

**STATEMENT OF WORK**  
**Malcom Randal VA Medical Center**  
**Cost Per Test (CPT)**

**A. SCOPE OF PROCUREMENT**

This solicitation is for the procurement of HPV mRNA and HPV 16 18/45 Genotype testing kits and maintenance service with accompanying molecular testing instrumentation and must have the capability of performing or reporting the clinical parameters as defined in the statement of work. The instrument is able to simultaneously perform the complete profile as described below and meet the performance characteristics for accuracy and precision as defined by the 1988 Clinical Laboratory Improvement Act (CLIA) and the Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS).

**B. DEFINITIONS**

a. Cost per Test (CPT)- as defined in the Federal Supply Schedule FSC Group 66, Part III, Cost-Per-Test Clinical Laboratory Analyzers – Contractors are required to provide a price for each test that can be performed on its equipment. The per test price shall include costs covering (1) 5 year equipment use; (2) all reagents, standards, quality controls, supplies, consumable/disposable items, parts, accessories and any other item required for the proper operation of the Contractor's equipment and necessary for the generation and reporting of a test result; (3) all necessary maintenance to keep the equipment in good operating condition (This element includes both preventive maintenance and emergency repairs); and (4) training for Government personnel. Contractors are required to provide delivery, installation and removal of equipment at no additional charge.

b. Molecular testing analyzer(s) – Base equipment existing at VA laboratory listed above that fully supports the scope of their operations (minimal requirements) as defined in this solicitation. Depending upon the technical functionality and the capabilities of the individual manufacturer's instrumentation, one analyzer or multiple analyzers may be required to meet the productivity specifications defined herein.

**C. TEST MENU**

Refer to Attachment A for a list of desired tests and their estimated annual volumes by Gainesville VA Medical Center facility.

**D. GENERAL REQUIREMENTS**

**1. Operational Features -** The general Molecular testing instrumentation must have:

- a) The capability of performing analysis on 100% of the tests listed in Attachment A on a fully automated platform with random access capability.
- b) Sufficient capacity and throughput to meet the volume and service demands as defined in the Test Menu (Attachment A).
- c) Sufficient safety features to avoid unnecessary exposure to biohazardous and chemical material. The exposure to and the volume of biohazardous and chemical material generated by the equipment must be minimal and require a minimum amount of handling.
- c) A bi-directional, bar-coded computer interface. The fully operational interface (both hardware and software) must be immediately available for implementation to the VA VistA hospital information system (Refer to Brief Summary of VistA Functionality below) at the time of contract award. If the host system software requires the use of a non-proprietary universal interfacing system to provide bi-directional interfacing capabilities, the Gainesville facility laboratory currently uses the Data Innovation systems. To achieve connection with this system, the awarded vendor will be responsible for the cost of the interface. Refer to the following section entitled "Support Features – Computer Interfacing Requirements for specific details.
- d) Molecular analyzer must fit into existing allotment of space. The Gainesville division allotted area is approximately 8 X 6 feet.

#### Brief Summary of VistA Functionality

VistA is a proprietary system to the VA whose functionality includes:

1. Management of patient information through a database,
2. Acceptance of test ordering information,
3. Transmittal of patient laboratory test results
4. Storage and retrieval of patient laboratory test results

VistA is very limited in its functionality to manage laboratory quality control, provide Levy-Jennings plots or administer an instrument maintenance program.

#### **2. Hardware Features** - The Molecular assay testing instrumentation must have the following:

- a) No batching restrictions. Can load any number of samples at any time
- b) High throughput, process up to 275 samples per 8-hour shift, to keep pace with high volume workload
- c) High-resolution touch screen for easy interaction
- d) Expanded ancillary reagent and fluid capacity
- e) Data archive feature reduces time for administrative tasks
- f) Universal sample rack design eliminates manual tasks
- g) The ability to run multiple assays simultaneously
- h) Disposable pipette tips eliminate sample-to-sample carryover
- i) Runs controls and calibrators once every 24 hours
- j) User interface adjusts for customized ergonomics
- k) No daily startup with automated maintenance features

#### **3. Support Features**

a) Supplies - The vendor must provide all reagents, calibrators, controls, consumable/disposable items, parts, accessories and any other item included on the list of supplies defined in the contract and required to establish instruments for operation. The vendor will perform, to the satisfaction of the Government, all validation studies including: precision, method comparison with current analyzer, accuracy (recovery), linearity (reportable range), calibration verification, verification of reference interval, and determination of sensitivity and specificity at no cost to the Government. The vendor will perform all of the statistical analysis and report data in an organized, clearly comprehensible format.

b) Training - The vendor must provide an instrument training program that is coordinated with and timely to the equipment installation, sufficient to the size and scope of the facility's services. This will include training on the operation of the system, data manipulation, and basic trouble shooting and repair. The vendor will provide training for two operators for each model of instrumentation placed. Utilization of the training slots will be mutually agreed upon between the Gainesville facility laboratory and the vendor. A training program that involves off-site travel shall include the cost of airfare, room and board for each participant.

