

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-6302

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: 618-19-1-106-0043

2. **Nature and/or Description of the Action Being Processed:** A firm-fixed price Blanket Purchase Agreement (BPA) to provide QuantiFERON TB Gold Supplies for the Minneapolis VA Health Care System.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** QuantiFERON-TB Gold Plus Reference Lab Pack (Item Number: 622832) and QuantiFERON-TB Gold Plus Dispenser Pack (Item Number 622433)

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

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):** QuantiFERON tuberculosis reagents and sELISA Plates for the analysis of M. Tuberculosis in blood samples. These items are manufactured and distributed solely by Qiagen as they have exclusive license rights to the QuantiFERON product technology. This is a patented whole blood method for detecting cell mediated immune responses. This blood test, known as an interferon-gamma release assay (IGRA), is a laboratory-based test with internal controls which is able to detect M. tuberculosis infections with higher sensitivity and specificity than the skin test and is not affected by the previous BCG-vaccination. Unlike the Mantoux Tuberculin skin test that requires the patient to return for a second visit for a reading, the whole blood sample allows for a single patient visit, in addition a response to

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multiple antigens simultaneously, and doesn't boost anamnestic immune responses. QIAGEN has exclusive rights to the patented QuantiFERON technology and licenses for exclusive use of tuberculosis specific antigens: ESAT-6, CFP-10 and TB 7.7(p4) in the QuantiFERON-TB Gold In-Tub test using whole blood, under US Patent no. 5955077, 6290969, and 6291190. Government Scientific Source is the sole distributor of these items for the Manufacturer, QIAGEN. Government Scientific Source, Inc is a verified Veteran-Owned Small Business (VOSB), and is the only authorized VOSB distributor for Qiagen. 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:** Qiagen 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 best interest of the government, as they are the only VOSB that can provide the requested testing supplies. A source sought was not issued, as Qiagen, has already confirmed that they have only one authorized VOSB distributor, and there is not a reasonable expectation that a source sought would identify additional SDVOSB/VOSB sources.
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: these items are available under FSS Schedule GS-07F-5934R, and in accordance with FAR 8.404(d), the pricing of these items has already been determined fair and reasonable.
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. Qiagen 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 TB testing supplies be needed, the government will conduct market research, and if additional sources are found any future procurement will be through a competitive solicitation.