

DEPARTMENT OF VETERANS AFFAIRS

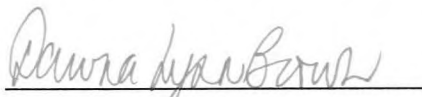
**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>\$150K)**

Acquisition Plan Action ID: VA246-17-AP-13391

1. **Contracting Activity:** Department of Veterans Affairs VISN 6 plans to contract by means other than full and open competition in response to procurement request 558-18-1-044-0029.
2. **Nature and/or Description of the Action Being Processed:** The procurement request is for Immunoassay Instrument Cost-per-Test or Reagent Rental 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. A firm-fixed price 60-month contract to Biomerieux (DUN 086785110) is planned with a period of performance of 10/1/2017 through 9/30/2022.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The Durham VAMC has a requirement for a multiparametric immunoassay instrument through a cost-per-test or reagent rental basis. Immunoassays are chemical tests used to detect or quantify a specific substance in blood or body fluid sample using an immunological reaction. The tests are highly sensitive and specific and are based on the principle that specific antigens will stimulate very specific (unique) immune responses. Their high specificity results from the use of antibodies and purified antigens as reagents. The instrument that Durham is seeking must be capable of testing for: Procalcitonin (PCT); CMVG; CMVM; HPY; Procalcitonin (PCT); VZG; TXGII KIT ASSEMBLY; and TXM. The FSC code for this procurement is 6640 and the NAICS code is 334516.
4. **Statutory Authority Permitting Other than Full and Open Competition:**
 - (X) (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 Immunoassay Instrument offered by Biomerieux has the capability of testing for Procalcitonin (PCT). One major advantage of PCT testing compared with other biomarkers is its early and rapid response to bacterial infections and sepsis. Rapid treatment of sepsis is of crucial importance for survival of patients. There is no other known Immunoassay Instrument on the market that currently can test for Procalcitonin.

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

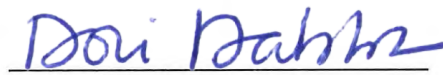
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** VIP was searched to comply with Veterans First program using NAICS code 334516 and keyword "disease". A second search was conducted using same NAICS code and keyword "immunoassay". Both searches produced no vendors. A Sources Sought Notice (VA246-17-N-0245) was posted on FedBizOpps from 7/6/17 until 8/9/17 (for 2 weeks). There were no responses received other than from Biomerieux.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The projected cost for a 60-month (5-year) Reagent Rental agreement for the VIDAS 3 Immunoassay Instrument is \$160,632.00 (\$32,124.40 per year). This instrument is not yet on Biomerieux's GSA contract- GS07F-9525S. However, Biomerieux has agreed to provide projected GSA pricing for this instrument reagent rental agreement.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** As stated above, Sources Sought Notice VA246-17-N-0245 was posted on FedBizOpps for 2 weeks, providing ample time for any potential offerors to respond.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** There are no other facts other than those already stated.
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:** Perhaps more Immunoassay instruments in the future have the capability to test for Procalcitonin (PCT).
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.


Dawna Lynn Brown
Laboratory Service
Durham VA Medical Center

8/10/17
Date

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

- a. **Contracting Officer or Designee's Certification:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.


Dori Dabbs
NCO 6 Contracting Officer

8/10/2017
Date

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

- 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.

Darryl T.

Person 420831

Darryl T. Person

Designee

NCO 6

Digitally signed by Darryl T. Person 420831
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ou=people,
0.9.2342.19200300.100.1.1=darryl.person@
va.gov, cn=Darryl T. Person 420831
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Date