

Statement of Work
Molecular Vaginitis Detection System
Southeast Louisiana Veterans Health Care System
New Orleans, LA

09/08/2016

1. PURPOSE

- 1.1 The overall purpose is to provide and install a Molecular Vaginitis Detection System at the Southeast Louisiana Veterans Health Care System (SLVHCS) Microbiology Laboratory, Pathology and Laboratory Medicine Service Laboratory, 2400 Canal St, Via 2401 Tulane Ave whse, New Orleans, LA 70119.

2. SCOPE

- 2.1 The Contractor shall provide, transport, install, and test all listed equipment. All products must meet all salient characteristics defined in this section.
- 2.2 All equipment and installation must meet manufacturers and VA specifications.
- 2.3 The Contractor shall furnish all supplies, equipment, facilities and services required for delivery and installation of the supplies and equipment.
- 2.4 The Contractor is responsible for any missing parts and components not included in order to carry out the Installation and proper instrument function.

2.5 SALIENT CHARACTERISTICS

2.5.1 Molecular Vaginitis Detection System

Equivalent to BD Affirm™ VPIII Microbial Identification System

- Shall simultaneously detect and differentiate *Gardnerella vaginalis*, *Candida species*, and *Trichomonas vaginalis* from a single vaginal specimen
- Shall use an automated molecular testing method of DNA direct probes targeted to the RNA of *Gardnerella vaginalis*, *Candida species*, and *Trichomonas vaginalis* for organism detections
- Shall use two distinct single-stranded nucleic acid probes for *Gardnerella vaginalis*, *Candida species*, and *Trichomonas vaginalis*
- Shall require less than 60 minutes of automated processing and report results within 90 minutes
- Shall use an ambient temperature transport system for specimen collection which maintains specimen integrity for at least 72 hours after collection at ambient temperature conditions (15-30°C).
- Shall be FDA approved
- Shall process a minimum of 5 specimens simultaneously with less than 5 minutes of user "hands on" time
- Shall have built-in thresholds of disease detection to prevent categorizing normal flora as an infection
- The system shall have a 24 month warranty which includes swapping out the instrument for a new instrument if a problem occurs with the existing instrument
- Shall have electrical requirements of 120VAC=/- 10%
- Shall be a countertop unit with dimensions no larger than 10 inches Height, 12 inches Width, 12 inches Depth, and weigh no more than 50 lbs.
- The instrument shall have annual service contract for one year
- Necessary reagents, test kits, supplies, and/or clinical specimens for validation and correlation studies on instruments shall be available. Vendor must work with P&LMS Microbiology COR to determine parameters of validation study.

- 2.5.2 Delivery and installation of instrumentation with assurance of proper operation shall be provided by the manufacturer.
- 2.5.3 On-site training at no costs for two (2) key operators and VA technical staff on instrumentation and software
- 2.5.4 Off- site training at no cost for two (2) key operators in instrumentation and software, if available (includes airfare, transportation, lodging and meals)
- 2.5.5 On-site or off-site training for two (2) Biomedical Engineers for Instrumentation (includes airfare, transportation, lodging and meals), if available
- 2.5.6 Two (2) Operator's Manuals for instrumentation (2.5.1)
- 2.5.7 Two (2) Technical Service Manuals for instrumentation (2.5.1)
- 2.5.8 Two Year Warranty for the Molecular Vaginitis Detection System (Includes instrument replacement) at no cost to the Government from 12/19/2016 - 12/18/2018.
- 2.5.9 Extended warranty for 1 year past the initial warranty for the Molecular Vaginitis Detection System (Includes all parts, labor, travel and preventative maintenance) from 12/19/2018 - 12/18/2019

