

**DEPARTMENT OF VETERANS AFFAIRS**

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

**Acquisition Plan Action ID:** VA241-17-AP-4746

- 1. Contracting Activity:** Department of Veterans Affairs, VISN 01, 689 VA Connecticut VA Health Care System – West Haven

Department of Veterans Affairs, VISN 1, VA New England Healthcare System, Network Consolidated Laboratory, Mary-Ann Bridgwood, Program Manager, NCL 113, 940 Belmont St., Brockton, MA 02301.

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

New contract request for base plus 4 option year agreement for reagent test kits and quality control material from Biomerieux for Lyme Disease Testing on the VIDAS 30. Total base plus four options is estimated at \$66,531.60 per year/\$332,658.00 total. Options will be exercised at the discretion of the Government.

- 3. Description of Supplies/Services Required to Meet the Agency's Needs:**

<u>Item Description</u>	<u>Vendor PN</u>	<u>Unit</u>	<u>Estimated FY volume</u>	<u>Cost per Unit</u>
VIDAS® Lyme IgG II (60 tests/kit)	417401	Kit	120	\$273.99
VIDAS® Lyme IgM II (60 tests/kit)	416436	Kit	120	\$273.99
VIDAS (QCV) QC kits (60 tests/kit)	0030706	Kit	6	\$129.00

- 4. Statutory Authority Permitting Other than Full and Open Competition:**

- (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;  
 (2) Unusual and Compelling Urgency per FAR 6.302-2;  
 (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;  
 (4) International Agreement per FAR 6.302-4  
 (5) Authorized or Required by Statute FAR 6.302-5;

- ( ) (6) National Security per FAR 6.302-6;
- ( ) (7) Public Interest per FAR 6.302-7;

**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 Biomerieux VIDAS 30 was purchased with equipment funds for performing Lyme Disease testing in the West Haven VA Molecular Lab. These test kits are specifically made for either the VIDAS 30 and only these kits can be run on the analyzers. Biomerieux is the manufacturer and sole source of supply for these test kits and the VIDAS 30 system. This is highly specialized equipment used for Lyme Disease testing. Any change would create a substantial duplication of costs, delay in patient testing, require purchase of new equipment and create unacceptable delays.

The acquisition of these Biomerieux supplies is essential to the Government's requirements, thereby precluding consideration of a product manufactured by any other vendor.

**6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** At this time, no other potential sources were sought. The VA owns this equipment. The reagents and supplies are proprietary.

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

The cost of these reagents is anticipated to be fair and reasonable despite the manufacturer being the sole distributor of the reagents and supplies. Because of the scope of the anticipated BPA volume discounts will be pursued by the CO and proposed pricing will be compared to catalogue prices, historical prices paid by the government as reported in FPDS data, and comparing to automated Lyme disease reagents manufactured by other entities for proprietary analyzers. No agreement will be established unless proposed pricing is determined to be fair and reasonable by the Contracting Officer and molecular laboratory technical experts.

**8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** No other market research was conducted other than ensuring the reagents and supplies are sole source.

**9. Any Other Facts Supporting the Use of Other than Full and Open Competition:**

The VIDAS Lyme method provides easy result interpretation. There is no equivocal zone for the VIDAS Lyme IgG results. It is clear cut and rapid allowing optimized treatment depending on the stage of the infection.

**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:** When the laboratory is ready to replace this analyzer, they will conduct full market research and consider any vendors who provide solutions for this testing.

Chapter VI: Other Than Full and Open Competition (OFOC) SOP  
Attachment 3: Request for Sole Source Justification Format >\$150K

**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.

Mary Goulart  
539147

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lart@va.gov, cn=Mary Goulart 539147  
Date: 2017.07.10 13:58:45 -04'00'

Mary Goulart  
Program Support Medical Technologist  
VA New England Healthcare System

July 10, 2017  
Date

**13. Approvals in accordance with the [VHAPM, Volume 6, Chapter VI: 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.

Joyce D. Goodale  
129292

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0.9.2342.19200300.100.1.1=joyce.goodale@va.gov  
, cn=Joyce D. Goodale 129292  
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Name  
Title  
Facility

Date

b. **Director of Contracting /Designee (Required over\$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

Salvatore E Voter  
253654

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Name  
NCO 1Director of Contracting or Designee  
Facility

Date