

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: 36C25219AP2216

1. **Contracting Activity:** Department of Veterans Affairs, VISN 12, Great Lakes Acquisition Center (GLAC) on behalf of the Edward Hines Jr. VA Hospital.

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

This is a justification and approval for a new indefinite-delivery, indefinite-quantity (IDIQ) contract with firm-fixed price line items for multiplex autoimmune testing reagents and ancillary supplies on a cost per reportable result basis.

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is 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:**

Hines VA Hospital requires reagents and ancillary supplies for the multiplex automated autoimmune testing on the Bioplex instrumentation owned by the facility. The reagents, in conjunction with the instrument, allow for the diagnosis and treatment of autoimmune diseases/disorders as well as measles, mumps, rubella, varicella (MMRV) testing. This contract will be for a five-year ordering period for the following estimated value:

Ordering period 1: \$119,006.50

Ordering period 2: \$122,579.70

Ordering period 3: \$126,254.00

Ordering period 4: \$130,041.62

Ordering period 5: \$133,942.86

Estimated total all ordering periods: \$631,821.68

The ceiling for this contract 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 reagents and ancillary supplies are produced by Bio-Rad. Bio-Rad makes the only reagents that can be utilized with this instrumentation. These proprietary reagents are required for the proper functionality of the instrument in conducting multiplexed autoimmune assays for several panels, providing for the diagnosis and treatment of autoimmune disorders and MMRV testing. The system, reagents and instrument, has been identified as the only fully-automated, random access, multiplex testing platform. The single reagent packs allow for simultaneous detection of multiple analytes from a single sample.

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

Prior to the instrument purchase, a sources sought notice was posted to Federal Business Opportunities (FBO) under 36C25218Q9495 requesting responses from contractors with the capabilities to support a requirement for a multiplexed Automated Autoimmune Immunoassay of patient samples to include Food and Drug Administration (FDA) approved instrumentation and reagents on a cost per test or cost per reportable result basis. A response was submitted by two contractors, Government Scientific Source (GSS) and Bio-Rad, for the same system-the Bioplex 2200 by Bio-Rad including associated reagents and ancillary supplies.

A notice of intent to sole source to Bio-Rad was posted under 36C25219P0581 and gave contractors the opportunity to respond if capabilities to provide reagents and ancillary supplies existed. One response was received from GSS. Based on pricing information received and pricing on the GSA schedule, the Contracting Officer determined it was not in the best interested of the government to compete the requirement between the small business distributor and the manufacturer. Pricing information demonstrated that the small business is significantly higher than the manufacturer with no anticipated additional value for cost.

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

Reagent kit prices from Bio-Rad were compared to the pricing available on GSA schedule. The pricing offered by the VA is lower than the published price on GSA which is deemed to be fair and reasonable by the awarding contracting officer.

Previous requirements for autoimmune testing by the NCO were not for exact like items as the contract was not a multiplexing instrument but was a cost per reportable result that included lease, service/maintenance, and reagents and ancillary supplies. Pricing of the reagents on the previous award is comparable to the pricing offered for this award in addition to the value achieved through newer technology.

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 on VIP under NAICS 325413 yielded 25 results. A second search on VIP under NAICS 334516 and keyword autoimmune yielded no results. A VIP search under keyword autoimmune yielded no results. A VIP search under 325413 and autoimmune yielded no contractors. A keyword search under Biorad yielded no results. AbilityOne and Unicor yielded no results. DSBS search under Autoimmune and NAICS 325413 yielded six contractors. A review of the three contractors did not yield multiplexing automated autoimmune instrumentation with the capabilities to

VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP
Attachment 2: Request for Sole Source Justification Format >SAT

provide all panels of testing required on the current BioPlex 2200 instrument or capabilities for multiplexing automated autoimmune reagents. Searches on GSA yielded reagents from one contractor only. A search of NAC FSS MedSurg under keyword Autoimmune did not yield reagents for the BioPlex 2200. A general search on the internet for multiplexing automated autoimmune equipment/instruments with the entire panel of testing required yielded only the Bioplex instrumentation from Bio-Rad.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** None.

10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Government Scientific Source (GSS)-small business distributor for Bio-Rad, CAGE Code 0S908.

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:**

There is currently no other system identified in the market with capabilities of the BioPlex 2200 for a multiplexing automated autoimmune testing platform. As such, competition is not viable at this time.

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.

Courtney Feldmann
Business Manager, VISN 12 PLMS
Edward Hines Jr VA Hospital

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
Great Lakes Acquisition Center, NCO 12

Date

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- 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.

David Picchi
Branch Chief, Supply
Great Lakes Acquisition Center, NCO 12

Date