2.6 DELIVERY AND INSTALLATION

2.6.1 DELIVERY

- 2.6.1.1 Contractor shall deliver all equipment to the Pathology & Laboratory Medicine Service, Room 4F122B at the Southeast Louisiana Veterans Health Care System (SLVHCS) 2400 Canal St, New Orleans, LA 70119 via at 2401 Tulane Avenue, New Orleans, LA 70119 on 12/19/2016.
- 2.6.1.2 -Deliver materials to job in manufacturer's original sealed containers with brand name marked thereon.
- 2.6.1.3 -Package to prevent damage or deterioration during shipment, handling, storage and installation. Maintain protective covering in place and in good repair until removal is necessary.
- 2.6.1.4 -Deliver specified items only when site is ready for installation work to proceed.
- 2.6.1.5 -Store products in dry condition inside enclosed facilities.
- 2.6.1.6 -Any government requested delayed delivery up to 90 days after initial delivery date, shall be at no additional cost to the Government.
- 2.6.1.7 -A pre-delivery meeting will be conducted 60 days prior to initial negotiated delivery date for verification of delivery and installation dates.
- 2.6.1.8 Delivery and Installation will be coordinated through the COR

2.6.2 INSTALLATION

- 2.6.2.1 Install all equipment to manufacturer's specifications maintaining Federal, and Local safety standards
- 2.6.2.2 Installation must be completed by 01/27/2017. All work shall be completed between 8:00 a.m. and 4:30 p.m. Monday – Friday. All federal holidays, excluded. Federal holidays are available at the [Federal Holiday OPM Site](#).
- 2.6.2.3 If there is an operational conflict with installation, night or weekend installation may be required. Government will provide a 72 hours' notice of change of installation hours.
- 2.6.2.4 The contractor shall coordinate all deliveries, staging areas, installations, and parking arrangements with the COR.
- 2.6.2.5 The Contractor shall remove all related shipping debris and cleanup any construction associated with delivery and installation of the specified items. Contractor shall remove all packaging from the SLVHCS premises. The Contractor shall be responsible for any damage to the building that occurs due to Contractor error or neglect.

2.7 SITE CONDITIONS

- 2.7.1 There shall be no smoking, eating, or drinking inside the hospital at any time.

3. INSPECTION AND ACCEPTANCE:

- 3.1 Contractor shall conduct a joint inspection with the COR upon delivery of equipment.
- 3.2 Contractor shall provide the VA COR a list of missing and damaged items found upon inspection and have those items replaced at no cost to the Government.

- 3.3 Contractor shall provide dates of completion of punch list items and replacement parts/ and/or short ship items from the manufacturer (s)
- 3.3 The COR shall ensure all work is completed satisfactorily prior to acceptance. Disputes shall be resolved by the VA Contracting Officer.

5. DELIVERABLES

- 5.1 Operation/Technical and Maintenance Manuals
 - 5.1.1 Binders - Quantity (2) each for items 2.5.1
 - 5.1.2 Digital Copies in CD form- Quantity (1) each for items 2.5.1
- 5.2 Deliver compilation of all manufacturer recommended maintenance schedule and operation materials packaged in binder(s) to VA COR upon completion of installation.

6. OPERATOR TRAINING

- 6.1 Contractor shall provide On-site training on the instrumentation and software to two (2) Key Operators and VA technical staff at no cost to the Government. Training must be completed by 1/27/2017. Scheduling of training or changes in training dates shall be coordinated with the SLVHCS COR after installation is complete.
- 6.2 Contractor shall provide off-site training , if available, on the instrumentation and software to two (2) key operators at no cost to the Government. Training must be completed by 1/27/2017. Scheduling of training or changes in training dates shall be coordinated with the SLVHCS COR.
- 6.3 Contractor shall provide on or off-site training , if available, on the instrumentation and software to two (2) SLVHCS BioMedical Engineers (includes airfare, transportation, lodging and meals if offsite), if available. Scheduling of training or changes in training dates shall be coordinated with the SLVHCS COR.

