

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA242-17-AP-8060

1. Contracting Activity: Department of Veterans Affairs, VISN 2, VA New Jersey Healthcare System, Northport VA Medical Center, Hudson Valley Healthcare System, James J. Peters VA Medical Center, and New York Harbor Healthcare System.
Purchase request number: 526-18-1-109-0004, 561-18-1-040-0014, 620-18-1-124-0002, 630-18-1-456-0002 and 632-18-1-080-0008.

2. Nature and/or Description of the Action Being Processed: This is a request for approval of an open market purchase order for full service maintenance coverage for Beckman Coulter Urinalysis analyzers and reagents. Only Beckman Coulter Urinalysis reagents are compatible with Beckman Coulter Urinalysis analyzers. This is a firm-fixed price purchase order. The anticipated period of performance is from October 01, 2017 to March 31, 2018 with the provision of two (2) three (3) month options periods. The base period cost is \$209,627.00 with an estimated total cost of \$419,250.12.

Base Year	10/01/2017 to 3/31/2018	\$253,564.00
Option Year 1	4/01/2018 to 6/30/2018	\$104,812.53
Option Year 2	7/01/2018 to 9/30/2018	\$104,812.53

Option pricing is consistent with the base period throughout the length of the contract with no increase in cost.

3. Description of Supplies/Services Required to Meet the Agency’s Needs:

VISN 2 SOUTH Pathology & Laboratory Medicine Service laboratories requires for full service maintenance coverage for Beckman Coulter Urinalysis analyzers and reagents. The Need for Cost Per Reportable Result (CPRR) method for equipment acquisition, including all consumables, all maintenance needed for normal operations, and peer comparison for QC. This method will allow for pricing per reportable result on reagents for processing patient Urinalysis tests on the Urinalysis analyzers. The need is for six (6) months with (2) three-month option periods for several reasons. There is currently a VISN 2 South Urinalysis Committee that was formed to put together an RFQ for a new acquisition for Urinalysis analyzers. This process can easily take one year or more before a contract is actually awarded to a vendor, due to contracting requirements, regulations, and reviews. After an award is made, it takes an estimate of two (2) months for the vendor to place the order for the awarded equipment to the manufacturer. Then the analyzers have to be shipped to the facilities and be installed. After installation, validations and correlations with the existing analyzers have to be performed as well as accuracy and precision studies. Normal ranges have to be validated and in some instances, changed. All the techs on all of the shifts have to be trained. Based on the above information, this is a very complex and time consuming process. It is not as simple as removing the existing equipment and installing the new ones. The purchase of new equipment is not in the best interest of the Government. Based on past procurement experiences, depending upon the size and configuration of the new analyzers, some construction of the laboratory have to be done in order to

accommodate the new equipment. Additionally, when new analyzers are brought in, in order do to correlation studies, the old analyzers are run in parallel with the new ones and results are not reported from the new analyzers until the studies are complete. While all this is happening, VISN 2 needs to continue testing patient's samples. The Beckman Coulter Urinalysis analyzers have been in place since calendar year 12 for patient testing at all VISN 2 SOUTH VAMC laboratories to process Urinalysis tests used by providers for patient diagnosis and treatment.

The purpose of the service agreement is to reduce service cost and improve equipment turn-around time and reliability.

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;
- (X) (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;

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

The Urinalysis analyzers are owned by Beckman Coulter, Inc. Beckman Coulter Urinalysis analyzers are only compatible with Beckman Coulter Urinalysis reagents. Under the current contract number V797P-7090A VA243-12-A-0038, the VISN 2 Medical Centers all have these Urinalysis analyzers in place, and these analyzers can only use Beckman Coulter Urinalysis reagents. There is a Urinalysis committee that has already formed for the purpose of putting together a new acquisition package. In the meantime, it is crucial to provide uninterrupted patient testing. These analyzers are used to provide Urinalysis results for patient management. All of the studies listed in section III, correlations, accuracy and precision studies; have already been performed on our analyzers that currently in use. These studies are necessary to determine accuracy of readings, and to establish reliability. It is imperative that the continuation of services for this requirement remains in place to allow for quality patient testing for the requested VISN 2 SOUTH facilities. This requested service is an urgent and compelling need because patient care and treatment would be jeopardized if this test was suspended.

Accordingly, Beckman Coulter, Inc. is the only firm capable of providing the supplies and services described in Section III above without the VISN 2 Veteran's Health Administration experiencing unacceptable delays in fulfilling its requirements. Beckman Coulter Urinalysis analyzers are only compatible with the manufacturer's (Beckman) reagents. Another manufacturer's reagents cannot be used.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

In situations involving complex medical equipment, it is difficult to remove barriers to competition because the OEM is the only qualified company capable to provide the repair and maintenance of its own specialized medical equipment. This is especially true where proprietary software, specific diagnostics tools, and specialized electronics are used to maintain the HTME (High tech Medical Equipment) in accordance with OEM specifications. Unless the manufacturer chooses to license its software and authorize local service providers to maintain the Beckman Coulter Urinalysis analyzers, the only alternative would be to replace the existing Urinalysis analyzers equipment with a more generic brand. At this time, VISN 2 VA Healthcare System is satisfied with the quality and operation of the installed equipment, its maintenance and repair. VISN 2 VA Healthcare System currently does not have the sufficient budget to replace the Beckman Coulter Urinalysis analyzers equipment. Considerations for new equipment will be made when the existing equipment reaches the end of its life cycle span.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** A determination by the contracting officer that the anticipated cost to the Government will be fair and reasonable:

The anticipated cost to the government is considered fair and reasonable based upon adequate previous competition on the VA BPA contract requirements and negotiation of prices prior to contract award. The pricing for this annual service requirement comes directly from the manufacturer, Beckman Coulter, Inc., is identical to the pricing available under their VA BPA expired contract. The Contracting Officer sought additional discounts from Beckman Coulter, Inc. on August 27, 2017. The Government Account Manager, George G. Meade indicated that no further discounts were available.

The Beckman Coulter Urinalysis analyzers are already in place, and Beckman Coulter Urinalysis analyzers are only compatible with Beckman Coulter reagents, no other manufacturer's reagents would be suitable to meet agency needs. Therefore, the continuation of services would result in cost per reportable prices remaining the same.

The proposed pricing for this purchase order has been compared to the price of the previous procurement as follows:

Contract # V797P-7090A VA243-12-A-0038 to Beckman Coulter, Brea, CA.

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

Due to the proprietary nature, Beckman Coulter is the only company than can access its systems and offer reagents that meet the original equipment manufacturer's specifications. Beckman Coulter technicians are the only OEM trained and certified personnel authorized to perform work on this HTME. However, GSA, VetBiz, and SBA websites were used to determine if there were any other sources of providing service maintenance agreements on the Beckman Coulter Urinalysis equipment. It has been determined that Beckman Coulter is the only company capable of providing these services on this highly specialized equipment to the agency.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:**

Beckman Coulter Urinalysis analyzers are only compatible with the manufacturer's (Beckman) reagents. Another manufacturer's reagents cannot be used.

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

Beckman Coulter, Inc. is the sole source for the reagents and consumables required for operation of the Beckman Coulter Iris Urinalysis instrumentation and only Beckman Coulter factory-trained personnel are certified to repair and maintain Beckman Coulter Iris Urinalysis instruments.

11. 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:

A committee has been formed to initiate the contracting process for new Urinalysis analyzers. The committee is in the process of putting together the acquisition package.

12. Requirements Certification: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.