN III).
  - 4. Squamous Cell Carcinoma.
- D. Glandular Cell
  - 1. Endometrial Cells in a Postmenopausal Woman or out of phase in a Premenopausal Woman.
  - 2. Atypical Glandular Cells of Undetermined Significance.
- E. Adenocarcinoma
- F. Unsatisfactory for Cytologic Evaluation

## **Onco Diagnostic Services, Inc.**

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**10401 Old Georgetown Road, Suite 408  
Bethesda, Maryland 20814  
Telephone (301) 530-5511  
Fax No. (301) 564-5748**

### **MINIMUM SQUAMOUS CELLULARITY CRITERIA**

#### **LIQUID-BASED PREPARATIONS**

An adequate liquid-based prepared pap smear should have an estimated minimum of at least 5000 well-visualized and well-preserved squamous cells. Some have advocated that LBPs with 5000 to 20,000 cells are of borderline or low squamous cellularity. In specimens with an apparent borderline or low squamous cellularity, an estimation of total cellularity can be obtained by performing representative field cell counts. A minimum of 10 microscopic fields, usually at 40X, should be assessed along a diameter that includes the center of the preparation and an average number of cells per field estimated. When there are holes or empty areas on the preparation, the percentage of the hypocellular areas should be estimated, and the fields counted should reflect this proportion.

LBP's should have a minimum of at least 10-12 cells per field observed to be considered adequate for evaluation.

## **Onco Diagnostic Services, Inc.**

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**10401 Old Georgetown Road, Suite 408  
Bethesda, Maryland 20814  
Telephone (301) 530-5511  
Fax No. (301) 564-5748**

### **ENDOCERVICAL/TRANSFORMATION ZONE COMPONENT**

For both conventional smears and liquid-based pap smears, an adequate transformation zone component requires at least 10 well-preserved endocervical or squamous metaplastic cells, singly or in clusters.

The presence or absence of a transformation zone component is reported in the specimen adequacy section unless the woman has had a total hysterectomy. If the specimen shows a high- grade lesion or cancer, it is not necessary to report presence/absence of a transformation component.

Degenerated cells in mucus and parabasal type cells should not be counted in assessing transformation zone sampling. It may be difficult to distinguish parabasal-type cells from squamous metaplastic cells in specimens showing atrophy due to a variety of hormonal changes including menopause, postpartum changes, and progestational agents. In such cases, the laboratory may elect to make a comment about the difficulty of assessing the transformation zone component.

## **Onco Diagnostic Services, Inc.**

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**10401 Old Georgetown Road, Suite 408  
Bethesda, Maryland 20814  
Telephone (301) 530-5511  
Fax No. (301)-564-5748**

### **Requirements for Unsatisfactory Specimens**

- A. Any smear that has abnormal or atypical cells present is never signed out as unsatisfactory.
- B. Scant squamous cells: less than 10% of well-preserved, well-visualize squamous cells over the slide surface.
- C. Note: liquid based – fewer than 5,000 cells per slide.
- D. Poor fixation or preservation (obscuring of the epithelial cells by).
- E. Thick smear -- 75% or more too thick for interpretation (obscuring epithelial cells by).
- F. Obscuring inflammation, blood, bacteria or mucus -- 75% or more of smear obscured. Note: use scanning power to determine extent of obscuring factor.
- G. Presence of foreign material – 75% or more obscured.

## **Onco Diagnostic Services, Inc.**

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**10401 Old Georgetown Road, Suite 408  
Bethesda, Maryland 20814  
Telephone (301) 530-5511  
Fax No. (301) 564-5748**

### **CYTOLOGY REJECTION POLICY**

Specimens with any of the following problems will not be processed unless the problem can be resolved.

1. Slide/specimen without accompanying requisition form.
2. Slide/container/ requisition form lacking appropriate patient identifiers.
3. Slide/container/requisition with discrepant information.
4. Slide broken beyond repair.
5. Specimens deemed too old for reliable results.
6. Specimens received in inappropriate fixative.
7. Specimens received in expired fixative.

When appropriate, specimens are returned to the client for corrective action. They are then sent back to the laboratory for processing, if acceptable.

