DRAFT Statement of Need
Microbiology Section of P&LMS

1. **GENERAL:** The Contractor shall provide the Brand name or equivalent Bacterial/Mycobacterial identification and susceptibility instrument(s), reagents, and required disposables to the Microbiology section of the Pathology and Laboratory Medicine Service of the James A. Haley Veterans' Hospital (JAHVH) in Tampa, Florida. All work is to be performed in accordance with guidelines established by Federal, State and local ordinances, with the FDA and manufacturer's guidelines, and with all terms, conditions, provisions, schedules and specifications provided herein.

2. **SCOPE:** The JAHVH is seeking a Cost per Test (Reagent Rental) agreement which includes: a) equipment rental, b) reagents and controls, c) service and necessary maintenance & parts to keep the equipment in optimal operating conditions, d) operational hardware and software upgrade/updates, e) user training for government personnel, f) reagents' delivery costs, g) consumables for the lifetime of the contract. Contractor is required to provide delivery and installation of equipment, as well as equipment return at end of contract, at no additional charge.

3. **EQUIPMENT: The System Basic Requirements:**
   a. Must contain random access technologies that improve workflow.
   b. Must require minimal maintenance including limited reagent preparation prior to use.
   c. Must have modem troubleshooting capabilities which meets HIPAA and VA confidentiality requirements for customer support staff and remote diagnostic services. The vendor must obtain a virtual private network (VPN) to be able to configure the system to allow for diagnostics and troubleshooting and support services.
   d. Only instruments which are FDA approved will be considered, and they must be operational and interface with *VA Laboratory Computer systems and upgrades.* Test methods must be FDA approved with limited recalls due to product failures. This must be a "turn-key" system.
   e. Not to exceed total space limitations for entire system 184" length x 36" width based on existing equipment.

   Bacterial/Yeast ID and Antimicrobial Susceptibility Testing (AST) Analytical System for the JAHVH Microbiology Laboratory:
   a. Expected throughput: Ability to manage testing workflow of high volume laboratory with greater than 12,000/ tests/year where at least 90% of the testing is performed during the day shift (6:30am-4pm) Sunday through Saturday.
   b. Specimen integrity evaluation on all supplies as needed at no additional cost.
   c. The system must be barcode driven, random access, with continuous loading and unloading of cards and consumables. The system must be compatible with the 4 VITEK multiple barcoding sample/card prep stations that the government purchased last year.
   d. The AST dilution station must be contained in the main system for efficient workflow.
   e. No additional reagents will be required after incubation of the identification cards.

   Microbiology Mass Spec Identification System for the JAHVH Microbiology Laboratory:
   a. Expected throughput: Ability to manage testing workflow of high volume laboratory of 192 tests per run with the ability to perform 192 tests in less than 200 minutes.
   b. Mass Spec slides must be disposable and have a built in barcode for traceability.
   c. FDA approval required for testing of 190 most common organisms. Must have FDA approval for gram negative, gram positive, yeast and anaerobic organisms.

   Middleware- Integrated Data Management for the JAHVH Microbiology Laboratory:
   a. Integrated central processing unit with sufficient data storage capacity to accommodate and provide immediate access to more than 2,000 patient records per day.
   b. Ability to connect rapid microbiology identification and susceptibility systems for specimen management and traceability.
   c. Specimen Integrity based rules to identify unusual phenotypes and make therapeutic corrections.
   d. Bi directional Interface — shall be able to interface and automate the Microbiology instruments with orders and results separated for optimal transmission capable of automatically uploading test results.

e. FDA approved database software required.
f. Software management with rules capable of preparing data for auto validation prior to host transmission.
g. System must interface instruments to Data Innovations.
h. Must include a Quality Control (QC) program that is compliant with regulatory agencies such as College of American Pathologists (CAP) and Clinical Laboratory Standards Institute (CLSI).
i. The contractor shall provide all required upgrades to the equipment hardware and operating software without additional charge to the facility.

TRAINING OF OPERATING PERSONNEL:

a. The contractor shall include off-site (manufacturer facility) training for two key operating personnel for each instrument installed and all automation system components at the time of installation of the contractor's equipment and each year thereafter that the contract remains in effect. User training is to include all costs of off-site training, training manuals, instructional videos, other appropriate course materials, transportation (air and ground), room and board.
b. On-site training by vendor shall also be supplied to all laboratory staff as needed.
c. Vendor shall provide/install/train users on the data management system with either off site or in house training. On-site refresher training in renewal option years of the contract shall also be made available annually.
d. In addition, the contractor shall provide supplemental operating training to above government personnel, without additional charge to the government, upon installation of the upgrade in equipment hardware or operating system software connected with the operation of an instrument already furnished.
e. The contractor, at his/her discretion, may make additional training available at his/her facility on terms and conditions mutually agreed upon by the agency and the contractor.

4. **REAGENTS AND CONSUMABLES:** Instruments use shall include all reagents and consumables required to produce a high quality patient result. The reagent quality must be high enough to satisfy proficiency testing standards of the College of American Pathologists (CAP) and The Joint Commission (TJC).

5. **SITE PREPARATION:** Specifications shall be furnished in writing by the contractor as part of the equipment proposal. These specifications shall be in such detail as to ensure that the equipment to be installed shall operate efficiently and conform to the manufacturer's claimed specifications. The government shall prepare the site at its own expense and in accordance with the specifications furnished by the contractor. Any alterations or modifications in site preparation which are attributable to incomplete or erroneous specifications provided by the contractor which would involve additional expense to the government, shall be made at the expense of the contractor. Configuration of the proposed equipment must be able to conform to the space previously allotted for this function. Crossover from current to new instrumentation must be performed timely with no interruption in patient care.

6. **OWNERSHIP OF EQUIPMENT:** shall remain with the contractor. All equipment accessories (hardware and software) furnished by the contractor shall accompany the equipment when returned to the contractor. The contractor, upon expiration of order(s) at termination and/or replacement of equipment, will remove the equipment. The contractor will disconnect the equipment and will be responsible for all packing and shipping required to remove the equipment within ten business days. Any computer hard drive that contains Personal Health Information (PHI) will remain in the possession of the JAHVH.

7. **INSTALLATION PROCEDURES**: The contractor shall be responsible for installation, which consists of in-house delivery, positioning, and mounting of all equipment listed on the delivery order and connections of all equipment and interconnecting wiring and cabling if applicable. Upon receipt of notice to proceed with installation, it shall be the contractor's responsibility to inform the Contracting Officer of any problems which may be anticipated in connection with installation or which will affect optimum performance once installation is completed. In the event that progress of the installation is interrupted through no fault of the contractor, the continuous installation referenced in the preceding paragraphs may be terminated until such time as the cause of delay has been eliminated, and then shall be resumed within 24 hours after the contractor has been notified that work may again proceed.

8. **MAINTENANCE:**

a. The contractor shall provide maintenance (labor and parts) to keep the equipment in good operating condition and subject to security regulations. The government shall provide the contractor access to the equipment to perform maintenance services. The contractor shall provide the government with a designated point of contact for maintenance.

b. The contractor shall perform emergency repair service within 24 hours of the time of notification of the malfunction.

c. The contractor shall furnish a malfunction incident report to the installation upon completion of each maintenance call. The report shall include, as a minimum, the following: (a date and time of notification, (b) date and time of arrival, (c) serial number type and model number(s) of equipment, (d) time spent for repair, (e) description of malfunction and (f) proof of repair. Parts (e) and (f) shall be written verification of quality control for a sample run.