

## **Attachment A**

### **STATEMENT OF WORK**

**1. GENERAL:** The Contractor shall provide one fully automated special protein analyzer, for performing Free Kappa and Free Lambda Light Chains assays, to the James A Haley Veterans' Hospital (JAHVH), in Tampa, Florida. All work is to be performed in accordance with the 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 the following: a) equipment use b) reagents and controls c) 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. Contractor is required to provide delivery and installation of equipment at no additional charge, and return shipping costs at end of contract.

**3. TERM OF CONTRACT:** The contract term is for 12 months 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. EQUIPMENT:**

The purpose of this solicitation is to identify a fully automated Special Protein analyzer or testing system and specify functionality and performance-based requirements of this system. The proposal shall provide descriptive literature that meets the following specifications:

#### **Special Protein Analyzer: (Location: James A Haley Veterans' Hospital)**

- Includes installation, in house training, and full service.
- Instrument system includes integrated data management system, external printer, and UPS.
- Application Specialists must be available for implementing and validating new assays.
- Instrument must include integrated sample barcode reader capable of reading multiple barcode symbologies.
- Physical Characteristics- Due to space limitations, analyzer must be bench top model, NTE 37" x 30" x 31" (WxDxH).
- Electrical Characteristics – 100-240V

#### **Functionality and Performance Specifications:**

- A fully automated system using at least 50 positions.
- Automatic re-dilution to end result.

- Continuous loading/unloading of sample, reagents and cuvettes.
- Instrument must be capable of performing Free Kappa and Free Lambda chains.
- The systems must be LIS compatible with bi-directional or host query interface. The interface must be compatible with Data Innovations middleware.
- The systems must improve the overall productivity, efficiency and workflow. The system should be 100% walk-away and not require monitoring during the testing process.
- The system should use disposable / single-use cuvettes to eliminate possible cross-contamination due to washing errors.

**General requirements:** The contractor is required to provide new state-of the art equipment. Discontinued models are not acceptable. 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 30 days of their issuance or date of first commercial availability.

All models shall perform satisfactorily at laboratory temperature range between 59 and 86 degrees F (15 and 30 degrees Celsius). All models shall perform satisfactorily in the laboratory relative humidity between 10 and 70%. An electronic operator's manual must be furnished with each model supplied.

**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.

**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 the equipment, will remove the equipment. The contractor will disconnect the equipment (gas, water, air, etc.) and will be responsible for all packing and shipping required to remove the equipment within ten business days.

**Government's Responsibility:** The user will perform daily and routine maintenance and cleaning as required in the manufacturer's operation and maintenance instructions. The user 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.

**Training of Operating Personnel:** The contractor shall provide the services of a qualified technical person, at the time of equipment installation and at such time designated by the Contracting Officer (CO) or Contracting Officer's Representative (COR) to provide on-site orientation and training to designated personnel in: (1) the operation and care of the equipment,

and (2) with techniques and procedures recommended by the manufacturer to achieve maximum dependable, efficient, and economical utilization of equipment. This training shall include actual demonstration and operation of the equipment including any adjustments or other actions which may be undertaken by operating personnel in the event of failure of equipment, provided that such adjustment or action will in no way jeopardize the Government's rights under contract guarantee clause.

**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.

Upon completion of installation the equipment will be turned over to the hospital for use. Final acceptance of the equipment and installation will be based upon an inspection and test to be performed within ten (10) calendar days from date of installation. If equipment passes inspection or if acceptance inspection is not conducted within ten (10) calendar days from installation, the Government shall accept installation.

**5. 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, from an authorized government agent within 48 hours from call orders. The contractor will assure that all supplies provided/ordered for use on their equipment will be of the quality necessary to produce accurate and reliable test results. The reagent quality must be high enough to satisfy proficiency testing standards of the College of American Pathologists (CAP) and The Joint Commission (TJC). In the event that the supplies to include reagents, controls, calibrators, and/or consumables are found to be defective and unsuitable for use with the contractor's equipment or the contractor has failed to comply with the requirements herein, the contractor is required to deliver the supplies within 48 hours of receipt of the verbal order for priority delivery from the government activity. This will be done at no cost to the government, in sufficient quantity as required to allow operation of the contractor's equipment for one week (under normal government test load volume).

**7. SERVICE & 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. Emergency repairs shall be performed after notification that the equipment is inoperative. 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. Travel, per diem and other expenses associated with the repair will be borne by the contractor. 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) there shall be written verification of quality control for a sample run.

**8. TRAINING AND TECHNICAL SERVICE:** The contractor, without additional charge to the government, shall provide training at an off-site or on site location for two (2) operating personnel per analyzer at the time of installation of the contractor's equipment. Additionally, the contractor, at his/her discretion, may make training available at his/her facility on terms and conditions mutually agreed upon by the agency and the contractor. In addition, the contractor shall provide supplemental operating training to the 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.

The C&A requirements do not apply and a Security Accreditation Package is not required.

## **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 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 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.
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.

### **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.