## **Onco Diagnostic Services, Inc.**

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**10401 Old Georgetown Road, Suite 408  
Bethesda, Maryland 20814  
Telephone (301) 530-5511  
Fax No. (301) 564-5748**

### **Quality Control**

As part of our Comprehensive Quality Assurance Program, a 10-15% rescreen of gynecological specimens from each primary screener, designated as within normal limits from randomly selected cases and those from "high-risk" individuals (based on available patient information) are made by a Supervisory-Qualified Cytotechnologist or Pathologist prior to reporting final results. Previously negative cytological and relevant histologic materials are reviewed to correlate results whenever current material shows a significant abnormality that could have been overlooked in the prior specimen, thus the five year review.

# Onco Diagnostic Services, Inc.

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10401 Old Georgetown Road, Suite 408  
Bethesda, Maryland 20814  
Telephone (301) 530-5511

Fax No. (301)-564-5748

November 10, 2009

Department of Administration  
Purchasing Division  
Building 15  
2019 Washington Street, East  
Charleston, WV 25305-0130

Subject: RFQ# MCH10037

Dear Sir:

Onco Diagnostic Services Inc. has enclosed a revised Cost Sheet for MCH10037 dated November 10, 2009 and signed copies of Addendum No. 3 and No. 4 (changing Bid Date to November 12, 2009 and revised cost information of current contract). Please attach this information with the original package Federal Express delivered on October 29, 2009.

Thank you for the opportunity to participate with RFQ# MCH 10037 in providing Cytology Services for the Office of Maternal, Child & Family Health, Family Planning Program and Breast & Cervical Cancer Screening Program for the State of West Virginia. If you have any questions, please contact me at the above telephone number.

Sincerely,



Nancy Rogowski  
President

Enclosures

aa

Onco Diagnostic Services, Inc.  
 10401 Old Georgetown Rd, #408  
 Bethesda MD 20814

**COST SHEET FOR MCH10037** FINAL 11/10/09

<u>Item #</u>	<u>Apprx. Annual Usage</u>	<u>DESCRIPTION</u>	<u>UNIT PRICE</u>	<u>TOTAL COST</u>
	<u>QUANTITY</u>			
1	60,000	THIN PREP LIQUID MEDIUM/MONOLAYER OR EQUAL	\$14.00	\$840,000
2	2,800	HPV/DNA TESTING (HIGH-RISK ONLY) THIN PREP LIQUID MEDIUM/MONOLAYER OR EQUAL	\$35.00	\$98,000
3	2,600	THIN PREP LIQUID MEDIUM/MONOLAYER OR EQUAL (PRIVATE PAY BY PROGRAM ELIGIBLE CLIENT)	\$14.00	\$36,400
		<b>TOTAL COST</b>		<b>\$974,400</b>

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



Nancy Rogowski, President 11/10/09, FEIN 56-2372362 Telephone # 301/530-5511



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

# Request for Quotation

RFQ NUMBER  
 MCH10037

PAGE  
 1

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

RFQ COPY

TYPE NAME/ADDRESS HERE

Onco Diagnostic Services Inc.  
 10401 Old Georgetown Rd #408  
 Bethesda MD 20814

VENDOR

SHIP TO

HEALTH AND HUMAN RESOURCES  
 BPH - MCH WAREHOUSE

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

DATE PRINTED	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
10/28/2009				
BID OPENING DATE: 11/12/2009		BID OPENING TIME 01:30PM		

LINE	QUANTITY	UOP	CAT NO	ITEM NUMBER	UNIT PRICE	AMOUNT
ADDENDUM NO. 3						
1. QUESTIONS AND ANSWERS ARE ATTACHED. REVISIONS TO SPECIFICATIONS ARE ATTACHED. 2. TO MOVE THE BID OPENING DATE FROM 10/30/2009 TO 11/12/2009. 3. ADDENDUM ACKNOWLEDGMENT IS ATTACHED. THIS DOCUMENT SHOULD BE SIGNED AND RETURNED WITH YOUR BID. FAILURE TO SIGN AND RETURN MAY RESULT IN DISQUALIFICATION OF YOUR BID.						
EXHIBIT 10						
REQUISITION NO. : MCH10037						
ADDENDUM ACKNOWLEDGEMENT						
I HEREBY ACKNOWLEDGE RECEIPT OF THE FOLLOWING CHECKED ADDENDUM(S) AND HAVE MADE THE NECESSARY REVISIONS TO MY PROPOSAL, PLANS AND/OR SPECIFICATION, ETC.						
ADDENDUM NO. 'S:						
NO. 1			X			
NO. 2			X			
NO. 3			X			
NO. 4						
NO. 5						
I UNDERSTAND THAT FAILURE TO CONFIRM THE RECEIPT OF THE						

