

# DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: 36C252-18-AP-0202

1. **Contracting Activity:** Department of Veterans Affairs, Veterans Integrated Service Network (VISN) 12, Great Lakes Acquisition Center (GLAC) on behalf of the Edward Hines Jr. VA Hospital, Hines, IL and Clement J. Zablocki VA Hospital, Milwaukee, WI.
2. **Nature and/or Description of the Action Being Processed:** This is a sole source justification to establish a new Indefinite Delivery Indefinite Quantity (IDIQ) agreement with firm-fixed price line items with Sebia for automated Electrophoresis and Immunofixation testing for VISN 12 via analyzers placed in the laboratories of the Edward J Hines VA Hospital and Clement J. Zablocki VA Hospital.

**FAR13.5 Simplified Procedures for Certain Commercial Items:** 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:** VISN 12 requires equipment within the laboratories of the Edward Hines Jr. VA Hospital and Clement J. Zablocki VA Hospital on which to conduct Electrophoresis and Immunofixation on patient serum and other body fluid samples for VISN 12 patients to diagnose and monitor patients with Multiple myeloma, monoclonal gammopathy of undetermined significance (MGUS) or other lymphoproliferative disorders.  
Price will be on a cost per test (CPT) basis and the contractor will include all required reagents, quality control materials, service and maintenance, instrument use, and ancillary supplies. The estimated annual value is \$141,508.60 with a four-year ordering period total of \$566,034.40. The period of performance would be July 1, 2018 through June 30, 2022 based on the need of the Government, satisfactory contractor performance, and availability of funding for subsequent ordering periods.

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), only one source reasonably available.

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

Sebia offers unique protein electrophoresis systems for the screening of protein abnormalities in serum and other body fluids. The CAPILLARYS 2 FLEX-PIERCING capillary electrophoresis system provides a complete automated solution for the direct detection and quantification of the different protein fractions. The semi-automated Hydrasys gel electrophoresis instrument allows

sample application, migration, washing, and staining of multiple samples simultaneously. The detection and quantitation of monoclonal protein abnormalities is clinically useful in the diagnosis and monitoring of conditions such as multiple myeloma, Waldenstrom's macroglobulinemia, Bence-Jones proteinuria, and Multiple Sclerosis.

In 2017, an award was made to Sebia for the electrophoresis and immunofixation requirement and instruments were deployed within both lab locations to conduct testing for all of VISN 12 in accordance with the contractor's National Acquisition Center (NAC) Federal Supply Schedule (FSS) for a base period with four, one-year option periods. Due to unforeseen circumstances a new schedule is not readily available to exercise option year one, however, for the likelihood of unacceptable delays and to avoid significant duplication of effort to deploy a new system it is prudent to continue utilizing the currently deployed instrumentation for the remaining useable life of the instruments. When new laboratory instruments are deployed, it is necessary to undergo validations on the instrument. Validations serve to verify and document that the instrument is performing consistently and reporting out results that are accurate and reliable, a meticulous and elaborate process, especially in a patient care setting, generally taking three to six months to accomplish. During the validation process it is also necessary to develop a standard operating procedure (SOP). In accordance with College of American Pathologists (CAP) accreditation and Clinical Laboratory Improvement Amendments (CLIA) certification standards the SOP that is developed outlines instrument operation instructions; how to run samples; how to interpret information received; frequency in which to run and interpret results on quality control reagents; and troubleshooting. Placing a new instrument in the laboratories will also require rewriting training documents for a new platform, retraining staff on a new instrument at both laboratory locations, validations of the new instrument against the current system, assessing lab staff competency on the new instrument, assessing lab staff competency on interpreting results, and retraining nurses and other staff on gathering patient specimen.

Based on the amount of resources required to place new instruments and go-live it would be significantly more costly to place a new platform than would be anticipated to gain in cost savings through resoliciting the requirement should a comparable system exist.

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 to the incumbent was posted on Federal Business Opportunities (FBO) for a period of 15 days. In the event a similar system exists, contractors were afforded the opportunity to demonstrate capabilities to meet the requirement. To date, no responses have been received. Due to the need to continue this requirement effective July 1, 2018 a new system would not be validated and ready to process patient samples.
7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** The incumbent contractor is agreeable to continuing to honor the pricing that was available on the previous NAC FSS contract. Prior to award, the NAC Contracting Officer determined that the price was fair and reasonable and thus awarded the contract to Sebia. Based on an analysis of continuing on a cost per test basis versus buying out the instrument, it is approximately \$84,000 cheaper to continue on a CPT basis. Also, the typical useable life of this type of instrument would be approximately five years and the current instrument has about four years remaining. At the end of the lifecycle for the instruments the facilities would be responsible for disposition costs, an additional cost to the VA with consideration to also decontamination due to biohazardous concerns.
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) using NAICS 334516 and yielded 81 matches. A subsequent search of NAICS and keyword "phoresis" yielded no matches. A search of keyword "phoresis" yielded no matches. A search on AbilityOne and Unicor yielded no capability to provide electrophoresis testing

or instrumentation. A search on DSBS was conducted using NAICS 334516 and yielded 2,268 matches. A subsequent search for NAICS 334516 and keyword “phoresis” yielded no results. A search for “phoresis” yielded no matches. A search on NAC MedSurg for “phoresis” yielded no matches. Sebia was the only known source on NAC FSS for Electrophoresis. A search on GSA Advantage for “phoresis” yielded no results. A general internet search for Immunofixation Electrophoresis yielded only sources known to conduct testing as a reference lab whereby samples are sent to the contractor and processed in a laboratory off-site.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** Sending samples out to a reference lab is more costly and requires courier service/shipping. Additional turnaround times for results are longer due to the nature of being reported from a source outside of the VA. VISN 12 has previously examined the outsourcing costs of this testing and determined it to be a more cost-effective solution to sending out samples.

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 anticipated need to continue this particular testing it is anticipated that, prior to conclusion of this proposed contract, a solicitation will be developed as necessary regarding available sources of supply in an attempt to foster competition. An implementation period will be afforded to validate new platforms and go-live.

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.

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Donna Wray  
Business Manager, PLMS  
Edward Hines Jr. VA Hospital

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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.

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Jessica Rasmussen  
Contracting Officer  
Great Lakes Acquisition Center, NCO 12

\_\_\_\_\_  
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.

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Ricky Bond  
Division Manager  
Great Lakes Acquisition Center, NCO 12

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Date