

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>\$150K)**

Acquisition Plan Action ID: VA247-17-AP-8139

1. **Contracting Activity:** Department of Veterans Affairs, VISN 07, Network Contracting Activity, Charlie Norwood VA Medical Center, Augusta, GA. 2237# 509-18-1-549-0014
2. **Nature and/or Description of the Action Being Processed:** This is a Leased Equipment upgrade request to sole source two fully automated urinalysis chemistry, microscopy, and body fluid compatible analyzers as a new award on a firm-fixed-price, base plus four-option year contract. The current system will be upgraded due to increased patient count. This cost per test agreement will begin Oct 1, 2017. The analyzers will provide the necessary diagnostic assessment of urine sediment requiring one person to operate one unit that performs a complete urinalysis and or body fluid testing.

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for two cost per test analyzers for a base plus four option year contract in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.

In accordance with Draft VA Handbook 7815 and GSAM Part 570:

- The VA will provide adequate space to allow for the use of two table top instruments no larger than each being 46 inches long, 25 inches wide, and 23 inches high. This does not include the area needed for electronic data management devices (PC, Printer, mouse, and tower).
 - The leased 1500 workcells will replace the current 2000 workcell unit and provide uninterrupted automated service for performing patient urinalysis testing which includes but not limited to urine pH, bilirubin, specific gravity, urobilinogen, wbc and rbc detection, protein, glucose, color, clarity, nitrite, and ketone chemistry analysis with microscopy for urine sediment and body fluid analysis. This lease will replace the current leased automated urinalysis instrument that performs urine chemistries and microscopies which expires Sept 30, 2017. It is currently in the Pathology & Laboratory Medicine Service Hematology Department at 950 15th St Charlie Norwood Medical Center, Augusta, GA. This will allow the continuation of testing without performing manual testing during downtime of one analyzer and manual body fluid testing.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Contractor must provide two iRICELL 1500 workcells with LIS connectivity; onsite technical and repair service to support the provided instruments, reagents, consumables, calibrators, and controls to perform automated urinalyses testing on approximately 3500 patient urine samples per month and 35 body fluid tests per month. Contract is based on a cost per test agreement and shipment of supplies will be adjusted accordingly to the actual workload numbers. This contract requires the inclusion at no cost to the

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government for specialized technical training (all expenses paid –travel, room and board) for one Key Operator to support the validation and correlation from the current system to the newly installed system. These analyzers (equipment) are needed to provide automated patient urinalysis results to include chemical, digital microscopy, and body fluid capability for the Charlie Norwood VAMC (two divisions) and three CBOCs – 24 hours a day, 7 days a week. Dual systems are necessary to ensure that critical test results are always available. In addition, all instrument shipment, set up, validation, linearity studies, correlation, precision, and carryover will be covered and performed by the contractor at no additional cost to the government. The decontamination, removal, and return shipment will be performed by the contractor at no additional cost to the government. The base year and 4 option years for this agreement is estimated to be \$ per year for a total of for the entire 5 year contractual period. The hard drive will become the ownership of the VA and must be removed prior to the return of the software component of each analyzer unit.

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In accordance with Draft VA Handbook 7815 and GSAM Part 570:

- There exists a bona fide need to provide automated patient urinalysis testing for a patient workload of approximately 3500 urine tests per month and 35 body fluid tests per month for the diagnostic treatment of hospital diverse population for inpatients, outpatient clinics, surgical, and urgent care patients. This includes testing 24hrs each day, 7 days each week, and holidays. A continual need for a base contract and 4 option year agreement for the leased instrumentation which includes totally walkaway capability, automated sample preparation (mixing, aspiration, testing and staining). Counter top space is adequate to accommodate approximately each unit that is 46 in long, 25 in wide and 23 in high. The instrument is the total ownership and property of Beckman Coulter Inc. There are no Tenant Improvement costs to the government.

4. Statutory Authority Permitting Other than Full and Open Competition:

- (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- () (2) Unusual and Compelling Urgency per FAR 6.302-2;
- () (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- () (4) International Agreement per FAR 6.302-4
- () (5) Authorized or Required by Statute FAR 6.302-5;
- () (6) National Security per FAR 6.302-6;
- () (7) Public Interest per FAR 6.302-7;

FAR13.5 Simplified Procedures for Certain Commercial Items:

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

a. **Only One Responsible Source (FAR 6.302-1)** –The iRICELL 1500 Upgraded system is a highly specialized equipment that offers the need to provide laboratory services for an automated urinalysis test system that includes chemistry, microscopic, and body fluid analysis that is one load and unload system for uninterrupted workflow. True walkaway capability that allows the operator to load, perform other patient testing, and return to a completed chemistry and microscopic analysis report for each patient at a minimum of 40 per hour. The same system must also provide automated body fluid analysis to maintain efficiency with the test rate of 35 per month. Manual body fluid testing is used at present and takes up to 2 hours per fluid to complete. This allows for a substantial reduction of operator time to attend to other urgent laboratory testing for coagulation

studies, complete blood cell counting and differential reporting. It also standardizes the accuracy for fluid counts and fluid analysis resulting from automation versus manual counting and analysis. It eliminates technical operator deviations and unnecessary delays especially when any manual count must be repeated. This is essential in increasing the accuracy, precision, and validity of the patient's results with a decrease in staff to provide testing 24 hours each day, quality control monitoring, and maintenance along with performing patient testing by one operator each shift.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** The GSA vendors Siemens, Sysmex, and Beckman Coulter were reviewed to see if a system for automated technology was available. This review included the status of minority, women, small business, and disabled veteran owned with instrumentation and service to offer the technology required to run a total urinary system of testing urine and body fluids on one analyzer and meeting all standards for quality, accuracy and precision. The only vendor adequate to perform the testing required was Beckman Coulter.

Sources Sought Synopsis: Previous suppliers of laboratory automated instrumentation for urinalysis chemistry, microscopy, and body fluid analysis with total walkaway capability was reviewed by GSA, past performance reviews from 2014 to present. The internet was used for assessing the productivity of automated urinalysis analyzers and consulting an area hospital.

Other Actions: A continuous review of new innovative instrumentation will allow for the opportunity during the option years or after the expiration of the contractual agreement to review and compete for other contractors of equal capability and competition.

7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:**

The upgraded equipment that will be leased, operated, and maintained will be fair and at a reasonable cost to the government with vendors capable of providing the equipment necessary to perform patient urinalysis testing. The cost in comparison to the existing lease of the instrument for one analyzer justifies to be a reasonable cost comparison. The total existing lease cost is valued at _____ and the new lease is valued at _____ for two upgraded analyzers.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:**

Market research reveals there are no SDVOSB/VOSB available, since this is an equipment upgrade, it is recommended to sole source this requirement to Beckman Coulter. (incumbent)

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition: Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Beckman Coulter

10. **A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:** None .

Several vendors provide automated urinalysis reporting as a separate instrument which would require the purchase of 3 different analyzers not connected to each for one load and unload capability, maintenance, quality control, and training that would require separate training locations,