RECEIVED  
 2009 OCT 29 A 10:14  
 PURCHASING DIVISION  
 STATE OF WV

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE <i>Amy Loggins</i>	TELEPHONE 301-530-5511	DATE 11/10/09
TITLE President	FERN 56-2372362	ADDRESS CHANGES TO BE NOTED ABOVE

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

**GENERAL TERMS & CONDITIONS**  
**REQUEST FOR QUOTATION (RFQ) AND REQUEST FOR PROPOSAL (RFP)**

1. Awards will be made in the best interest of the State of West Virginia
2. The State may accept or reject in part, or in whole, any bid.
3. All quotations are governed by the *West Virginia Code* and the *Legislative Rules* of the Purchasing Division
4. Prior to any award, the apparent successful vendor must be properly registered with the Purchasing Division and have paid the required \$125 fee.
5. All services performed or goods delivered under State Purchase Order/Contracts are to be continued for the term of the Purchase Order/Contracts, contingent upon funds being appropriated by the Legislature or otherwise being made available. In the event funds are not appropriated or otherwise available for these services or goods, this Purchase Order/Contract becomes void and of no effect after June 30.
6. Payment may only be made after the delivery and acceptance of goods or services
7. Interest may be paid for late payment in accordance with the *West Virginia Code*
8. Vendor preference will be granted upon written request in accordance with the *West Virginia Code*.
9. The State of West Virginia is exempt from federal and state taxes and will not pay or reimburse such taxes
10. The Director of Purchasing may cancel any Purchase Order/Contract upon 30 days written notice to the seller
11. The laws of the State of West Virginia and the *Legislative Rules* of the Purchasing Division shall govern all rights and duties under the Contract, including without limitation the validity of this Purchase Order/Contract
12. Any reference to automatic renewal is hereby deleted. The Contract may be renewed only upon mutual written agreement of the parties
13. **BANKRUPTCY:** In the event the vendor/contractor files for bankruptcy protection, the State may deem this contract null and void, and terminate such contract without further order
14. **HIPAA BUSINESS ASSOCIATE ADDENDUM:** The West Virginia State Government HIPAA Business Associate Addendum (BAA), approved by the Attorney General, and available online at the Purchasing Division's web site (<http://www.state.wv.us/admin/purchase/vrc/hipaa.htm>) is hereby made part of the agreement. Provided that, the Agency meets the definition of a Cover Entity (45 CFR §160.103) and will be disclosing Protected Health Information (45 CFR §160.103) to the vendor.
15. **WEST VIRGINIA ALCOHOL & DRUG-FREE WORKPLACE ACT:** If this Contract constitutes a public improvement construction contract as set forth in Article 1D, Chapter 21 of the West Virginia Code ("The West Virginia Alcohol and Drug-Free Workplace Act"), then the following language shall hereby become part of this Contract: "The contractor and its subcontractors shall implement and maintain a written drug-free workplace policy in compliance with the West Virginia Alcohol and Drug-Free Workplace Act, as set forth in Article 1D, Chapter 21 of the West Virginia Code. The contractor and its subcontractors shall provide a sworn statement in writing, under the penalties of perjury, that they maintain a valid drug-free workplace policy in compliance with the West Virginia and Drug-Free Workplace Act. It is understood and agreed that this Contract shall be cancelled by the awarding authority if the Contractor: 1) Fails to implement its drug-free workplace policy; 2) Fails to provide information regarding implementation of the contractor's drug-free workplace policy at the request of the public authority; or 3) Provides to the public authority false information regarding the contractor's drug free workplace policy."

