

Attachment – VA246-17-Q-0169

Offeror's Technical Response

Table 1- Technical SOW Response

SOW Sections/Subsections	Required Vendor Response
1. GENERAL REQUIREMENTS	
<p>1.1 The vendor shall provide all supplies and services as described herein to the participating VAMC facilities. This contract will be fixed-price for the duration of the contract.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>1.1.1 The awarded reagent rental agreement or cost-per-test agreement shall be available for any additional existing and/or new VISN 6 facilities to participate. Should a new or additional VISN 6 facility request to be included in this agreement, the site will be added to the contract by modification.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>1.2 A listing of estimated yearly quantities by participating facility to be provided under this agreement is located in Appendix A. Quantities as listed in the appendix are estimated based upon prior history of actual volumes and are not a guaranteed minimum. The Government anticipates award of a single contract using the quantities listed in the pricing schedule to provide offerors a basis of calculating their pricing.</p>	<p>No response required.</p>
<p>1.3 Vendor shall provide each participating facility with Food and Drug Administration (FDA) approved analyzer/equipment, incubator/ heating block, reagents, controls, disposables and any consumable part necessary for analyzing testing and must include the following capabilities listed at 2.0 System Requirements.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>1.4 Equipment must be able to meet the volume and match or improve the turnaround time requirements of the using-facilities (see Appendix A - Table of Estimated Test Volumes).</p>	<p>Check one: <input type="checkbox"/> Equipment meets Requirement <input type="checkbox"/> Equipment does not meet Requirement</p>
<p>2. SYSTEM REQUIREMENTS 2.1 SYSTEM REQUIREMENTS</p>	
<p>2.1.1 Vendor shall provide a microbial identification test for the detection of vaginitis/ bacterial vaginosis using an automated DNA direct probe detection method for the simultaneous detection and differentiation of Gardnerella vaginalis, Candida species and Trichomonas vaginalis from a single vaginal specimen.</p>	<p>Check one: <input type="checkbox"/> Equipment meets Requirement <input type="checkbox"/> Equipment does not meet Requirement</p>
<p>2.1.2 Software, hardware, reagents, consumables, and analyzers/instrumentation throughout the facilities choosing to participate within the network shall be standardized.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>2.1.3 System shall be a rapid automated processing microbial identification system and provide final results within one hour from start to finish.</p>	<p>Check one: <input type="checkbox"/> Equipment meets Requirement <input type="checkbox"/> Equipment does not meet Requirement</p>
<p>2.1.4 System shall be able to identify infections caused by multiple organisms.</p>	<p>Check one: <input type="checkbox"/> Equipment meets Requirement <input type="checkbox"/> Equipment does not meet Requirement</p>
<p>2.1.5 System shall be user-friendly requiring minimal hands-on time with walk-away capability and present clear visible results for interpretation by the user.</p>	<p>Check one: <input type="checkbox"/> Equipment meets Requirement <input type="checkbox"/> Equipment does not meet Requirement</p>

<p>2.1.6 System shall not be affected by interfering substances such as vaginal lubricants.</p>	<p>Check one: <input type="checkbox"/> Equipment meets Requirement <input type="checkbox"/> Equipment does not meet Requirement</p>
<p>2.1.7 System shall include a specimen transport system that is stable for at least 72 hours at ambient temperature for those specimens collected at outpatient clinics and remote sites requiring an extended transport time. Vendor shall provide manufacturer verified documentation of sample stability for specimens up to 72 hours collection.</p>	<p>Check one: <input type="checkbox"/> Equipment meets Requirement <input type="checkbox"/> Equipment does not meet Requirement</p>
<p>2.1.8 System shall have the ability to perform batch testing. Note: If volume indicates, additional instruments may be required to be added at the facility in order to meet desired turn-around times.</p>	<p>Check one: <input type="checkbox"/> Equipment meets Requirement <input type="checkbox"/> Equipment does not meet Requirement</p>
<p>2.1.9 System shall include a quality control program that meets College of American Pathologists (CAP) and regulatory guidelines and ensures proper test performance including but not limited to: 1) internal quality control with each test performed, and 2) external quality.</p>	<p>Check one: <input type="checkbox"/> Equipment meets Requirement <input type="checkbox"/> Equipment does not meet Requirement</p>
<p>2.1.10 The proposed equipment shall have at least one year proven experience.</p>	<p>Check one: <input type="checkbox"/> Equipment meets Requirement <input type="checkbox"/> Equipment does not meet Requirement</p>
<p>2.1.11 The footprint of system shall be small and fit on a typical laboratory counter top (ie., less than 24" deep x 24"wide x 18" high)</p>	<p>Check one: <input type="checkbox"/> Equipment meets Requirement <input type="checkbox"/> Equipment does not meet Requirement (enter dimensions here) Click here to enter text.</p>
<p>2.2 INSTRUMENTATION AND SOFTWARE</p>	
<p>2.2.1 The vendor is to complete with their proposal the Medical Equipment Pre-procurement Assessment (VA Directive 6550) and Manufacturer Disclosure Statement for Medical Device Security (MDS2) for any medical devices that will be connected to the VA information network. The vendor then shall provide evidence of VA approved remote network communication system that continuously collects and monitors performance data of the analytical systems following all the policies and procedures outlined in the VA Directive 6500, Information Security Program, and its handbooks to ensure appropriate security controls are in place (see Attachments listed in Section D)</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>2.2.2 The vendor shall supply all equipment (to include as required for testing, specimen processor/s and incubator/ heating block unit/s), reagents, and disposables required for operating the microbial identification system and producing quality results.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>2.2.3 System shall have a data management system that allows the user to monitor and analyze data and quality control. System should include flags for unusual results and failed quality control.</p>	<p>Check one: <input type="checkbox"/> Equipment meets Requirement <input type="checkbox"/> Equipment does not meet Requirement Click here to enter text.</p>
<p>2.2.4 Software shall be compatible with all barcode styles and have a proven uni-directional or bi-directional interface capability with VISTA and Data Innovations, or other LSI systems.</p>	<p>Check one: <input type="checkbox"/> Equipment meets Requirement <input type="checkbox"/> Equipment does not meet Requirement Click here to enter text.</p>

