

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>SAT)**

Acquisition Plan Action ID: 36C252-19-AP-2586

1. **Contracting Activity:** Department of Veterans Affairs, Great Lakes Acquisition Center on behalf of the Clement J. Zablocki VA Hospital, Milwaukee, WI.

2. **Nature and/or Description of the Action Being Processed:**

This is a justification and approval for a new firm-fixed price indefinite delivery, indefinite quantity with firm-fixed price line items.

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for a reagent rental agreement for an instrument and reagent supplies to conduct Immunohistochemistry and in-situ hybridization testing 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.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The Clement J. Zablocki Hospital requires an additional Immunohistochemistry (IHC)/in-situ hybridization (ISH) instrument to include reagents and ancillary supplies. This instrument is required due to the increased volume and cost of immunohistochemistry stains run on the current two Leica BondMax processing modules. Information from the IHC/ISH testing is utilized for patient diagnoses which effects patient treatment. This testing can also be utilize for cancer diagnosis. This reagent rental will be for a 5-year period with orders to be placed at the discretion of the Government beginning approximately 7/15/2019 through 7/14/2024. The following is the estimated yearly price breakdown:

Ordering period 1: \$126,264.00
Ordering period 2: \$126,264.00
Ordering period 3: \$126,264.00
Ordering period 4: \$126,264.00
Ordering period 5: \$126,264.00
Estimated value: \$631,320.00

The ceiling for this requirement is \$675,000.00.

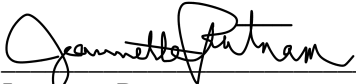
4. **Statutory Authority Permitting Other than Full and Open Competition:**

FAR13.5 Simplified Procedures for Certain Commercial Items: The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).

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 Clement J. Zablocki has been running two Leica BondMax instruments conducting IHC and ISH testing, however, one of the units has become inoperable, leaving the facility with only one instrument. Due to the volume of IHC and ISH testing conducted by the facility, the single unit is not able to support

the entire volume of testing resulting in a negative impact on turnaround time for diagnosis and subsequent medical care. This second instrument is required for workload balancing and to assist with timely test results and also functions in the event the other instrument is down for service. For consistency of result the additional instrument must be identical to the instrument currently deployed. Only Leica Biosystems can offer the identical second instrument and provide service/maintenance and reagents and ancillary supplies on a reagent rental basis.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A notice of intent to sole source was posted to FBO under 36C25219D0074 for any contractors believing he/she could provide the required items, however, no responses were received. Due to the requirement to deploy an identical second instrument with service/maintenance and reagents/ancillary supplies, competition is not viable at this time.
7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** Though this is a reagent rental agreement, the costs of the instrument is rolled into the reagent pricing and spread over the life of the contract. The ultimate purchase price of the instrument is lower than the price of the instrument on the schedule of a GSA schedule holder, Government Scientific Source (GSS), schedule GS-07F-5934R. In comparison of the reagents and supplies on schedule, the pricing offered by Leica Biosystems, the manufacturer, is lower. Based on this information the CO anticipates the cost will be considered fair and reasonable.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** In accordance with the Vets First Contracting Program, 38 U.S.C. 8127 & 8128 Implementation Policy and Procedures, a search was conducted on the Vendor Information Pages (VIP) under NAICS 325413 yielded 26 results. A subsequent VIP search under NAICS 325413 and keyword Leica yielded 0 results. A VIP search under NAICS 325413 and keyword Immuno yielded 0 results. A search of VIP keyword in-situ yielded 0 results. A search of VIP keyword Immuno yielded 0 results. A search of DSBS NAICS 325413 yielded 457 results. A search of DSBS NAICS 325413 and keyword Leica yielded 0 results; DSBS NAICS search 325413 yielded 457, DSBS NAICS 325413 and keyword Leica yielded 0 results; UNICOR and AbilityOne are not known to sell the required items.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** Not applicable.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** None.
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:**
Due to the requirement to deploy an identical second instrument with service/maintenance and reagents/ancillary supplies, competition is not viable at this time. At the conclusion of a useable lifecycle of the proposed instrumentation, or should new technology be developed, the facility will consider replacement with a new manufacturer's system.
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.



Jeannette Putnam
Medical Technologist

07/29/2019

Date

13. **Approvals in accordance with the [VHAPM Part 806.3 OFOC SOP](#):**

- a. **Contracting Officer or Designee's Certification (required)**: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Jessica Rasmussen
Contracting Officer

7-29-2019

Date

- b. **One Level Above the Contracting Officer (Required over SAT but not exceeding \$700K)**: I certify the justification meets requirements for other than full and open competition.

Scott Ivy
Division Manager, NCO 12
Equipment, Medical Sharing, Services and Supply

8/13/2019

Date