7. PROTECTION OF PROPERTY

- 7.1 Contractor shall protect all items from damage. The Contractor shall take precaution against damage to the building(s), grounds and furnishings. The Contractor shall repair or replace any items related to building(s) or grounds damaged accidentally or on purpose due to actions by the Contractor.
- 7.2 The Contractor shall perform an inspection of the building(s) and grounds with the COR prior to commencing work. To insure that the Contractor shall be able to repair or replace any items, components, building(s) or grounds damaged due to negligence and/or actions taken by the Contractor. The source of all repairs beyond simple surface cleaning is the facility construction contractor (or appropriate subcontractor), so that building warranty is maintained. Concurrence from the VA Facilities Management POC and COR is required before the Contractor may perform any significant repair work. In all cases, repairs shall utilize materials of the same quality, size, texture, grade, and color to match adjacent existing work.
- 7.3 The Contractor shall be responsible for security of the areas in which the work is being performed prior to completion.
- 7.4 Contractor shall provide floor protection while working in all VA facilities. All material handling equipment shall have rubber wheels.

8. SECURITY REQUIREMENTS

1. GENERAL

Contractors, contractor personnel, subcontractors, and subcontractor personnel shall be subject to the same Federal laws, regulations, standards, and VA Directives and Handbooks as VA personnel regarding information and information system security.

2. SECURITY CLAUSE

Assessment & Authorization (A & A) requirements do not apply--Security Accreditation Package is not required.

3. VA INFORMATION CUSTODIAL LANGUAGE

a. Information made available to the contractor or subcontractor by VA for the performance or administration of this contract or information developed by the contractor/subcontractor in performance or administration of the contract shall be used only for those purposes and shall not be used in any other way without the prior written agreement of the VA. This clause expressly limits the contractor/subcontractor's rights to use data as described in Rights in Data - General, FAR 52.227-14(d) (1).

b. VA information should not be co-mingled, if possible, with any other data on the contractors/subcontractor's information systems or media storage systems in order to ensure VA requirements related to data protection and media sanitization can be met. If co-mingling must be allowed to meet the requirements of the business need, the contractor must ensure that VA's information is returned to the VA or destroyed in accordance with VA's sanitization requirements. VA reserves the right to conduct onsite inspections of contractor and subcontractor IT resources to ensure data security controls, separation of data and job duties, and destruction/media sanitization procedures are in compliance with VA directive requirements.

c. Prior to termination or completion of this contract, contractor/subcontractor must not destroy information received from VA, or gathered/created by the contractor in the course of performing this contract without prior written approval by the VA. Any data destruction done on behalf of VA by a contractor/subcontractor must be done in accordance with National Archives and Records Administration (NARA) requirements as outlined in VA Directive 6300, Records and Information Management and its Handbook 6300.1 Records Management Procedures, applicable VA Records Control Schedules, and VA Handbook 6500.1, Electronic Media Sanitization. Self-certification by the contractor that the data destruction requirements above have been met must be sent to the VA Contracting Officer within 30 days of termination of the contract.

d. The contractor/subcontractor must receive, gather, store, back up, maintain, use, disclose and dispose of VA information only in compliance with the terms of the contract and applicable Federal and VA information confidentiality and security laws, regulations and policies. If Federal or VA information confidentiality and security laws, regulations and policies become applicable to the VA information or information systems after execution of the contract, or if NIST issues or updates applicable FIPS or Special Publications (SP) after execution of this contract, the parties agree to negotiate in good faith to implement the information confidentiality and security laws, regulations and policies in this contract.

e. The contractor/subcontractor shall not make copies of VA information except as authorized and necessary to perform the terms of the agreement or to preserve electronic information stored on contractor/subcontractor electronic storage media for restoration in case any electronic equipment or data used by the contractor/subcontractor needs to be restored to an operating state. If copies are made for restoration purposes, after the restoration is complete, the copies must be appropriately destroyed.

f. If VA determines that the contractor has violated any of the information confidentiality, privacy, and security provisions of the contract, it shall be sufficient grounds for VA to withhold payment to the contractor or third party or terminate the contract for default or terminate for cause under Federal Acquisition Regulation (FAR) part 12.

