

STATEMENT OF WORK (SOW)

FOR

MICROBIOLOGY ANALYZER

INTRODUCTION

The 99th Medical Group Clinical Pathology Department is seeking a vendor who can provide automated microbial identification and antibiotic susceptibility testing of various bacterial and yeast organisms. The requirement is for an Indefinite Delivery Infinite Quantity contract with one year base contract and 4 option years.

BACKGROUND

The Microbiology department at the 99 MDG performs extensive testing on patient specimens. The results of these tests are used by providers to aid in the diagnosis and treatment of injuries and disease as well as the prescribing of medications. Automated microbial identification and antibiotic susceptibility testing supports the 99 MDG in providing preventative, emergency, and acute care services for approximately 238K beneficiaries to include active duty, Guard, Reserve, NATO, retirees, VA, and all eligible dependents.

SCOPE

The vendor shall provide all personnel, equipment, tools, materials, reagents, supervision, transportation, service/operator's manuals and other items and services necessary for the installation and maintenance of the Microbiology Identification and Antibiotic Susceptibility Testing analyzer and ancillary equipment in the Microbiology Laboratory located at the Mike O'Callaghan Military Medical Center, Nellis AFB, NV. Vendor shall comply with current National Electric Code (NEC), National Fire Protection Association (NFPA) standards, and all Environmental and Safety codes, laws, and regulations. Contract pricing shall be all-inclusive, and vendor shall submit a Cost Per Test (CPT). The services shall be provided for a base year with 4 option years.

LOCATION

The delivery area for the analyzer and the reagents is the 99 MDG Medical Logistics Warehouse, 5601 Stafford Dr, Building 1301, Las Vegas, NV 89191. The analyzer will be located in Building 1300, Room 1256 after delivery & installation.

MINIMUM REQUIREMENTS FOR MICROBIOLOGY IDENTIFICATION AND ANTIMICROBIAL SUSCEPTIBILITY TESTING

A. GENERAL REQUIREMENTS

- Instruments and assays are FDA cleared/approved (vendor must provide proof of certification)
- System must have automated microbial platform capable of identification and susceptibility testing.
- System must be capable of automated panel/plate inoculation and loading.

- System must be capable of automated ejection at completion of testing into appropriate biohazard waste receptacle.
- System must be capable of processing a minimum of 50 panels per day. The vendor will provide instrumentation, reagent and consumables to complete approximately 3,250 Identifications and 2100 antimicrobial susceptibility panels annually.
- Must be able to perform ID and AST on minimal organism colonies from aerobic, throat, blood, stool, respiratory, and urine specimens/cultures.
- Must have specialty identification panels for Yeast, Anaerobes, Haemophilus and Neisseria
- Analyzer must have a closed system to avoid leakage and contamination.
- System must have an Authority to Operate and/or be approved for connection/interfacing to the Military Health System Genesis platform.
- Vendor will supply an uninterruptable power supply (UPS) for each computer/instrument system capable of maintaining instrument operations for a minimum of 15 minutes.
- System must utilize standard 110 V power.
- All system requirements (instrument, peripherals, UPS, printer) must fit into a space no larger than 60 x 60 x 34
- Equipment/Software must allow for customizable reports
- Equipment/Software must have audit trail capability (operator ID, panel type, date loaded, etc.)
- All gram positive and gram-negative identification results must not be held for greater than 24 hours from the time they are placed on the analyzer
- All organism identification results must be objective without technician manipulation.
- System should have method to perform automated optical reads of onboard cards/plates every 15 minutes.
- Vendor must assess equipment, workflow, workload volumes and space to meet the individual site requirements with minimum costs.

B. MIDDLEWARE REQUIREMENTS:

- Operating System will run on Windows 7 or newer and will be upgraded as necessary to ensure system is maintained in accordance with Defense Health Agency/Air Force guidance
- System must have auto-verification capabilities
- System must provide bi-directional laboratory information system that is compatible with Medical Health System Genesis or the current LIS system of MOMMC laboratory.
- System should have capability of interface link between Biochemical ID instrumentation, and Antibiotic Susceptibility Instrumentation

C. SERVICE/MAINTENANCE REQUIREMENTS:

- Maintain the instrument, the system's computer(s) and software at its fullest capability for the term of this agreement at the business hours agreement stated below to include remote troubleshooting as is needed.
- The instrument will have an average mean time between failure of at least 400 days.
- If a replacement system is needed before the end of the term, the contractor will provide a replacement at no cost to the government. The system replacement will take place after the manufacturer has exhausted its troubleshooting options through its service escalation process.
- All vendor employees must check in with the 99th Medical Group's Biomedical Equipment Repair Office (BMET) prior to performing any repairs or maintenance.

