

Attachment B: Statement of Work

STATEMENT OF WORK

1. GENERAL: The purpose of this contract is to obtain a Cost Per Test (Reagent Rental) Award for Real Time PCR analyzers and reagents for the Microbiology / Molecular Diagnostics at the James A. Haley Veterans Hospital (JAHVH), Tampa, Florida. The equipment must be capable of detecting MRSA from Nasal Swabs, MTB/RIF from respiratory samples, C-diff and Norovirus from stool samples, Vancomycin Resistant Enterococcus (VRE), Carba-R from rectal swabs, Influenza A, B, and H1N1, Enterovirus (EV), RSV, BCR/ABL, Factor II (P20210A), and Factor V Leiden.

2. SCOPE: The JAHVH is seeking Cost per Test Contract 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. TERM of CONTRACT: The contract term is for a 12-month base, with four options of 12 months, each beginning upon signature of the contract. The JAHVH will issue a delivery order only for the base contract year. The VA's obligation under this contract shall terminate at the end of each contract year. The JAHVH shall unilaterally renew by issuing a renewal delivery order that shall be effective on the first day of each succeeding 12-month period.

4. ESTIMATED COST PER TEST PRICING

The Cost Per Test award will include pricing to perform the following **estimated** annual patient testing:

17,400	MRSA	2800	Influenza A / B / H1N1
15	MTB/RIF	14	Enterovirus
1200	C Diff	2800	RSV
100	Norovirus	550	BCR/ABL
15	VRE	320	Factor II / V
30	Carba R		

CLINICAL LABORATORY INSTRUMENTS

5. EQUIPMENT CAPABLE OF DETECTING MRSA FROM NASAL SWABS, MTB/RIF FROM RESPIRATORY SAMPLES, C-DIFF AND NOROVIRUS FROM STOOL SAMPLES, VANCOMYCIN RESISTANT ENTEROCOCCUS (VRE), CARBA-R FROM RECTAL SWABS, INFLUENZA A, B, AND H1N1, ENTEROVIRUS (EV), RSV, BCR/ABL, FACTOR II (P20210A), AND FACTOR V LEIDEN: The purpose of this solicitation is to identify the salient characteristics of Real Time PCR instrument(s) capable of performing Real Time PCR testing with specific functionality and performance-based requirements of the system. The quote shall provide descriptive literature that meets the following specifications:

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Characteristics of the Laboratory Instrument System

- The instrument(s) must contain random access technologies on an integrated platform that improve workflow processes in the laboratory. It must reduce turnaround times, minimize individual analyzers and maximize efficiency.
- The analyzer(s) must provide a high throughput that can handle approximately 32 tests in 2 hours for the JAHVH.
- The equipment must be able to run individual samples without the need for batching or running external daily Quality Control (QC), provide for reagents room or refrigeration temperature storage conditions, and have the ability to run different assays simultaneously.
- Configuration shall include an on-board QC program capable of printing/displaying all internal QC/calibrations to facilitate the detection of outliers or failures.
- The instrument(s) must provide closed-cartridge technology to reduce cross-contamination.
- Bar-coded data entry capabilities.
- Fast, easy setup and walkaway operation.
- Reagent stability should be at least 12 months.
- The analyzer(s) must have the capability to process more than 4 different assays at the same time.
- The vendor must provide the reagents, controls and consumables necessary to perform the tests. The vendor is required to provide instrumentation that meets all laboratory requirements. Discontinued models are not acceptable.
- The vendor must provide the appropriate UPS for the instrument and replace it when necessary. Printers must also be provided and replaced when broken.
- The analyzer must have a dedicated STAT port that accepts samples at any time.
- All work shall be performed in accordance with the guidelines established by Federal, State and local ordinances, FDA manufacturer's guidelines, and with all terms, conditions, provisions and specifications provide herein.

Performance Requirements:

Equipment Capabilities:

The clinical laboratory system offered under this contract shall comply with all general requirements stated herein. The offered clinical system software shall have the immediate capability to interface with the Governments' current VISTA system, if required, without using commercial software packages.