g. If a VHA contract is terminated for cause, the associated BAA must also be terminated and appropriate actions taken in accordance with VHA Handbook 1600.01, Business Associate Agreements. Absent an agreement to use or disclose protected health information, there is no business associate relationship.

h. The contractor/subcontractor must store, transport, or transmit VA sensitive information in an encrypted form, using VA-approved encryption tools that are, at a minimum, FIPS 140-2 validated.

i. The contractor/subcontractor's firewall and Web services security controls, if applicable, shall meet or exceed VA's minimum requirements. VA Configuration Guidelines are available upon request.

j. Except for uses and disclosures of VA information authorized by this contract for performance of the contract, the contractor/subcontractor may use and disclose VA information only in two other situations: (i) in response to a qualifying order of a court of competent jurisdiction, or (ii) with VA's prior written approval. The contractor/subcontractor must refer all requests for, demands for production of, or inquiries about, VA information and information systems to the VA contracting officer for response.

k. Notwithstanding the provision above, the contractor/subcontractor shall not release VA records protected by Title 38 U.S.C. 5705, confidentiality of medical quality assurance records and/or Title 38 U.S.C. 7332, confidentiality of certain health records pertaining to drug addiction, sickle cell anemia, alcoholism or alcohol abuse, or infection with human immunodeficiency virus. If the contractor/subcontractor is in receipt of a court order or other requests for the above mentioned information, that contractor/subcontractor shall immediately refer such court orders or other requests to the VA contracting officer for response.

l. Bio-Medical devices and other equipment or systems containing media (hard drives, optical disks, etc.) with VA sensitive information must not be returned to the vendor at the end of lease, for trade-in, or other purposes.

The options are:

- (1) Vendor must accept the system without the drive;
- (2) VA's initial medical device purchase includes a spare drive which must be installed in place of the original drive at time of turn-in; or
- (3) VA must reimburse the company for media at a reasonable open market replacement cost at time of purchase.
- (4) Due to the highly specialized and sometimes proprietary hardware and software associated with medical equipment/systems, if it is not possible for the VA to retain the hard drive, then;

(a) The equipment vendor must have an existing BAA if the device being traded in has sensitive information stored on it and hard drive(s) from the system are being returned physically intact;

(b) Any fixed hard drive on the device must be non-destructively sanitized to the greatest extent possible without negatively impacting system operation. Selective clearing down to patient data folder level is recommended using VA approved and validated overwriting technologies/methods/tools. Applicable media sanitization specifications need to be preapproved and described in the purchase order or contract.

(c) A statement needs to be signed by the Director (System Owner) that states that the drive could not be removed and that (a) and (b) controls above are in place and completed.

The ISO needs to maintain the documentation.

4. SECURITY INCIDENT INVESTIGATION

a. The term "security incident" means an event that has, or could have, resulted in unauthorized access to, loss or damage to VA assets, or sensitive information, or an action that breaches VA security procedures. The contractor/subcontractor shall immediately notify the COTR and simultaneously, the designated ISO and Privacy Officer for the contract of any known or suspected security/privacy incidents, or any unauthorized disclosure of sensitive information, including that contained in system(s) to which the contractor/subcontractor has access.

b. To the extent known by the contractor/subcontractor, the contractor/subcontractor's notice to VA shall identify the information involved, the circumstances surrounding the incident including to whom, how, when, and where the VA information or assets were placed at risk or compromised), and any other information that the contractor/subcontractor considers relevant.

c. With respect to unsecured protected health information, the business associate is deemed to have discovered a data breach when the business associate knew or should have known of a breach of such information. Upon discovery, the business associate must notify the covered entity of the breach. Notifications need to be made in accordance with the executed business associate agreement.

d. In instances of theft or break-in or other criminal activity, the contractor/subcontractor must concurrently report the incident to the appropriate law enforcement entity (or entities) of jurisdiction, including the VA OIG and Security and Law Enforcement. The contractor, its employees, and its subcontractors and their employees shall cooperate with VA and any law enforcement authority responsible for the investigation and prosecution of any possible criminal law violation(s) associated with any incident. The contractor/subcontractor shall cooperate with VA in any civil litigation to recover.

