AUTOMATED SYSTEM FOR THE IDENTIFICATION AND SUSCEPTIBILITY TESTING OF MICROORGANISMS (ID/SUS)

SCOPE:

The VISN 6 Medical Centers (VAMC) listed below have a requirement to create a contract for analyzers and supplies in support of the testing for identification and susceptibility on microorganisms isolated from the respective patient populations. These analyzers and supplies must be provided to each Medical Center based on the estimated volumes noted in Section D of the solicitation. The participating VISN 6 Medical Centers are:

1. VAMC Hampton, 100 Emancipation Drive, Hampton, VA 23667
2. VAMC Salem, 1970 Roanoke Blvd, Salem, VA 24153
3. VAMC Beckley, 200 Veterans Avenue, Beckley, WVA 25801
4. VAMC Salisbury, 1601 Brenner Avenue, Salisbury, NC 28144
5. VAMC Asheville, 1100 Tunnel Road, Asheville, NC 28805
6. VAMC Fayetteville, 2300 Ramsey Street, Fayetteville NC, 28301

1. GENERAL REQUIREMENTS

1.1 The contractor shall furnish all clinical laboratory supplies, materials, equipment, and requisite services necessary for the performance of the work as described herein to the participating VAMC facilities in accordance with the applicable Federal Supply Schedule contract. Any agreement resulting from this solicitation will be fixed-price for the duration of the agreement in accordance with the terms and conditions of the contractor's Federal Supply Schedule. A listing of estimated yearly quantities by participating facility to be provided under this agreement is located in Section D. The Government anticipates single award, firm-fixed price contract.

1.2 The system shall streamline all aspects of testing, thereby enhancing operational efficiency, supporting improved patient outcomes, and improving the productivity of the facilities. Vendor shall define measures to streamline testing to promote efficiency.

1.3 The pricing shall be based on new state of the art equipment. Remanufactured or used models will not be accepted. The vendor's offered ID/MIC analyzer shall conform to the facilities/clinics existing space. The vendor shall work with each facility to place an analyzer that best accommodates their defined space requirements.

1.4 Vendors shall provide each participating facility with Food and Drug Administration (FDA) approved analyzer, microorganism identification cards, MIC cards, disposables, and any consumable part necessary for analysis/ testing. The vendor shall list the consumable parts provided. The vendor shall state any parameter or function which is pending FDA approval at the close of this solicitation.

2. SYSTEM REQUIREMENTS

2.1 System must provide these basic tests: Routine identification and susceptibility testing of isolates routinely encountered in a clinical microbiology laboratory including but not limited to:
Enterobacteriaceae,
Pseudomonas,
Non-Enterobacteriaceae (Nonfermenter),
Staphylococcus,
Alpha, beta, and gamma hemolytic Streptococcus,
Enterococcus,
Yeasts, and other miscellaneous organisms.

The system must perform routine identification of Corynebacterium sp., Haemophilus sp., anaerobic bacteria, Neisseria sp., and other HACEK organisms. The system shall follow regulatory agency guidelines including

Clinical and Laboratory Standards Institute (CLSI) and Federal Drug Administration (FDA). The basic ID/Sus test kits include: GN ID; GN AST; GP ID; GP AST; YST ID; NH ID; ANC ID; and AST YST.

2.2 System shall have the ability to accurately detect and report resistance based on naturally occurring (intrinsic), acquired (extrinsic) resistance, and exceptional resistance phenotypes. The system must have the ability to detect resistance by genotype and phenotype comparison.

2.3. System shall have the ability to detect and confirm, when appropriate, emerging resistance patterns including but not limited to extended spectrum beta-lactamase (ESBL) testing, beta-lactamase detection, vancomycin resistance, methicillin resistance, high level aminoglycoside resistance and CRE (carbapenem resistant Enterobacteriaceae) detection, etc. The system must have the capability to confirm ESBL resistance, to confirm inducible clindamycin resistance, and contain the cefoxitin screen for MRSA.