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**INSTRUCTIONS TO BIDDERS**

1. Use the quotation forms provided by the Purchasing Division
2. **SPECIFICATIONS:** Items offered must be in compliance with the specifications. Any deviation from the specifications must be clearly indicated by the bidder. Alternates offered by the bidder as **EQUAL** to the specifications must be clearly defined. A bidder offering an alternate should attach complete specifications and literature to the bid. The Purchasing Division may waive minor deviations to specifications
3. Complete all sections of the quotation form
4. Unit prices shall prevail in case of discrepancy
5. All quotations are considered F.O.B. destination unless alternate shipping terms are clearly identified in the quotation
6. **BID SUBMISSION:** All quotations must be delivered by the bidder to the office listed below prior to the date and time of the bid opening. Failure of the bidder to deliver the quotations on time will result in bid disqualifications: Department of Administration, Purchasing Division, 2019 Washington Street East, P.O. Box 50130, Charleston, WV 25305-0130



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

# Request for Quotation

RFQ NUMBER  
 MCH10037

PAGE  
 2

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

RFQ COPY

TYPE NAME/ADDRESS HERE

ROBERTA WAGNER

Onco Diagnostic Services Inc.  
 010401 Old Georgetown Rd. #408  
 Bethesda MD 20814

SHIP TO

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

DATE PRINTED	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
10/28/2009				
BID OPENING DATE: 11/12/2009		BID OPENING TIME 01:30PM		

LINE	QUANTITY	UOP	CAT NO.	ITEM NUMBER	UNIT PRICE	AMOUNT
<p>ADDENDUM(S) MAY BE CAUSE FOR REJECTION OF BIDS.</p> <p>VENDOR MUST CLEARLY 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.</p> <p style="text-align: right;">  President            SIGNATURE            Onco Diagnostic Services Inc.            COMPANY            November 10, 2009            DATE         </p> <p>NOTE: THIS ADDENDUM ACKNOWLEDGEMENT SHOULD BE SUBMITTED WITH THE BID.</p> <p>REV 09/21/2009</p> <p style="text-align: center;">END OF ADDENDUM NO. 3</p>						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE 	TELEPHONE 301-530-5511	DATE 11/10/09
TITLE President	FEBN 56-2372362	ADDRESS CHANGES TO BE NOTED ABOVE

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

**STATE OF WEST VIRGINIA  
PURCHASE CONTINUATION SHEET**

Page \_\_\_ of \_\_\_ Pages

Requisition / P.O. No :  
MCH10037

File: \_\_\_\_\_ Acct No: \_\_\_\_\_

Vendor: \_\_\_\_\_ P.O. Date: \_\_\_\_\_

Spending Unit:  
WVDHHR/OMCFH/FPP

Item No.	Quantity	Description	Unit Price	Amount
		<p>TO CHANGE SECTION 3 2 AND 2 1 A OF SPECIFICATIONS:</p> <p>TO CHANGE SECTION 3 2 FROM:</p> <p>SUBCONTRACTS PROHIBITED:</p> <p>The successful vendor will be solely responsible for all work performed under the contract. The vendor shall not enter into written or oral subcontracts for the performance of work under the contract without written permission of the agency</p> <p>TO CHANGE SECTION 3 2 OF SPECIFICATIONS TO:</p> <p>3 2 SUBCONTRACT/JOINT VENTURES:</p> <p>The vendor is solely responsible for all work performed under the contract and shall assume prime contractor responsibility for all services offered and products to be delivered under the terms of this contract. The state will consider the vendor to be the sole point of contact with regard to all contractual matters. The vendor may, with prior written consent of the state, enter into written subcontracts for performance of work under this contract; However, the vendor is totally responsible for payment of all contractors. Any licensing requirement in this contract must be met by the vendor and all subcontractors of the vendor</p> <p>TO CHANGE SECTION 2 1 A FROM:</p> <p>The vendor will provide participating FPP and BCCSP providers all supplies necessary for collection of Liquid-Based Pap test specimens. These supplies shall include, but not to be limited to, requisition forms mailers, specimen containers that provide space for writing the patient's name, cervical scrapers and cytobrushes</p> <p>TO CHANGE SECTION 2 1 A TO:</p> <p>The vendor will provide participating FPP and BCCSP providers all supplies necessary for collection of Thin Prep Liquid Medium/Monolayer System test specimens or equal. These supplies shall include, but not to be limited to, requisition forms mailers, specimen containers that provide space for writing the patient's name cervical scrapers and cytobrushes</p> <p>TO SUBMIT REVISED COST SHEET (ATTACHED)</p> <p>TO ANSWER VENDOR QUESTION:</p> <p>We are currently working on RFQ MCH10037. Can you direct me to the previous RFQ so that we can find the current bid? I found the FOIA and some other helpful information on your website but I'm not sure exactly where to go to find the current bid</p> <p>ANSWER:</p> <p>The current PO# is MCH70449, and the costs are:</p> <p>Liquid Based Pap Test: \$15.00 per test HPV/DNA Testing(high risk only): \$37.00 per test</p> <p>QUESTION:</p> <p>Just to clarify, page 6 of the RFQ list HPV's and Liquid based Pap test for Private Pay Program Eligible Clients. What does Private Pay by Program Eligible Clients mean? Are they people without insurance and are going to pay their Pap smear and HPV out of their own pocket? Please advise.</p> <p>ANSWER:</p> <p>These are FPP and BCCSP eligible client that will pay out of pocket for a Pap test outside of the criteria under which FPP and BCCSP can pay for, i.e. annually, when a repeat at 3 months. In these instance, the client would pay for the Pap test</p> <p>PLEASE NOTE: ALL INQUIRIES RELATED TO THIS RFQ MUST BE DIRECTED THROUGH THE DEPARTMENT OF ADMINISTRATION BUYER, ROBERTA WAGNER</p> <p>BID OPENING IS BEING DELAYED UNTIL 11/12/2009</p>		