The contractor shall provide the following new state-of-the-art equipment with all attachments and accessories:

Testing System

- Fully-integrated System
- Automated real-time PCR Testing
- Self-contained Test Cartridges
- CLIA Moderate Complexity
- Random Access Platform
- Bi-directional Interface
- User friendly software that provides access to amplification curves within runs
- Ability to run multiple assay protocols simultaneously
- 6 Color excitation and detection modules for multiplexing; provides thermal and optical data in real time, increasing the number of targets and controls available in tests design and implementation
- Shall transmit data through a network connection if required

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Software:

- Contractor shall provide all necessary software/hardware (drivers) for bidirectional interface with Data Innovations
- Shall provide supporting documentation required to maintain or improve level of data retrieval, which may be used for epidemiology measures
- Shall be capable of printing/displaying all internal QC/calibration
- Shall be compatible with the present barcode styles formats being utilized

Ancillary:

- The printer and the UPS shall be replaced by the contractor when inoperable for the lifetime of the contract
- The contractor shall provide all upgrades to the equipment hardware and operating system software, all-inclusive with established cost
- An operator's manual shall be furnished with each model supplied. Electronic formats (e.g. on CD) are acceptable. Procedures shall be provided in accordance to the Clinical and Laboratory Standards Institute (CLSI) format
- A Service manual shall be furnished with each model supplied. Electric formats (e.g. on CD) are acceptable

The Contractor shall provide reagents for the validation and implementation of new assays and the cost will be borne by the contractor. The contractor will provide all operational upgrades to the equipment hardware and operating system software that materially affects the performance of the equipment, without additional charge to the government. These enhancements to the contractor's equipment shall be delivered to the government site and installed by the contractor within 60 days of their issuance or date of first commercial availability.

All models shall perform satisfactorily at any laboratory temperature between 59 and 89 degrees F (15 and 32 degrees Celsius). All models shall perform satisfactorily at any laboratory relative humidity <80% at 32C (89F) without condensation. An electronic operator's manual must be furnished with each model supplied. Trade-in of existing equipment will be negotiated at JAHVH and not included in the scope of this contract.

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 manufacturers 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.

With all new equipment, Ownership of Equipment shall remain with the contractor for the life of the contract. The standard and acceptance of performance shall begin on the installation date. It shall end on the earlier date of when a certificate of acceptance has been signed or the equipment has met the standard of performance for a period of 30 consecutive calendar days by operating in conformation with the contractor's technical specification or as quoted in any contract at effectiveness level of 90% or more. In the event the equipment does not meet the standard of performance during the initial 30 consecutive calendar days, the standard of performance test shall continue on a day-by-day basis until the standard of performance is met for a total of 30 consecutive days.

All equipment accessories (hardware or 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

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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.

Operational use time for performance testing for a system is defined as the accumulated time during which the equipment is in actual use. System failure downtime is that period when any machine in the system is inoperable due to equipment failure. Downtime for each incident shall start from the time the government makes a bona fide attempt to contact the contractor's designated representative at the prearranged contact point until the system or machine(s) is returned to the government in proper operating condition.

During the performance period for a system, a minimum of 100 hours of operational use time with productive or simulated work will be required as a basis for computation of the effectiveness level. However, in computing the effectiveness level, the actual number of operational use hours shall be used when more than the minimum of 100 hours. The government shall maintain appropriate daily records to satisfy the requirements of this paragraph and shall notify the contractor in writing of the date of the first day of the successful performance period. Operations use time and downtime shall be measured in hours and whole minutes.

6. GOVERNMENT'S RESPONSIBILITY: The user will perform daily routine operator maintenance and cleaning as required in the manufacturer's operation and maintenance instructions.

7. PERFORMANCE, DELIVERY, INSPECTION AND ACCEPTANCE: The VA shall require the contractor to deliver the equipment ordered under this contract not later than SIXTY (60) calendar days after receipt of notice of award.

a. Reagents Delivery terms, Quality of Reagents, Supplies and Disposables: The VA shall require the delivery of reagents for all services required under this contract. The contractor shall deliver reagents, shipping cost included, monthly from call orders of a JAHVH representative. The contractor will assure that all supplies provided/ordered for use on their equipment will be of the quality necessary to produce a quality slide product. The reagent quality must be high enough to satisfy proficiency testing standards of the College of American Pathologists (CAP) and The Joint Commission (TJC).

b. 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 installation may be suspended until such time as the cause of delay has been eliminated. The Contractor shall resume the subject installation within 24 hours after the contractor has been notification.

8. MAINTENANCE: 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. Preventive maintenance by contractor will provide regular, scheduled maintenance to assure the continued reliable operation of the equipment. These preventive maintenance visits shall be of a frequency that conforms to the manufacturer's operation and maintenance instructions for the supported equipment

9. TRAINING: The contractor, without additional charge to the government, shall provide training at a government location for two (2) operating personnel at the time of installation of the contractor's equipment. In addition, the contractor shall provide supplemental operating training to the government personnel, without additional charge to the government, upon installation of an upgrade in equipment hardware or operating system software connected with the operation of an instrument already furnished.

