

Attachment 1: Request for SDVOSB/VOSB Sole Source Justification Format >SAT

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA263-18-AP-5542

1. **Contracting Activity:** Department of Veterans Affairs, Network 23 Contracting Office (NCO23), 4801 Veterans Drive, Saint Cloud, MN 56303

Organization Activity: Department of Veterans Affairs, Minneapolis VA Health Care System, One Veterans Drive, Minneapolis, MN 55417

2237 Number: 618-19-1-106-0005

2. **Nature and/or Description of the Action Being Processed:** A firm-fixed price requirements contract to provide two (2) D100 Bio-Rad ion-exchange high performance liquid chromatography instruments on a cost-per-test basis to conduct Automated Hemoglobin A1C Testing at the Minneapolis VA Health Care System.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** two (2) D100 Bio-Rad ion-exchange high performance liquid chromatography instruments on a cost-per-test basis to include the following: instrumentation, reagents, calibrators, controls, consumable supplies, linearity testing material, installation, bi-directional interfacing (includes software and hardware compatible with Data Innovations and windows 10), training of end users, system preventative maintenance (including parts, labor, and travel), all shipping costs, and support required to keep the instrument operational for the term of the contract.

Period of Performance is 10/1/2018 to 9/30/2018, with four one-year option periods.

4. **Statutory Authority Permitting Other than Full and Open Competition:** 41 USC §3304(a)(5), 38 U.S. Code § 8127, as implemented by FAR 6.302-5 (Authorized or Required by Statute). COs may use the non-competitive (sole source) procedures authorized in VAAR 819.7007 or 819.7008 up to \$5,000,000. Check the specific VAAR clause used below:
(X) 819.7007 Sole source awards to a verified service-disabled veteran-owned small business; or
() 819.7008 Sole source awards to a verified veteran-owned small business

Attachment 1: Request for SDVOSB/VOSB Sole Source Justification Format >SAT

5. **Demonstration that the Contractor's Unique Qualifications and/or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** This is a highly specific and highly specialized instrument required for use by the Minneapolis VA laboratory. There are multiple technical features required to meet the needs of the Minneapolis VA laboratory. This instrument must utilize ion-exchange high performance liquid chromatography (HPLC), all other methods are found to be unacceptable for use. Other technical requirements are as follows:
- a. Less than 50 second sample analysis time.
 - b. 10,000 injection cartridge life time.
 - c. 2,000 injection pre-filter/ guard lifetime.
 - d. Automatic calibrator dilution.
 - e. Reportable HbA1C results in the Presence of Fetal Hb with a cut-off of at least 30% of total Hb.
 - f. Reportable HbA1C results in the presence of HbA2.
 - g. Separate detection windows for Hbs, Hbc, HbD, HbE.
 - h. On board stability of kit is 90 days.
 - i. Onboard advisor rules.
 - j. Automatic sample repeat capability based on set flags.
 - k. Ability to replace buffer while the system is running.
 - l. No Daily maintenance required.
 - m. HbA1C results expressed in NGSP or IFCC units.
 - n. Must be able to support multiple barcode formats (Code 39 and Code 128) and accept 10 characters (numeric and alphabetic) for specimen identifier.
 - o. Onboard reagent inventory system.
 - p. Complete separation of labile and stabile hemoglobin A1C.
 - q. Must be cap piercing and require no pretreatment of primary tube for sampling.
 - r. Ability to perform off line dilution if required.
 - s. Instrument detects low reagent volumes and alerts user.

Only Bio-Rad instrumentations have been found to utilize the HPLC methodology. This is a Brand name only purchase of the Bio-Rad instruments that utilize this method of testing. Government Scientific Source is the sole distributor of these items for the Manufacturer, Bio-rad. Government Scientific Source, Inc is a verified Veteran-Owned Small Business (VOSB), and is the only authorized VOSB distributor for Bio-rad. This requirement is being sole sourced to a VOSB as authorized by 38 U.S.C. 8127.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A source sought was not issued to confirm that there were no other vendors that can provide Automated Hemoglobin A1C Instrumentation that utilize ion-exchange high performance liquid chromatography (HPLC) methodology, and no instrumentation was identified that utilizes the required methodology. Bio-rad currently has one authorized Veteran Small Business distributor, Government Scientific Source, Inc. Only this VOSB was reviewed, as the government is not willing to accept Grey Market Items. Sole sourcing to Government Scientific Source, Inc is in the

Attachment 1: Request for SDVOSB/VOSB Sole Source Justification Format >SAT

best interest of the government, as they are the only VOSB that can provide the requested testing instrumentation, supplies, and services.

7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** A determination by Contracting Officer that the anticipated cost to the Government will be fair and reasonable: a comparison will be made to the prices found reasonable on previous purchase IAW FAR 13.106-3 (a)(2)(ii).
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market Research was conducted on the Vetbiz registry, using NAICS code 325413, and 27 results were returned. Bio-Rad currently has one authorized Veteran Small Business distributor, Government Scientific Source, Inc.
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:** 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:** In the future, should additional Automated Hemoglobin A1C testing supplies on a cost-per-test bases be needed, the government will conduct market research to determine if additional sources can be found that utilize the required testing methodology, and if so any future procurement will be through a competitive solicitation.