<p>2.2.5 Requests for additional instrumentation, upgrades or replacement, due to workload increase, excessive instrumentation/ test kit failures/malfunctions, breakdowns, or service calls will be evaluated as needed and annually by the facility laboratory with communication to the vendor for modification of the contract. A high incidence of problems with any instrumentation/ test kits supplied may indicate probable non-compliance with the terms of this contract and will entitle the facility to replacement with equipment/ test kits that can produce the required criteria of this contract satisfactorily to the user.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>2.2.6 Vendor to provide upgrades to equipment software at no additional charge to the Government.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>2.2.7 Vendor to provide users with utility requirements (electrical, guidelines for disposal of waste and hazardous reagents, etc.). Vendor shall provide a mechanism for the Laboratory to meet local discharge requirements. Any additional costs such as Industrial Funding Fees, special shipping and handling fees, or other usage fees must be clearly indicated in the price quote.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>2.2.8 Vendor to provide users with environmental requirements (heat/cool, humidity, lighting, etc.) for instrument operation and reagent storage. Vendor shall indicate the needs for freezer, refrigerator, etc.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>2.2.9 The vendor shall remove all equipment within 90 days after notification of the expiration of the terms of this contract, but not until the completion of new vendor's equipment installation inclusive of completed cross over studies.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>3. INSTALLATION AND VALIDATION</p>	
<p>3.1 At installation of new equipment, vendor shall provide technical support specialist(s) to assist in equipment installation/set-up, correlation studies (evaluation/comparison of data sufficient to satisfy CAP standards), staff training and methodology problems and questions. Vendor is to supply all validation material for initial validation.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>3.2 Vendor shall provide all manpower, reagents/supplies, procedures/instructions to complete validation studies.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>3.3 Vendor shall provide required statistical analysis in a binder for on-site staff approval. The process must be completed, the data reviewed and Director approval received before leaving the site following the installation of the system at the site.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>4. SUPPORT SYSTEMS (SERVICE, PREVENTATIVE MAINTENANCE, AND SHIPPING OF SUPPLIE(S))</p>	
<p>4.1 Vendor shall provide service sufficient to meet the needs of the using-facility Monday through Friday 8:00am to 4:30pm. Field engineer service support shall be available within three (3) hours of notification, Monday through Friday. All repairs on instrument/equipment must be completed within 24 hours from the time the field engineer arrives. All replacement instrument/equipment must be received within 24 hours from the time the field engineer arrives. Requests for services will be through one contractor.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>

<p>4.2 Vendor shall provide a twenty-four hour/seven-day service hotline with technical support through one contractor. All calls shall be answered within one hour via telephone.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>4.3 Vendor shall provide at no charge all parts necessary for the operation of the system.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>4.4 Service is to include all travel, parts for repair or replacement, and labor.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>4.5 Vendor is to provide alternative testing if the equipment requiring repair is down in excess of 24 hours at no additional cost to the Government. Costs to be reimbursed by vendor for those costs incurred during downtime to include but not limited to, reagents, labor, and reference laboratory services.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>4.6 Vendor shall provide service agreement that includes replacement or repair of all ancillary equipment (i.e. processors, incubators/heating blocks).</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>4.7 The vendor is to define the maintenance required. Vendor is to indicate which maintenance is performed by user and which are not. Vendor is to define actual hands-on maintenance time.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>4.8 Vendor shall provide all necessary MSDS records.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>4.9 Frequency of shipments: Vendor shall provide initial inventory based on expected use, then establish a standing weekly/monthly/quarterly shipment based on current use, with the capacity to fill emergency requests on-demand.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>4.10 Vendor shall pay all routine shipping fees for all supplies, consumables, and equipment to perform testing and will pay for shipping for volume adjustments should additional testing supplies be required.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>5. TRAINING AND PROCEDURES</p>	
<p>5.1 Vendor shall provide all education/training on site during installations or update to the equipment. Training to include staff on all shifts. Training shall include basic operation, quality control, interpretation and reporting of results, required user performed maintenance, and troubleshooting. Vendor shall provide a documented record of training (training checklist) completed for all trained staff before leaving site following installation at the site.</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes: Click here to enter text.</p>
<p>5.2 Vendor shall supply all necessary procedure manuals, troubleshooting manuals and operator manuals (also available on CD format or on-line). Procedures must be in the Clinical and Laboratory Standards Institute (CLSI) format. Vendor shall provide assistance in creating preventive</p>	<p>Check one: <input type="checkbox"/> Vendor Accepts Requirement <input type="checkbox"/> Vendor Rejects Requirement Comments/Requested changes:</p>

maintenance and quality control records or logs to meet the needs of the facility.	Click here to enter text.
6.3 Software is compatible with all barcode styles and has a proven uni-directional or bi-directional interface capability with VISTA and Data Innovations, or other LSI systems.	Check one: <input type="checkbox"/> Equipment meets this characteristic <input type="checkbox"/> Equipment does not meet characteristic Click here to enter text.

Offeror's Company Name

Offeror's Signature and Date