2.4 System shall offer rapid test capability (5-18 hours) and have a low rate (<1%) of supplemental off-line tests.

2.5. System shall have a data management system that allows users to monitor and analyze data. System must allow for the user to set up defined rules and provide a proactive alerting system for defined alerts and unusual results. Data management capabilities must be capable of generating antibiogram reports, the ability to generate MRSA, VRE, CRE, ESBL reports and other user defined custom reports for infection control and antibiotic stewardship.

2.6 System shall allow for a customized reporting format including use of cascade reporting, varied reporting format, selection of antibiotics reported, antibiotic suppression, etc.

2.7 Agreement shall allow flexibility in the selection of panel/card types based on facility needs. Antibiotics available on panels/cards will be current and updated regularly. Panels/cards will be available in both MIC and Breakpoint formats.

2.8. Vendor shall provide information on daily, weekly, monthly, and yearly maintenance and will define the approximate hands-one time to complete this required maintenance.

2.9 Vendor shall provide hard copies or access to electronic copies of all certificates of analysis for the documentation of media as required by CLSI and CAP regulations.

2.10 Instrument/cards/panels shall comply with OSHA's Bloodborne Pathogen Standards.

2.11 System shall provide a rapid, streamlined method of inoculating cards/panels. Vendor shall describe the inoculation process with approximate hands on times included.

2.12 Vendor shall provide initial inventory of supplies based on previous use, then if requested by the facility, work with the facility to establish a standing order based on current use. The vendor should have the capacity to fill emergency orders on demand with shipping charges paid by vendor.

3. INSTRUMENTATION AND SOFTWARE

3.1 Equipment shall include 120 volt UPS system that has a 24 hour backup capability. The vendor will be responsible for replacing the UPS should it become dysfunctional and provide battery replacement as needed.

3.2 Any additional costs such as Industrial Funding Fees, special shipping and handling fees, or other usage fees shall be clearly indicated in the price quote.

3.3 Instrument shall have computer capabilities that are compatible with customer LIS software, offer LCD display monitor with built-in speakers and printer.

3.4 Vendor shall provide technical support and routing to link Data Innovation or Cerner with the instrument by insuring LIS and instruments are communicating properly.

3.5 The system shall support multiple barcode formats including but not limited to Code 39, Code 128, and Codabar or current VA standardized barcode that may be enabled concurrently.

3.6 The system shall have a barcode reader for sample identification and download from host. The barcode reader must be able to read current standardized VA barcode formats.

3.7 The vendor shall provide the following interfacing requirements for the system:

a. Any additional hardware and software needed to interface the analyzer and technical assistance with interfacing the analyzer;
b. Any required (additional) interface connection license(s);
c. Instrument - LIS interface must be bi-directional;
d. Provide documentation of successful interfacing with other VA facilities (provide two VAMC references to include contact person, address, and telephone number);
e. Interface must use automatic host query to download sample ID's, test requests, and patient demographics;
f. Instrument interface must transmit test results to the host computer system via automatic upload;
g. In lieu of an LIS interface, the vendor may provide a TCP/IP interface preapproved/ certified by VACO; for use with VA computer systems and applications such as VistA. Proof of Certification must be provided;
h. The vendor will provide all necessary information (including logical ports) for VA staff to write an access control list.

3.8 The system shall be able to store and retransmit records (24 hours of maximum instrument throughput) in case of interface downtime. The vendor is to state how many samples can be stored. The system shall have the ability to edit sample/patient identifier after interface downtime and then be able to resend the sample/patient information to the host for verification.

3.9 Installation shall include all evaluation/comparison data sufficient to satisfy CAP standards. Vendor shall provide all cross-over supplies and reagents.

3.10 The system shall have an automatic back-up function to store all data from the hard drive. Vendor shall describe the back-up option. The preferred back-up option is storage directly to a VA SAN or other VA storage system.

3.11 The vendor shall provide all upgrades to the equipment hardware, software, and operating systems without additional charge to the Government. These enhancements to the vendor's equipment shall be delivered and installed at the site within two months of their issuance or date of first commercial availability. The vendor will at all times maintain compatibility of systems with whatever host LIS or TCP/IP interface is in place, especially when vendor software is upgraded.