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10. SERVICE: Emergency repairs shall be performed within 24 hours after notification that the equipment is inoperative. The scheduled maintenance and service shall be performed by a qualified engineer with notice to the Contracting Officer Representative (COR). JAHVH normal business hours are 6:00 am - 6:00 p.m., excluding weekends and holidays. Telephone response does not satisfy this requirement. The contractor shall provide the government with a designated point of contact and shall make arrangements to enable his maintenance representative to receive such notification. The contractor will provide all parts and labor needed to repair the malfunction. The travel, per diem and other expenses associated with the repair will be borne by the contractor. Otherwise, all services will be performed at no charge to the Government during this period.

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.

With No Sensitive Data but Requires Training

VA INFORMATION AND INFORMATION SYSTEM SECURITY/PRIVACY LANGUAGE

VA INFORMATION CUSTODIAL LANGUAGE:

- a. Contractors, contractor personnel, subcontractors, and subcontractor personnel shall be subject to the same Federal laws, regulations, standards, and VA Directives and Handbooks as VA and VA personnel regarding information and information system security.
- b. 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.
- c. A contractor/subcontractor shall request logical (technical) or physical access to VA information and VA information systems for their employees, subcontractors, and affiliates only to the extent necessary to perform the services specified in the contract, agreement, or task order.
- d. All contractors, subcontractors, and third-party servicers and associates working with VA information are subject to the same investigative requirements as those of VA appointees or employees who have access to the same types of information. The level and process of background security investigations for contractors must be in accordance with VA Directive and Handbook 0710, *Personnel Suitability and Security Program*. The Office for Operations, Security, and Preparedness is responsible for these policies and procedures.

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 COR and simultaneously, the designated ISO and Privacy Officer for the contract of any known or

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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 VA information, obtain monetary or other compensation from a third party for damages arising from any incident, or obtain injunctive relief against any third party arising from, or related to, the incident.

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.

SECURITY CONTROLS COMPLIANCE TESTING:

On a periodic basis, VA, including the Office of Inspector General, reserves the right to evaluate any or all of the security controls and privacy practices implemented by the contractor under the clauses contained within the contract. With 10 working-days' notice, at the request of the

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government, the contractor must fully cooperate and assist in a government-sponsored security controls assessment at each location wherein VA information is processed or stored, or information systems are developed, operated, maintained, or used on behalf of VA, including those initiated by the Office of Inspector General. The government may conduct a security control assessment on shorter notice (to include unannounced assessments) as determined by VA in the event of a security incident or at any other time.

TRAINING:

a. All contractor employees and subcontractor employees requiring access to VA information and VA information systems shall complete VA Privacy and Information Security Awareness and Rules of Behavior Training before being granted access to VA information and its systems.

(1) Sign and acknowledge (either manually or electronically) understanding of and responsibilities for compliance with the *Rules of Behavior* before being granted access to VA information and its systems.

b. The contractor shall provide to the contracting officer and/or the COR a copy of the training certificates and certification of signing the Rules of Behavior for each applicable employee within 1 week of the initiation of the contract and annually thereafter, as required.

c. Failure to complete the mandatory annual training and sign the Rules of Behavior annually, within the timeframe required, is grounds for suspension or termination of all physical or electronic access privileges and removal from work on the contract until such time as the training and documents are complete.

The Certification and Accreditation (C&A) requirements do not apply and a Security Accreditation Package is not required for this SOW.

Records Management Contract Language

The following standard items relate to records generated in executing the contract and should be included in a typical Electronic Information Systems (EIS) procurement contract:

1. Citations to pertinent laws, codes and regulations such as 44 U.S.C chapters 21, 29, 31 and 33; Freedom of Information Act (5 U.S.C. 552); Privacy Act (5 U.S.C. 552a); 36 CFR Part 1222 and Part 1228.
2. Contractor shall treat all deliverables under the contract as the property of the U.S. Government for which the Government Agency shall have unlimited rights to use, dispose of, or disclose such data contained therein as it determines to be in the public interest.
3. Contractor shall not create or maintain any records that are not specifically tied to or authorized by the contract using Government IT equipment and/or Government records.

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4. Contractor shall not retain, use, sell, or disseminate copies of any deliverable that contains information covered by the Privacy Act of 1974 or that which is generally protected by the Freedom of Information Act.
5. Contractor shall not create or maintain any records containing any Government Agency records that are not specifically tied to or authorized by the contract.
6. The Government Agency owns the rights to all data/records produced as part of this contract.
7. The Government Agency owns the rights to all electronic information (electronic data, electronic information systems, electronic databases, etc.) and all supporting documentation created as part of this contract. Contractor must deliver sufficient technical documentation with all data deliverables to permit the agency to use the data.
8. Contractor agrees to comply with Federal and Agency records management policies, including those policies associated with the safeguarding of records covered by the Privacy Act of 1974. These policies include the preservation of all records created or received regardless of format [paper, electronic, etc.] or mode of transmission [e-mail, fax, etc.] or state of completion [draft, final, etc.].
9. No disposition of documents will be allowed without the prior written consent of the Contracting Officer. The Agency and its contractors are responsible for preventing the alienation or unauthorized destruction of records, including all forms of mutilation. Willful and unlawful destruction, damage or alienation of Federal records is subject to the fines and penalties imposed by 18 U.S.C. 2701. Records may not be removed from the legal custody of the Agency or destroyed without regard to the provisions of the agency records schedules.
10. Contractor is required to obtain the Contracting Officer's approval prior to engaging in any contractual relationship (sub-contractor) in support of this contract requiring the disclosure of information, documentary material and/or records generated under, or relating to, this contract. The Contractor (and any sub-contractor) is required to abide by Government and Agency guidance for protecting sensitive and proprietary information.

