

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA244-17-AP-9246/642-18-1-025-0003

- 1. Contracting Activity:** Department of Veterans Affairs, VISN 04, Corporal Michael J. Crescenz VA Medical Center (CMC VAMC), Philadelphia, PA, SAO East, Network Contracting Office 4 (NCO4), Clinical Support Services (Med 2).
- 2. Nature and/or Description of the Action Being Processed:** The CMC VAMC's Pathology & Laboratory Medicine Service (P&LM) Chemistry section, is requesting award of a firm fixed price contract, with an up to five year period of performance consisting of one base year, and an additional four, one year options (base + 4). Contract will also provides an option to purchase equipment in accordance with FAR 52.207-5. Contract type was selected as the Government is able adequately predict the exact number of supplies and equipment services that will be needed on a yearly basis. Award is to be made on a sole source basis to **Helena Laboratories Corporation**, 1530 Lindbergh Drive, Beaumont, TX 77707. 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:** Said contract will provide proprietary Electrophoresis and Serum/Urine Immunifiaction, equipment (SPIFE 4000 Analyzer) and associated reagents and consumables. Electrophoresis testing of patient urine specimens is used to estimate how much of certain proteins are present in urine. These measurements can in part be used to diagnose multiple myeloma and multiple sclerosis as well indicate a need for additional types of testing in pursuing a patient diagnosis. Electrophoresis testing is conducted several times per week. Total estimated value is **\$267,815.40**. Applicable NAICS and PSC codes are 325413- In-Vitro Diagnostic Substance Manufacturing, and 6550-In-Vitro Diagnostic Substances, Reagents, Test Kits and Sets. Anticipated contract period is 06/01/2018 through 05/31/2023.

[REDACTED] Total costs by year along with option to purchase equipment are listed below:

- Base Year - \$38,418.00
- Option Year I - \$38,790.12
- Option Year II - \$39,359.22
- Option Year III - \$39,945.91
- Option Year IV - \$48,549.87
- Option to Purchase Equipment (SPIFE 4000 Analyzer) - \$70,852.28

Total = \$267,815.40

4. **Statutory Authority Permitting Other than Full and Open Competition:** Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1; *also*, the authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented 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 P&LM Chemistry section is in need of the Helena SPIFE 4000 Electrophoresis Analyzer and associated reagents and consumables because the electrophoresis equipment currently being used is well past its life cycle and is breaking down frequently. The equipment now in use is over 17 years old. Existing vendor cannot support the computer that runs the densitometer any longer due to its age. In addition, newer automated equipment is available to streamline testing and save significant labor in performing electrophoresis testing.

The Helena Laboratories SPIFE 4000 analyzer is a “fully” automated electrophoresis instrument that will transition the current testing process from fully manual to fully automated testing. There are *no* other vendors that have a fully automated Gel Electrophoresis system that supports automation from start to finish. This is a “Load and Go” or “walkaway” analyzer that will free up technologists’ to complete other duties and tasks while the electrophoresis platform is running independently with extremely little hands on time for the technologist. There are other vendor’s that offer electrophoresis testing that were researched and evaluated during the market research process. These vendors were found to not offer a fully automated gel electrophoresis process. There are no other vendors that have a fully automated gel electrophoresis system that supports automation from start to finish.

This analyzer will significantly impact the workload and time at task of the testing and also be able to increase productivity in other testing that occurs in the Chemistry section by eliminating the need for a medical technologist to manipulate sampling of specimen, gel application, staining, blotting and drying. The SPIFE 4000 is a truly “walkaway” platform that is imperative to be implemented in the chemistry lab who has had significantly less staff (currently 3FTEE short) to complete the increasing workload. Helena’s instrumentation fits into the laboratory. It offers the tests needed and is a fully automated platform that will replace a manual process that takes 8 hours of tech time to do 58 Protein electrophoresis patients completely manually or up to 18 IFE’s in an 8 hour day. The SPIFE 4000 platform is capable of performing 756 Protein Electrophoresis tests and 100 IFE’s in a 8 hour day that will only take 30 minutes of technologist time and then the technologist is free to perform other tasks/tests or duties since this platform is “fully Automated”. Note that associated reagents are proprietary to the Helena analyzer and other vendor’s reagents are not compatible.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** CMC VAMC P&LM in conjunction with NCO4 reviewed both the Helena Laboratories and Sebia, Inc electrophoresis analyzers. Both companies provided information to CMC VAMC P&LM for review.
7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** Prices under the contemplated contract are anticipated to be fair and reasonable based on the following rationale:

- Prices are expected to be equal to or less than prices paid under previous procurements of these same Helena reagents by NCO4 and VISN4.

- Furthermore prices are anticipated to be equal to or less than Helena’s current open market price list prices applicable to this analyzer and associated reagents.
- This Contracting Officer further anticipates that the Government and VISN4 will pay the same prices as similarly situated healthcare entities in the commercial marketplace.

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

The P&LM Chemistry section did look at other vendors who offer similar test menus, specifically Sebia, Inc. Their equipment requires significantly more technologist “hands on time” and does not offer fully automated gel electrophoresis.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition: N/A.

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition: Helena Laboratories Corporation, Beaumont, TX and Sebia, Inc, Norcross, GA.

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: CMC VAMC P&LM will stay abreast of the latest FDA approved electrophoresis testing methodologies and products and will conduct a competitive best value procurement at a time when it is deemed prudent to change their testing methodologies and instruments or otherwise consider use of electrophoresis testing reagents other than Helena’s for detecting protein levels in urine.

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.

Rosemary Millili 382015	Digitally signed by Rosemary Millili 382015 Date: 2018.04.11 16:05:12 -04'00'
Rosemary Millili Chemistry & Toxicology Supervisor CMC VAMC, P&LM	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.

Matthew D Parlett 360547	Digitally signed by Matthew D Parlett 360547 Date: 2018.04.11 16:24:23 -04'00'
Matthew D. Parlett Contracting Officer NCO4, Clinical Support Services (Med 2)	Date

- b. **One Level Above the Contracting Officer (Required over \$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

NANCY L. PORTER
128170

Digitally signed by NANCY L.
PORTER 128170
Date: 2018.04.11 14:58:21 -04'00'

04/11/2018

Nancy L. Porter
Branch Chief
NCO4, Clinical Support Services (Med 2)

Date