3.12 Requests for additional instrumentation, upgrades, or replacement, due to workload increase, excessive instrumentation / 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 supplied may indicate probable non-compliance with the terms of this agreement and will entitle the facility to replacement with equipment that can produce the required criteria of this contract satisfactorily to the user.

3.13 Service agreement shall include replacement or repair of all ancillary equipment (i.e., printers, monitors, UPS).

3.14 System shall include an on-board QC program capable of printing/displaying all QC/ calibrations. System indicates out-of-limit results.

3.15 Contractor shall remove all equipment within 90 days after notification of the expiration of the terms of this contract but not until the completion of the new vendor's equipment installation inclusive of completed cross over studies. Each facility, per their protocol, will be responsible for the removal / erasing of the hard drive at analyzer removal/upgrade. If a VA facility chooses to retain the hard drive, it will be at no additional cost to the VA.

3.16 Vendor shall provide education/training on site, and basic operating and maintenance training during installations or update to the equipment.

3.17 Vendor shall conduct and complete the Medical Equipment Pre-Procurement Assessment (VA Directive 6550, Section D) for the Office of Information Technology (OI&T) for each facility for any medical devices that will be connected to the VA information network. The vendor then must provide an approved remote network communication system that allows the VA to remotely connect with the vendor's technical services department for purposes of instrument troubleshooting/problem resolution, following all the policies and procedures outlined in VA Directive 6500, *Information Security Program,* and its handbooks to ensure appropriate security controls are in place. Refer to Attachment "VA Information and Information System Security/ Privacy Language" (Section B).

3.18 Vendor shall provide a software package capable of tracking or flagging internal calibration, error messages, and internal temperatures/optics.

3.19 Antivirus software shall be provided by the vendor at no additional cost.

3.20 Vendor shall supply equipment that will perform in relative humidity between 15 to 85 percent and in temperatures between 50 to 90 degrees Fahrenheit (10 to 30 degrees Celsius).

4. INSTALLATION AND VALIDATION

4.1 The vendor shall list analyzer/utility requirements (electrical, water, plumbing, bio-hazardous disposal, etc., and provide weight and dimensions of proposed analyzer.

4.2 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, CLSI and related documents, and Federal Regulations), and staff training.

4.3 The vendor shall provide each participating facility/clinic with all supplies needed at installation and during training of staff. The vendor shall pay all shipping costs for the analyzers and all supplies needed for the installation, correlation studies and training of staff. Test counts for billing will begin after all CAP required studies, performed at installation of new equipment, are reviewed, approved by the department supervisor and the Chief Pathologist, and the analyzer has been placed in use for patient testing.

4.4 At installation/set-up the vendor/technical support specialist shall perform and place in a labeled binder all validation studies including: installation/set-up, correlation studies, linearity and cross-over studies. Evaluation/ comparison data shall be sufficient to satisfy CAP standards and shall be completed within two weeks of installation at each facility/clinic. The support specialist shall assist with staff training, in-services to laboratory personnel and clinicians, and assist with any methodology problems and questions. The technical support specialist must be available for installation/set-up/validation studies/training for a minimum of 40 hours during regular office hours on a 5 days/week basis.

4.5 The vendor shall provide equipment installation and possible reinstallation costs if the equipment is required to be moved due to construction or laboratory redesign.

4.6 The vendor shall specify their routine shipment table of supplies, whether monthly or quarterly, and how much storage space would be needed for each. The vendor shall ensure that all reagents/supplies received, whether it is monthly or quarterly standing order, have at least a six month expiration date. The vendor shall work with each facility/clinic to adjust reagent supply to match workload changes and to provide the option annually for each facility/clinic to adjust the shipment table. The vendor shall state what their policy is in regards to adjusting a standing order or ordering an additional shipment of supplies.

5. SUPPORT SYSTEMS (SERVICE, PREVENTATIVE MAINTENANCE AND SHIPPING OF SUPPLIES)

5.1 Vendor shall provide technical support services at no additional charge to all VISN 6 facilities. Technical support by telephone shall be available 7 days a week, 24 hours a day. Technical support shall return all downtime calls within one hour. Should on-site service be required, the contractor's field service organization shall provide on-site service response within 24 hours after being contacted. All replacement instrument/equipment must be received within 24 hours from the time the on-site service arrives. The repair person shall also, prior to departure, provide the visited site with written documentation of services performed.

