

Attachment A - Justification and Approval

DEPARTMENT OF VETERANS AFFAIRS
Justification and Approval
For
Other Than Full and Open Competition

1. Contracting Activity: Department of Veterans Affairs, Network Contracting Office 16, Biloxi VA Medical Center. The 2237 # associated with this action is 520-13-4-077-0165.

2. Nature and/or Description of the Action Being Processed: The procurement of the use of the below Anatomic Pathology Stainer with Reagents on a cost-per-test basis that includes the following:

- a. Bond-Max Processing Module (1 each)
- b. Bond System Control Kit (1 each)
- c. Silver Service Contract-Bond (4 each)
- d. Bond Polymer Refine Detection (1 each)
- e. BondTM Wash Solution 10X - 1L (1 each)
- f. Bond Slide Labels and Printer Ribbon (1 each)
- g. Bond TM Mixint Stations (1 each)
- h. Bond Open Containers 7ml (1 each)
- i. BondTM Universal Convertiles - 100 Pack (1 pack)
- j. Bond Dewax Solution (1 each)
- k. BondTM Epitope Retrieval 1-1L (1 each)
- l. BondTM Epitope Retrieval 2-1L (1 each)
- m. Bond Enzyme Pretreatment Kit (1 each)
- n. RTU's (1 each)

An Indefinite Delivery Indefinite Quantity Contract (IDIQ) is contemplated on a firm fixed-price basis.

3. Description of Supplies/Services Required to Meet the Agency's Needs: The procurement of the use of an Anatomic Pathology Stainer with Reagents on a cost-per-test basis. The Period of Performance is as follows: 1-each 12-month Base Period and 4-each 12-month Option Periods. The estimated value including option periods is [REDACTED] total broken down as follows:

- Base Period: [REDACTED]
 - Option Period #1: [REDACTED]
 - Option Period #2: [REDACTED]
 - Option Period #3: [REDACTED]
 - Option Period #4: [REDACTED]
- Total Estimated Amount: [REDACTED]

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):**

Only One Responsible Source (FAR 6.302-1) – The stainer from Leica Microsystems possesses the following specific (unique) features that the Diagnostic Medicine Service requires. We are not aware of any other vendor (manufacturer) being able to provide these specific features individually or all of these required features in one single unit:

- a. Capability of 3 trays of 10 slide options (30 total).
- b. Continuous processing (with the ability to add slides after the initial run is started).
- c. Technology that allows for coverage of the tissue so reagent and air is never applied directly to the tissue.
- d. Separate waste dispensers for both hazardous waste and non-hazardous waste (with a separation sensor for hazardous waste).
- e. Ability to use third party antibodies.
- f. Ability to change reagents during testing.
- g. Error sensing reports.
- h. Step by step testing reporting system.
- i. Barcode driven slides but has the ability to read non-barcode slides.

The above specific features are essential to the Government's requirements thereby precluding consideration of equipment manufactured by another company.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** VetBiz Registry, SBA Dynamic Small Business, GSA Advantage, and Internet searches were conducted. While there were numerous small businesses of various sizes identified in our search of the sources identified above, the limited number of equipment vendors (manufacturers) we were able to identify who are truly in the anatomic pathology equipment manufacturing and leasing business were all large businesses with the exception of one company who was a small business. It was originally thought that these services were covered by a VISN 16 Blanket Purchase Agreement (BPA) but a further search revealed that they were not. A Sources Sought Notice was placed on the Federal Business Opportunities (FBO) website on July 26, 2013 under Request for Proposal Number VA256-13-R-1394 seeking businesses capable of providing an anatomic pathology stainer with reagents