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

# Request for Quotation

RFO NUMBER  
 MCH10037

PAGE  
 1

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

VENDOR

Onco Diagnostic Services, Inc  
 10401 Old Georgetown Road, Suite 408  
 Bethesda, MD 20814

SHIP TO

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

DATE PRINTED 10/30/2009	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
BID OPENING DATE: 11/12/2009		BID OPENING TIME 01:30PM		

LINE	QUANTITY	UOP	CAT NO	ITEM NUMBER	UNIT PRICE	AMOUNT
ADDENDUM NO. 4						
1. QUESTIONS AND ANSWERS ATTACHED.						
2. ADDENDUM ACKNOWLEDGEMENT IS ATTACHED. THIS DOCUMENT SHOULD BE SIGNED AND RETURNED WITH YOUR BID. FAILURE TO SIGN AND RETURN MAY RESULT IN DISQUALIFICATION OF YOUR BID.						
EXHIBIT 10						
REQUISITION NO.: MCH10037						
ADDENDUM ACKNOWLEDGEMENT						
I HEREBY ACKNOWLEDGE RECEIPT OF THE FOLLOWING CHECKED ADDENDUM(S) AND HAVE MADE THE NECESSARY REVISIONS TO MY PROPOSAL, PLANS AND/OR SPECIFICATION, ETC.						
ADDENDUM NO. S:						
NO. 1			X			
NO. 2			X			
NO. 3			X			
NO. 4			X			
NO. 5						
I UNDERSTAND THAT FAILURE TO CONFIRM THE RECEIPT OF THE ADDENDUM(S) MAY BE CAUSE FOR REJECTION OF BIDS.						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE <i>Nancy Rogan</i>	TELEPHONE 301-530-5511	DATE 11/10/09
TITLE President	FEIN 56-2372362	ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO RFQ, 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

# Request for Quotation

RFQ NUMBER  
 MCH10037

PAGE  
 2

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

RFQ COPY

TYPE NAME/ADDRESS HERE

V  
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Onco Diagnostic Services Inc.  
 10401 Old Georgetown Rd, #408  
 Bethesda MD 20814

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HEALTH AND HUMAN RESOURCES  
 BPH - MCH WAREHOUSE  
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DATE PRINTED 10/30/2009	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
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LINE	QUANTITY	UOP	CAT NO.	ITEM NUMBER	UNIT PRICE	AMOUNT
<p>VENDOR MUST CLEARLY 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.</p> <p><i>Nancy Rogowski</i> President            SIGNATURE            Onco Diagnostic Services Inc.            COMPANY            November 10, 2009            DATE</p> <p>NOTE: THIS ADDENDUM ACKNOWLEDGEMENT SHOULD BE SUBMITTED WITH THE BID.</p> <p>REV. 09/21/2009</p> <p>END OF ADDENDUM NO. 4</p>						