5.2 Technical support shall place a service call for repairs if the technologist is unable to repair the analyzer within one hour of trouble-shooting with the hotline or on weekends/holidays/irregular tours when technologists may be unable to work with the hotline due to the facilities staffing.

5.3 Service shall include, at no charge, all labor, travel, and parts necessary to make repairs.

5.4 Requests for services shall be through one contractor.

5.5 The vendor shall provide instrument support service sufficient to provide assistance with troubleshooting and repair of the analyzer. The vendor may list their service options available. Or the following service option may be available: 24 hours/day, 7 days/week basis for hospitals, and 5 days/week basis for clinics. The support service shall follow-up all down calls within 1 hour. The FSR at all times shall keep the facility/clinic informed of the time line for when repairs are to be completed. All repairs on instrument shall be complete (at no cost to the facility/clinic) within 24 hours from the time the field service engineer arrives.

5.6 The vendor shall pay for the laboratory testing at a reference facility if the equipment requiring repair is inoperative due to malfunction through no fault or negligence of the facility/clinic for a total of more than 24 hours. The cost incurred from the reference facility testing, packaging and shipping will be applied to the invoice in the form of a credit or deduction. Downtime for each incident shall start from the time the facility/clinic makes a bona fide attempt to contact the vendor's designated representative until the analyzer is returned to good operating order.

5.7 In the event that the consumables are found to be defective and unsuitable for use with the vendor's equipment, or the vendor has failed to comply with the requirements for routine supply delivery, the contractor shall deliver the consumable supplies within a period of twenty-four hours after receipt of the verbal order for priority delivery from the Government activity. If either circumstance has occurred, the contractor shall deliver to the requesting VISN 6 facility site, in the most expeditious manner possible, without additional cost to the Government, the necessary consumables in sufficient quantity as required to allow operation of the contractor's equipment for one week (under normal Government test load volume). If additional requests for emergency supply delivery are required by the Government, they will be honored by the vendor until the arrival at the Government site of the monthly standing order/routine supplies delivery. Failure to reserve adequate inventory may result in action taken by the Contracting Officer.

5.8 Vendor will pay all routine shipping fees for all supplies, consumables, and equipment to perform testing and will pay for shipping for volume adjustments should additional supplies be required. Vendor should pay for shipping charges for emergency orders. Vendor will state how reagents /supplies are shipped, taking into account temperature sensitive shipping requirements.

5.9 The vendor shall provide replacement parts at no charge and any components necessary for the operation of the instrument(s) to produce patient results.

5.10 The vendor's technical service representatives shall comply with each facility's requirements for onsite vendor representatives. This may require a low risk background investigation by federal authorities paid for by the vendor.

5.11 Vendor shall provide a preventative maintenance schedule to include a minimum of two scheduled preventative maintenance visits per year.

5.12 A preventative maintenance schedule shall be provided, to include a minimum of two scheduled preventative maintenance visits per year for vendor providing services.

6. TRAINING AND PROCEDURES

6.1 Vendor shall provide all education/training on site during installations or update to the equipment. Training will include staff on all shifts if requested by the facility. Training must include basic operation, interpretation and reporting of results, required user performed maintenance, and troubleshooting. Vendor must provide a documented record of training (training checklist) completed for all trained staff before leaving site following installation at the site.

6.2 Vendor shall provide initial in-depth training for two key operators at each site and annual training for one VA equipment operator, per participating VISN 6 Medical Center Key operator training is to include all costs of off-site training, i.e., transportation (air and ground), room and board, etc.

6.3 Vendor shall provide on-site refresher instrument training in renewal option years of the contract if so exercised.

6.4 Vendor shall supply all necessary procedure manuals, troubleshooting manuals, operator manuals, and MSDSs (also available on CD format or on-line). Procedures must be in the Clinical and Laboratory Standards Institute (CLSI) format. Vendor must provide assistance in creating preventative maintenance and quality control records or logs to meet the needs of the facility.