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Compliance & Business Integrity (CBI) Language for Contracts

The _____ has a CBI Program. If the contractor detects and/or suspects any noncompliance relative to the revenue cycle when providing treatment to our veterans, he/she is to notify the Contracting Officer's Representative (COR) or the _____ CBI Officer. CBI Awareness training is available on the Talent Management System website. Any contract staff who does VA work is required to take basic compliance awareness training, annual CBI refresher training. Job-specific training may be required for staff in specific positions that relates to the revenue cycle. Contact the _____ CBI Officer or COR for examples of CBI training that would satisfy this requirement. The contractor is to show proof of completing this training by submitting a completed copy of the VISN 6 CBI Certification Form to the COR. You may contact the _____ CBI Officer for more information regarding CBI training.

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All Contractor, Pharmaceutical Company Representative (PCR), and Healthcare Industry Representatives (HIR) will coordinate with Contracting Officer Representative for instructions so they are in compliance with James A. Haley Veterans' Hospital policies:

HPM NO. 90-25; JANUARY 2014; HEALTHCARE VENDOR ACCESS AND COMPETENCY
HPM NO. 132-04; DECEMBER 2012; SECURITY MANAGEMENT PROGRAM
HPM NO. 132-05; DECEMBER 2012; HOSPITAL IDENTIFICATION PROGRAM
HPM NO. 11-91; MAY 2013; PHARMACEUTICAL COMPANY REPRESENTATIVES

HIR are required to report to MSDU (Room GC-003), immediately after entering the facility. HIR will be required to sign into the monitoring system and print a badge for proper identification. . The Healthcare Industry Representatives for Nutrition and Food Services, Office of Information and Technology, and Social Work Services are included in this policy; vendors (HIR) for Pharmacy Services are to follow (HPM 11-91) policy. HIR must be sponsored by a physician, a Service Chief, or their designee, for a specified date and a specified case. HIR are not permitted in patient care areas or clinics unless a prior appointment has been made.

Pharmaceutical Company Representative (PCR) refers to anyone acting on behalf of a pharmaceutical company or its business partners for the purpose of promoting the use of items managed under the VA formulary process. These items primarily include drugs, but to a lesser extent also include any medical supplies, nutritional supplements, and similar commodities managed under the VA formulary process.

a. Sign-In: PCRs may visit VA Medical care facilities no earlier than 8:00 a.m. and stay no later than 3:30 p.m., Monday through Friday, unless they receive prior approval from both the Chief of the Service that they will be visiting and the Chief of Pharmacy. Representatives visiting the JAHVH must sign in at the Pharmacy Administrative Office (Located in Trailer 78) and wear a visitor's badge as well as their company's personal name badge while in the hospital.

Vendors: Reference Hospital Memorandum Policy Number 90-25 Healthcare Vendor Access and Competency.

Contractors and/or project managers: Will be issued a PIV/ID badge in accordance with the facility PIV Policy. Contractors will contact their assigned VA Contracting Officer Representative (COR) for coordination.

Contract Personnel/Sub-Contractors: Contractors are responsible for the daily accountability and identification of all personnel assigned to their respective contract including sub-contractors. Contractors will identify personnel using the following procedures as appropriate.

Construction Project contract personnel will report to the contractor for issuance of a temporary self-adhesive identification badge. This badge will be issued on a daily basis and must include the following information: Company name, project number, date and name of individual. Contractor will maintain a daily log of all personnel.

Contract personnel not involved in an actual construction project will report to police dispatch for issuance of a numbered badge. A driver's license or photo ID will be required each day upon entering the facility, in exchange for the badge, and will be given back once the badge is returned to police dispatch. The contractor will provide Police Service with a list of names for all sub-contract personnel requiring access to the facility. It is the responsibility of the contractor to update the list as necessary.

NPR OPC; CBOCs and Off-site Lease facilities with VA Police staffing: As above with check-in with VA Police.

Off-site Lease facilities w/o VA Police staffing: Coordinate with COR, Administrative Officer, or Service Point of Contact.