5. LIQUIDATED DAMAGES FOR DATA BREACH

a. Consistent with the requirements of 38 U.S.C. §5725, a contract may require access to sensitive personal information. If so, the contractor is liable to VA for liquidated damages in the event of a data breach or privacy incident involving any SPI the contractor/subcontractor processes or maintains under this contract. However, it is the policy of VA to forgo collection of liquidated damages in the event the contractor provides payment of actual damages in an amount determined to be adequate by the agency.

b. The contractor/subcontractor shall provide notice to VA of a “security incident” as set forth in the Security Incident Investigation section above. Upon such notification, VA must secure from a non-Department entity or the VA Office of Inspector General an independent risk analysis of the data breach to determine the level of risk associated with the data breach for the potential misuse of any sensitive personal information involved in the data breach. The term 'data breach' means the loss, theft, or other unauthorized access, or any access other than that incidental to the scope of employment, to data containing sensitive personal information, in electronic or printed form, that results in the potential compromise of the confidentiality or integrity of the data. Contractor shall fully cooperate with the entity performing the risk analysis. Failure to cooperate may be deemed a material breach and grounds for contract termination.

c. Each risk analysis shall address all relevant information concerning the data breach, including the following:

(1) Nature of the event (loss, theft, unauthorized access);

(2) Description of the event, including:

(a) Date of occurrence;

(b) Data elements involved, including any PII, such as full name, social security number, date of birth, home address, account number, disability code;

(3) Number of individuals affected or potentially affected;

(4) Names of individuals or groups affected or potentially affected;

(5) Ease of logical data access to the lost, stolen or improperly accessed data in light of the degree of protection for the data, e.g., unencrypted, plain text;

(6) Amount of time the data has been out of VA control;

(7) The likelihood that the sensitive personal information will or has been compromised (made accessible to and usable by unauthorized persons); VA information, obtain monetary or other

(8) Known misuses of data containing sensitive personal information, if any;

(9) Assessment of the potential harm to the affected individuals;

(10) Data breach analysis as outlined in 6500.2 Handbook, Management of Security and

Privacy Incidents, as appropriate; and

(11) Whether credit protection services may assist record subjects in avoiding or mitigating the results of identity theft based on the sensitive personal information that may have been compromised.

d. Based on the determinations of the independent risk analysis, the contractor shall be responsible for paying to the VA liquidated damages in the amount of \$37.50 per affected individual to cover the cost of providing credit protection services to affected individuals consisting of the following:

(1) Notification;

(2) One year of credit monitoring services consisting of automatic daily monitoring of at least 3 relevant credit bureau reports;

(3) Data breach analysis;

(4) Fraud resolution services, including writing dispute letters, initiating fraud alerts and credit freezes, to assist affected individuals to bring matters to resolution;

(5) One year of identity theft insurance with \$20,000.00 coverage at \$0 deductible; and

(6) Necessary legal expenses the subjects may incur to repair falsified or damaged credit records, histories, or financial affairs.

6. CONFIDENTIALITY AND NONDISCLOSURE

It is agreed that:

a. The preliminary and final deliverables and all associated working papers, application source code, and other material deemed relevant by the VA which have been generated by the contractor in the performance of this task order are the exclusive property of the U.S. Government and shall be submitted to the CO at the conclusion of the task order.

b. The CO will be the sole authorized official to release verbally or in writing, any data, the draft deliverables, the final deliverables, or any other written or printed materials pertaining to this task order. No information shall be released by the contractor. Any request for information relating to this task order presented to the contractor shall be submitted to the CO for response.

c. Press releases, marketing material or any other printed or electronic documentation related to this project, shall not be publicized without the written approval of the CO.

9. WARRANTY

9.1 The contractor shall provide a two year manufacturer's warranty on all parts and labor which includes preventative maintenance

9.2 The warranty shall include all travel and shipping costs associated with any warranty repair.