- When all necessary repairs or maintenance are completed, the vendor's representative will supply the laboratory with a detailed service report (written or electronic) prior to departing the facility. Additionally, the vendor representative must check out with the BMET office.
- The vendor shall provide a maintenance and service agreement to include:
 - Years 1-5: must provide at least a routine service IAW manufacturer's standards (Mon-Fri, 0700-1600).
 - If on-site repair is needed based on vendor service escalation process, response shall be within 24 hours.
 - The vendor will monitor equipment and ensure instrument downtime does not exceed 48 hours for a single occurrence.
 - Technical phone support 24 hours a day/7 day a week (including holidays).
 - Receive one (1) preventative maintenance visit per year with 48-hour notice prior to arrival.
 - The vendor shall be responsible for all parts required to maintain a serviceable instrument.

INSTALLATION/OPERATIONAL REQUIREMENTS:

- The Vendor shall provide the government fourteen (14) days advanced written notice before commencement of work. Vendor shall identify in writing to Microbiology supervisor the names and number of individuals that will be working during installation.
- The vendor will send factor trained representatives to install, validate, and correlate analyzers per College of American Pathologist guidelines at the company's expense with results approved by the Laboratory Medical Director and Microbiology Technical Supervisor.
- The vendor shall assist with set-up and validation of auto-verification rules.
- Vendor must provide a specialist to perform instrument installation, correlation, and instrument rule validation prior to live patient testing.
- Vendor must assist in the acquisition of specimens required for validation/correlation.

TRAINING REQUIREMENTS

- Vendor shall provide initial training and recurring training to technicians on instrument use, maintenance, and troubleshooting.
 - Initial training will be provided for a maximum of 3 technicians in person on-site by a factor trained representative.
 - Recurring training shall include a web-based training program available on demand, or an equivalent training program accessible through the year, and quarterly onsite training. The web-based training program, or its equivalent, must allow for an unlimited number of trainees to have personalized training plans that are accessed and tracked. Web-based training, or its equivalent, shall include instructions for operation and maintenance of all included equipment.
- At least quarterly, the contractor will provide a factory trained representative to provide hands-on analyzer training to conduct onsite training for one day. Contractor shall provide comprehensive written operating instructions for all aspects of equipment functions (i.e., routine specimen analysis, calibrations, etc.) and training materials to MOMC equipment operators on the daily, weekly, monthly, and as required maintenance when required or requested by the contracting officer. If the testing capabilities increase beyond the capabilities of the instrument additional instrumentation/training will be provided to continue testing.

SHIPPING AND HANDLING

The vendor shall provide all manufacturer brand reagents and consumables necessary to meet the required test volume as stated in the General Services Administration (GSA)/Federal Supply Schedule (FSS) Price List assuming reasonably efficient utilization and utilize Cost Per Reportable Test pricing.

- These reagents and consumables must be provided on an as-needed basis at no additional cost to the government.
- The mode of shipment used shall be appropriate for the product being shipped to arrive within manufacturer's specifications.
- The shipment of any temperature-controlled products that are restricted from shipping over weekends and holidays shall be sent to arrive during normal duty hours (0700-1600 Mon-Fri).
- The vendor must provide all freight charges incurred to have the instrument delivered for installation.
- The vendor shall provide all manufacturer brand repair parts/materials at no additional cost to the government.
- The vendor shall provide service to the Myla middleware.

HOURS OF OPERATION: The laboratory operates on a 24-hour basis. Normal work hours are from 0700 to 1600 hours, Monday thru Friday, excluding holidays and family days. Off-shift work hours are 1600 to 0700 hours, Monday through Sunday. Requests for work during off shift work hours must be coordinated and approved by Laboratory Management.

- Delivery of consumables shall be done during normal business hours (0700-1600 Monday through Friday).
- No preventative maintenance or consumable deliveries shall be made on Saturday, Sunday, or federal holidays as shown:
 - New Year's Day – 1 January
 - Martin Luther King Day – Third Monday in January
 - President's Day – Third Monday in February
 - Memorial Day – Last Monday in May
 - Juneteenth National Independence Day- 19 June
 - Independence Day – 4 July
 - Labor Day – First Monday in September
 - Columbus Day – Second Monday in October
 - Veteran's Day – 10 November
 - Thanksgiving – Fourth Thursday in November
 - Christmas Day – 25 December

SUPERVISION: The laboratory POCs shall be the Microbiology Technical Supervisor (TSV) 702-653-2809 and Officer in Charge (OIC), 702-653-2847.

- Laboratory leadership will ensure a minimum of one (1) technician remains on-site during the length of the installation project to safeguard/secure laboratory supplies.

GENERAL INFORMATION: When the vendor representative is working in a potential infectious area of the laboratory, they must wear a lab coat and gloves which will be provided.

CLEAN-UP: The vendor's personnel shall maintain the work area in a clean condition by the end of the contract performance period. Vendor shall dispose of all waste appropriately.

APPEARANCE: Vendor's personnel shall present a neat appearance and be easily recognized. This may be accomplished by wearing distinctive clothing bearing the name of the company or by wearing appropriate badges, which contain the company and employee's name. The wear of open-toed shoes and sleeveless clothing is prohibited for safety and infection control purposes.