

DEPARTMENT OF VETERANS AFFAIRS

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

1. **Acquisition Plan Action ID:** VAA244-16-AP-8334/2237#693-17-1-050-0004
2. **Contracting Activity:** Department of Veterans Affairs, NC04, VA Pittsburgh Healthcare System, H.J. Heinz Medical Center.
3. **Nature and/or Description of the Action Being Processed:** Brand Name purchase and Sole Source Award of a Base and Four Option Year Firm Fixed Price ID Requirements Contract to Biomerieux.

Period of Performance:

Base Year: From award date in October 2016 through 9/30/2017.

Option Year One: 10/1/2017 through 9/30/2018

Option Year Two: 10/1/2018 through 9/30/2019

Option Year Three: 10/1/2019 through 9/30/2020

Option Year Four: 10/1/2020 through 9/30/2021

Estimated Contract Amount:

Base Year estimated amount: \$94,000

Total Base and Four Option Year estimated amount: \$470,000

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for the award of a Contract, in accordance with FAR Part 13.5 Simplified Acquisition Procedures for certain commercial items.

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

Biomerieux PCT Test Kits. This request is for the purchase of reagent and Quality Control Material to perform Procalcitonin testing in the Laboratory using existing owned equipment. The equipment being used is the BioMerieux Mini Vidas. This Sole Source Justification is specifically for the purchase of these two materials which are made exactly for this instrument. No other reagent or Quality Control (QC) material can be used on our instrument. The reagent and QC is made by BioMerieux. However, the reagent and QC material can be purchase from BioMerieux or from Fisher Scientific. Either vendor is acceptable. Again, the sole source is for the materials, not the vendor.

	<u>BioMerieux</u>	<u>Quantity Needed</u>
Procalcitonin (PCT) reagent #304501-01		60
QC kits #30706		8

Base Year Estimated Total: \$94,020

Base and Four Option Year Total: \$470,000.

5. **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;

6. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**

It is essential to the Government to purchase the Biomerieux PCT Test Kits, for the following reasons:

Currently, the laboratory owns two instruments that can perform the procalcitonin testing. The instruments are both BioMeriux MiniVidas. The only reagent that is able to be used on the MiniVidas for this testing is manufactured by BioMeriux. Just the way the reagent is packaged and the compatibility for the instrument is unique to the instrument. The methodology in testing is also somewhat unique. Additionally, we have done a complete Method Validation on this reagent for the testing that meets the College of American Pathologists Accreditation Standards that is required to be performed prior to testing and reporting of patient results. While this is the only reagent that can be used on the instrument, the reagent can be purchased through Fisher Scientific as a distributor. The BioMeriux MiniVidas allows for only the reagent and QC manufactured by BioMeriux to be used on the instrument. This is the only instrument in the laboratory that can perform this test. The need exists to continue to perform this testing on a STAT basis for the diagnosis of sepsis. Further, this test went through a very lengthy Method Validation using this test method in the laboratory.

The VA must purchase the above items from Biomerieux, since they are the sole seller of their PCT Test Kits. (See email from Biomerieux, dated, 10/5/2016, under P02 in the Procurement Action Briefcase of the eCMS Contract File).

7. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A Notice of Intent to Sole Source will be posted to FBO for 3-5 days.

8. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The prices quoted by Biomerieux are deemed fair and reasonable, since the price quoted by Biomerieux for Product# 304501-01 and Product# 30706, is less than the FSS price the VA paid under previous VA DO/Contract# VA244-16-F-0034 .

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

Written confirmation was obtained from Biomerieux, stating they are the Sole Source for the needed items. Biomerieux has indicated that Fisher Scientific is no longer their re-seller for the items listed under #3 above.

A Query of the VetBiz Website using the Keywords Biomerieux and NAIC Code revealed no results.

A Query of the GSA Advantage Website, using the word Biomerieux revealed no results. Biomerieux has indicated they do not sell these items off any FSS Contract.

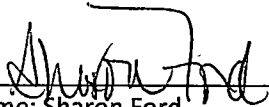
10. **Any Other Facts Supporting the Use of Other than Full and Open Competition:**

These products are packaged in reagent cartridges to fit on the specific Instrument , BioMerieux MiniVidas. Other manufacturers do not make reagent and quality control products to fit on this instrument.

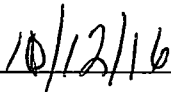
11. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** None

12. **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:** None

13. **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.


Name: Sharon Ford

Title: Medical Technologist/Lab Manager
Facility: Wilkes-Barre VA Medical Center


Date

14. **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.

Name: Ronald Mazzei
Title: Contract Specialist/Contracting Officer
Facility: H.J. Heinz

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.

Name: Edward A. Boddie
Branch Chief Hybrid Team 1
Facility: Philadelphia

Date