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE <i>Nancy Rogowski</i> President	TELEPHONE 301-530-5511	DATE 11/10/09
TITLE President	FEIN 56-2372362	ADDRESS CHANGES TO BE NOTED ABOVE

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

STATE OF WEST VIRGINIA  
**PURCHASE CONTINUATION SHEET**

Page \_\_\_ of \_\_\_ Pages

Requisition / P.O. No.:  
MCH10037 ADDENDUM 4

File:  
RW22

Acct. No.:  
MUL MUL MUL

Vendor: \_\_\_\_\_ P.O. Date: \_\_\_\_\_

Spending Unit:  
WVDHHR/OMCFH/FPP

Item No.	Quantity	Description	Unit Price	Amount
		<p>TO RESPOND TO ADDITIONAL VENDOR INQUIRY ABOUT COST OF LIQUID BASED PAP TEST:</p> <p>THE LOW BID WAS \$15.50 PER TEST. HOWEVER, WITH EACH RENEWAL THE VENDOR HAS QUOTED \$15.00 PER TEST AND THAT IS WHAT WE'VE BEEN PAYING.</p>		



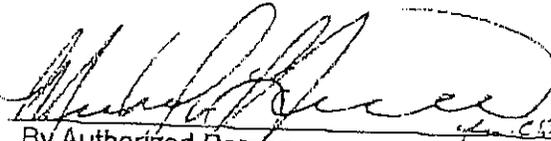
**LABORATORY SERVICE AGREEMENT**

This Agreement, entered into on November 15, 2007, by and between Cytology Services of Maryland, hereinafter called "CSM", and the West Virginia Department of Health and Human Resources hereinafter called "WVDHHR", shall commence on November 15, 2007. This Agreement is effective as of this date of execution and shall remain effective for twelve (12) months. This Agreement shall be subject to the terms and conditions stated below and in the Proposal for Laboratory Services **MCH70449** (dated October 19, 2006).

- I. All prices are fixed for twelve (12) months from the date of execution of this contract. The price for Cytoc's ThinPrep® Pap Test™ shall be \$15.00 per test (reduced from \$15.50 as stated in the original contract), Digene's High-Risk HPV DNA Hybrid Capture 2 Test (B Probe) shall be \$37.00
- II. Renewal. The term of this Agreement shall be from November 15, 2007 through November 14, 2008.

For Cytology Services of Maryland

For West Virginia Dept of Health and Human Resources.

  
By Authorized Person

  
By Authorized Person

Michael LaFriniere

JAMES A. JACKSON

Name (Please Print)

Name (Please Print)

Executive Director

Senior Buyer

Title

Title

October 2, 2007

October 12, 2007

Date

Date

  
Witness

  
Witness

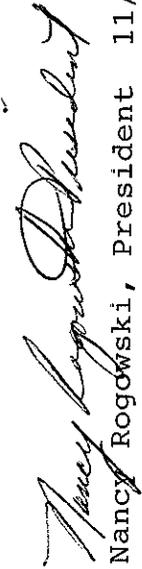
Onco Diagnostic Services, Inc.  
 10401 Old Georgetown Rd, #408  
 Bethesda MD 20814

**COST SHEET FOR MCH10037**

FINAL 11/10/09

<u>Item #</u>	<u>Apprx. Annual Usage</u> <u>QUANTITY</u>	<u>DESCRIPTION</u>	<u>UNIT PRICE</u>	<u>TOTAL COST</u>
1	60,000	THIN PREP LIQUID MEDIUM/MONOLAYER OR EQUAL	\$14.00	\$840,000
2	2,800	HPV/DNA TESTING (HIGH-RISK ONLY) THIN PREP LIQUID MEDIUM/MONOLAYER OR EQUAL	\$35.00	\$98,000
3	2,600	THIN PREP LIQUID MEDIUM/MONOLAYER OR EQUAL (PRIVATE PAY BY PROGRAM ELIGIBLE CLIENT)	\$14.00	\$36,400
		<b>TOTAL COST</b>		<b>\$974,400</b>

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

  
 Nancy Rogowski, President

11/10/09, FEIN 56-2372362

Telephone # 301/530-5511