c) Equipment Preventative Maintenance/Repair Service - The vendor must be able to provide emergency equipment repair and preventative maintenance on all instrumentation and any incremental support equipment, e.g. water system, offered according to the following terms:

1. A technical assistance center must be available by telephone 7am to 10pm EST with a maximum call back response time of 2 hours.
2. Equipment repair service must be provided during routine business hours. Certain circumstances may dictate the need for repair service to be conducted outside routine business hours. All such arrangements will be coordinated between the contractor and VA laboratory personnel.
3. Equipment response time will be no more than 12 hours.
4. A minimum of two scheduled preventative maintenance calls per year.
5. A malfunction incident report shall be furnished to the installed site upon completion of each repair call.

The report shall include, as a minimum, the following:

- (a) date and time notified
- (b) date and time of arrival
- (c) serial number, type and model number of equipment
- (d) time spent for repair, and

(e) proof of repair that includes documentation of a sample run of quality control verifying acceptable performance.

6. During the term of the BPA, should the repair record of any individual piece of laboratory equipment reflect a downtime of 2% or greater of the normal working days in one calendar month, a determination will be made by the designated representative of the Government to replace the malfunctioning equipment with new equipment. The responsibility for maintaining the equipment furnished in good condition in accordance with manufacturer's instructions, shall be solely that of the contractor. Each instrument provided by the contractor shall maintain an uptime of 98% in each month of the term of the agreement.

7. Each notification for an emergency repair service call will be treated as a separate and new service call.

e) Upgrades or Replacement: Request for instrumentation upgrades or replacement, due to workload increase, menu changes, technological upgrades, excessive instrumentation failures/malfunctions, breakdowns, or service calls will be evaluated as needed/annually with communication to the vendor for modification of the contract. A high incidence of problems with any equipment/analyzer supplied may indicate probable non-compliance with the terms of this contract and will entitle the facility/clinic to its replacement with another analyzer(s) that can produce the required criteria of this contract satisfactorily to the user. Removal of instrument by the vendor shall be performed within 60 days after request. The vendor must provide upgrades to both the equipment hardware and software in order to maintain the integrity of the system and the state-of-the-art technology, at no additional charge to the Government. These must be provided as they become commercially available and at the same time as they are being provided to commercial customers.

f) Ancillary support equipment - The vendor will provide, install and maintain, as indicated, any and all ancillary support equipment to fully operate the molecular analyzer as defined in these specifications, e.g. installation of telephone lines for modem operations, cabinetry to support/house the analyzer (if necessary), water systems (including consumable polishers, filters, etc.), and universal interface equipment, etc. In addition, the vendor will include all ancillary components that are customarily sold or provided with the model of equipment proposed, e.g. starter kits, tables/stands, etc.

g) Invoicing – All invoices shall be issued monthly in arrears stating the test name, monthly volume of patient reportable results and the individual cost per reportable price as awarded per contract. Additional invoice charges associated with reagent and/or supply wastage or repair parts included at no charge will not be accepted.

h) Computer Interfacing Requirements - The fully operational interface (both hardware and software) must be immediately available for implementation to the VA VistA hospital information system at the time of contract award.

The vendor is responsible for providing all hardware required for the connection, implementation and operation of the interface to the universal interface and any incremental fee that is required each time an instrument is added to an existing universal interface system (see requirements below). Likewise, the vendor will provide any and all necessary software support for insuring that successful interfacing has been established. Specific requirements for the communication of the data streams will be unique to the instrument system involved and dictated by the manufacturer itself. Information necessary to make the determination for type and amount of interfacing equipment is supplied in the chart below. If there are any software upgrades in the instrument during its life, the vendor is responsible for seeing that the interface can accommodate any changes in the data stream going to the VistA.

i) Commercial offerings - The vendor will provide to the VA facility any additional support material that is routinely provided to equivalent commercial customers and will assist in regulatory compliance, e.g. PC computer diskette of their procedure manual or an on-line procedure manual in the instrument software.

j) Implementation/transition timeframe - The implementation of the services/requirements described in this solicitation shall be completed no later than 60 days after the award of the contract. This timeline is based on a reasonable attempt of the vendor to complete all of the necessary implementation requirements within the stated timeframe. Vendors will not be penalized for implementation timelines that extend beyond the 60 day timeframe, if the extension is through no fault of the vendor and is a result of delays due to the Government.

## **F. EVALUATION OF OFFERS**

1. Minimum Requirements. Each respondent for award shall meet all the minimum specifications as outlined in General Requirements.

**G. DELIVERY:**

Department of Veterans Affairs  
Malcom Randall VA Medical Center  
1601 SW Archer Road  
Gainesville, Fl

**Test Menu and Estimated Annual Usage:**

**Attachment A**

<b>Test</b>	<b>Volume</b>
Aptima HPV mRNA	2100
Aptima HPV 16 18/45	160