included in the monthly price (12-month base period plus 4-each 12-month option periods) on a cost per test basis with the following minimum capabilities: tabletop staining unit; complete and fully automated IHC and ISH stainer; complete onboard baking, staining, dewax, and antigen retrieval (using heat and enzyme); data management system; patient data management system; patient reporting and protocol reporting systems; continuous processing (the ability to add slides after the initial run is started); ability to change reagents during testing; coverage of the tissue so reagent and air is never applied directly to the tissue; and continuous feed with no interruption in other slide processing (slide trays act independently of each other). No replies have been received to date in response to the subject Federal Business Opportunities (FBO) Sources Sought Notice where nine of the VA's minimum required capabilities were listed. The VA's requirement will be posted in a FBO Solicitation Notice where vendors are welcome to challenge our assertion that this requirement is a sole-source procurement. If any vendor challenges our position, we will certainly investigate their position further to see if they can, in-fact, meet our customer's minimum requirements.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable: The undersigned Contracting Officer does not anticipate adequate price competition being received as our plan is to procure this requirement on a sole-source basis. As such, other price analysis techniques will be employed to include (a) comparison of the proposed prices to historical prices paid by other VA or Governmental Agencies for the same or similar items; (b) comparison of proposed prices with competitive published price lists (if any); and (c) comparison of proposed prices obtained through market research for the same or similar items. Through the use of these price analysis techniques, the undersigned Contracting Officer believes that the final contract price can be determined to be fair and reasonable.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted: As noted in Paragraph 6 above; there are a very limited number of vendors (manufacturers) in the commercial equipment market who specialize in leasing stainers for anatomic pathology testing. The VA is basically paying for the cost (or use) of the stainer through the purchase of the reagents used for the testing in what amounts to a cost-per-test basis. In other words, the price of the use of the stainer is being passed through to the VA in the cost of the reagents. Edward P. Fuller, MD, Chief, Pathology and Laboratory Medicine Service, and his staff conducted research concerning anatomic pathology stainers in the commercial market. Their research consisted of speaking with various vendors in the commercial market, reviewing product (equipment) literature, speaking with their diagnostic medicine counterparts at other VA's, conducting Internet searches, and was also based upon their own personal experience in working with similar equipment. Dr. Fuller indicated to the undersigned that he knows of no other manufacturer's equipment (other than that of Leica Microsystems) in the commercial market that will perform in the manner required for their needs. The undersigned Contracting Officer's research found that there were a very limited number of vendors (manufacturers) in the commercial equipment market who specialize in anatomic pathology stainers. This research was supported by an Internet report excerpt entitled "Anatomic Pathology Markets in The United States (Excepts From Our New Report)" from 2011 which states in the Table of Contents "Nine Manufacturers/Ninety Percent of the Market" (please see attached report excerpt). While there were numerous small businesses of various

sizes identified in our search of GSA Advantage, VetBiz Registry, SBA Dynamic Small Business Search, and a check with other NCO 16 Contracting Officials, the limited number of equipment vendors (manufacturers) we were able to identify who are truly in the anatomic pathology equipment manufacturing and leasing business were all large businesses with the exception of one company who was a small business. It was originally thought that these services were covered by a VISN 16 Blanket Purchase Agreement (BPA) but further research revealed that they were not. A Sources Sought Notice was published on the Federal Business Opportunities Website on July 26, 2013 with no responses received to date.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition: In the undersigned Contracting Officer's discussions with Dr. Fuller concerning this requirement, it was clear that if any other vendor (manufacturer) had the technology available like that being proposed by Leica Microsystems through their stainer, it would most certainly be considered. However, Dr. Fuller is unaware of any technology that comes even close to that provided in this case by Leica Microsystems. Dr. Fuller has also informed the undersigned Contracting Officer that the stainer technology provided by Leica Microsystems will result in an approximately 30% increase in productivity (samples being able to be tested) along with approximately 25% savings in reagents and labor costs associated with testing actions. This is very significant in light of recent budgeting cuts/constraints to be able to anticipate this type of productivity increase along with this level of cost savings.

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition: Leica Microsystems is the only vendor who has expressed an interest in this requirement to date.

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: Dr. Fuller and his staff will continue to monitor the commercial anatomic pathology equipment testing market for any significant technology changes and for other sources of supply before making subsequent requests for the same or similar supplies and services. At this time, no future acquisition for these same services and supplies is planned for as this requirement as this acquisition is for a 1-year base period and four (4) each 12-month option periods. This lengthy period of time is necessary in order for the vendor to be able to recoup the cost of providing the stainer itself.

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.

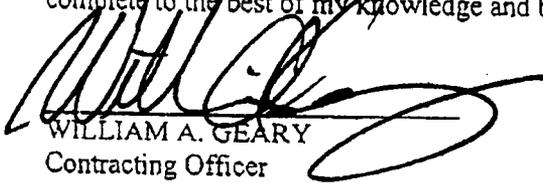

EDWARD P. FULLER, MD
Chief, Pathology and Laboratory Medicine Service
Biloxi VA Medical Center

8/2/2017

Date

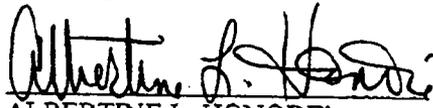
13. Approvals in accordance with FAR 6.304

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


WILLIAM A. GEARY
Contracting Officer

3 Aug 2013
Date

b. P&C: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.


ALBERTINE L. HONORE
Chief, Purchasing and Contracting
Biloxi VA Medical Center, Network Contracting Office 16

5 Aug 2013
Date

c. NCM/PCM: I certify the justification meets requirements for other than full and open competition.


AARON VILLALPANDO
Network Contract Manager
Network Contracting Office 16

8/13/2013
Date

d. SAO: I certify the justification meets requirements for other than full and open competition.

RICKY L. LEMMON
SAO Director, Central Region

Date

c. VHA HCA's Review and Approval: I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve it for other than full and open competition.

MR. NORBERT DOYLE
Chief Procurement Officer
VHA, Head of Contracting Activity

Date