

## **STATEMENT OF NEED**

**1. GENERAL:** The Contractor shall provide an immunoassay analyzer testing system 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 anticipates the award of a Brand name Siemens or equal Cost per Test / Cost per Reportable Result contract for use of the instrument, supplies, installation, training, and service of the equipment (for life of agreement) as identified below.

**3. TERM OF CONTRACT:** The contract term is for a base of 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 current fiscal year. The VA's obligation under this contract shall terminate at the end of each fiscal year. The JAHVH shall unilaterally renew by issuing a renewal delivery order that shall be effective on the first day of each succeeding fiscal year.

**4. ESTIMATED COST-PER-TEST:** The Cost per Test price includes (a) equipment use, (b) all reagents, controls, and consumables required for testing, (c) all necessary maintenance including spare parts to keep the equipment in good operating condition, (d) operational hardware and software upgrades, (e) user training for government personnel. Contractor is required to provide delivery and installation of equipment at no additional charge, and return shipping costs at end of contract.

**5. EQUIPMENT:** The purpose of this solicitation is to identify an immunoassay analyzer testing system and specify functionality and performance-based requirements of this system. The proposal shall provide descriptive literature that meets the following specifications:

### **Immunoassay Analyzer:**

- Fully automated laboratory instrument system (s) with the capacity to perform random access assays at a throughput of at least 200 tests per hour.
- Sample loading and tracking, primary tube sampling, automatic reflex testing and on-board dilutions.
- Instrument(s) must be capable of performing a wide range of testing including the following assays: Vitamin B12, Folate, ACTH, Homocysteine, Alpha-feto Protein (AFP), Follicle Stimulating Hormone (FSH), Luteinizing Hormone (LH), Prolactin, Insulin-like Growth Factor 1 (IGF 1), Beta-2-Microglobulin, Helicobacter pylori, Thyroglobulin, Thyroglobulin Antibody (TG), Thyroid Peroxidase Antibody (TPO), Estradiol, and Allergens. See Attachment A for estimated annual volumes.
- Instrument system includes integrated data management system, external printer, and UPS.
- All systems must utilize the same operating system and user interface.
- Instruments must include integrated sample and reagent barcode readers capable of reading multiple barcode symbologies.
- Electrical Characteristics – 220 Volts

- Physical Characteristics- Individual analyzer size NTE 60" wide x 30" deep and 80" high due to limited space
- Due to space limitations, the complete system must fit in a space NTE 127" x 137"
- Complete system capable of performing tests for all allergens See Attachment A Allergens.

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

- The systems should be barcode driven, with random access sampling.
- The systems should include an automated sample handler with a minimum throughput of 200 tests per hour.
- Application Specialists must be available for implementing and validating new assays.
- The systems should utilize barcoded reagent tracking consisting of material name, lot number, expiration date, and on-board stability and volume.
- The systems must have repeat and reflex testing capabilities based on user-defined criteria.
- The systems must have a floor drain compatible waste system.
- The systems must have a quality control program with configurable multi-rules to evaluate the validity and accuracy of testing. Vendor must provide peer comparison review and evaluation of quality control statistics.
- The systems must provide online documentation of quality control corrective action.
- 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.

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

All models shall perform satisfactorily at any laboratory temperature between 59 and 86 degrees F (15 and 30 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.

**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 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 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 Contracting Officer (CO) or Contracting Officer's Representative (COR) to on-site orientation and training to designated personnel in: (1) operation and care of equipment (2) techniques and procedures recommended by 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 regarding installation or which will affect optimum performance once installation is completed. If progress of the installation is interrupted through no fault of the contractor, the continuous installation referenced in the preceding paragraphs may be terminated until 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.

**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, ordered by 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). If 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).

**6. 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. Technical Support must be available Monday – Friday, 8am to 5 pm EST. Service telephone response will occur within 4 hours of receipt of call on the toll-free hotline. Emergency repairs shall be performed within one business day after notification that the equipment is inoperative. Should a service required incident occur, vendor will repair the instrumentation, inspect the instrument, and perform an operation accuracy check on the system.

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) shall be written verification of quality control for a sample run.

**7. 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.

ATTACHMENT A

**Estimated Volumes:** The estimated number of patient tests processed per year is indicated below...

Vitamin B12	56,350
Folate	48,500
ACTH	425
Homocysteine	665
AFP	5,200
FSH	1,250
LH	1,250
Prolactin	1,850
IGF 1	300
Beta-2 Microglobulin	1,100
H Pylori	400
Thyroglobulin	400
TG Ab	600
TPO Ab	550
Estradiol	850
Allergens:	15,000 (500 of each listed below)
Bahia Grass	
Bermuda Grass	
Johnson Grass	
Per. Rye Grass	
Timothy Grass	
Orchard Grass	
Common Ragweed	
Giant Ragweed	
Lamb's Quarters	
Rough Marsh Eld	
Rough Pigweed	
Sheep Sorrel	
Australian Pine	
Elm	
Mountain Cedar	
Oak Mix	
Pecan	
White Mulberry	
A. Tenuis	

A. fumigatus

E. purpurascens

F. moniliforme

P. notatum

S. botrysum

Cat Dander

Cockroach

D. Farinae

D.Pteronyssinus

Dog Dander

HD H. Stier