

## DEPARTMENT OF VETERANS AFFAIRS

### Justification and Approval

For

### Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, VISN 4, SAO East, Pittsburgh VA Medical Center 646. Purchase Request number 646-13-2-080-0593 & 646-13-3-080-0673. VA Medical Center, 1010 Delafield Road, Pittsburgh, PA 15215.
2. **Nature and/or Description of the Action Being Processed:** This is a request for other than full and open competition. The Department of Veterans Affairs proposes to award a sole source procurement to Ventana Medical Systems, Inc. for the procurement of antibodies and reagents utilized in the facilities Ventana immunostainers. These reagents are used to diagnose disease in patients. All supplies for the analyzer equipment are proprietary to Ventana. The award will be firm fixed price.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** This procurement is to provide biochemically engineered monoclonal and polyclonal antibodies, conditioners and reagents specific to Ventana equipment. Procurement of these reagents and supplies is needed to support the testing of samples and proper diagnosis of patients.
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;
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 reagents are proprietary to Ventana and there are no other known sources for these specific stains that will properly work with our current Ventana equipment. Not using Ventana certified slides may lead to incorrect diagnosis of patients. Ventana is the only manufacturer of these reagents which come in prepackaged, self-contained and pre-diluted slides which are configured to communicate, via electronic chip, the date used, the expiration date and the volume of reagent to the Ventana Bechmark Immunostainer. Furthermore, the vendor is the only source that can provide the necessary liquid cover slips that are compatible with their machines.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Prior to the purchase of the Ventana strainers utilized in the VAMC Dept of Pathology, bids were received from Dako Biomedical and Leica Biomedical for similar units. Market research indicates that the only reagents compatible with the Ventana equipment is manufactured and sold solely by Ventana.

Other reagents that are available from other source are for manual tests only and cannot be used with Ventana equipment. GSA Advantage, Elibrary, FPDS, FBO and the NAC websites where all reviewed for substitute goods, alternatives and Vendors. The findings indicate that other government agencies have had the same results and utilized sole source justifications as there are no substitute good or other vendors for the needed supplies. Vendors have also been contacted I the past to see if they can provide these supplies and have not been able to do so.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** All antibodies and reagents are comparable in price to competitors. Past procurements from the VAPHS and other government agencies for these items indicate that the current price is fair and reasonable.

Referenced acquisitions: 646-A30265  
646-A30213  
646-A30127

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Ventana Biomedical has over 4500 immunostaining units (similar to the ones utilized in the pathology department) in place throughout the United States. GSA Advantage, Elibrary, FPDS, FBO and the NAC websites where all reviewed for substitute goods, alternatives and Vendors. The findings indicate that other government agencies have had the same results and utilized sole source justifications as there are no substitute good or other vendors for the needed supplies. Vendors have also been contacted I the past to see if they can provide these supplies and have not been able to do so.

Referenced acquisitions: VA259-12-Q-0238-001  
PR623283

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** Ventana antibodies and reagents are pH balanced to be used in protocols ordered by the department's pathologists.

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:** Continually checking with Ventana for distributors is an option however, at this time there are no actions we can take to overcome the need for a justification for these supplies.

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.

Frank A. Fusca (PA ASCP)  
Health Science Services Supervisor 4/9/2013\_\_\_\_\_

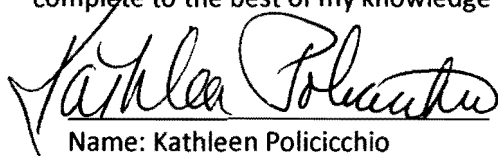
13. Approvals in accordance with FAR 6.304

- a. **ACO:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

  
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Name: Erik Whitaker  
Title: ACO  
Facility: 646, Pittsburgh

4/16/2013  
Date

- b. **Contracting Officer's Certification: (required)** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

  
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Name: Kathleen Policicchio  
Title: CO  
Facility: 646, Pittsburgh

4/16/2013  
Date

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

  
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Name: Michael J. Lamo  
Network Contract Manager  
VISN/PCA X

4/16/2013  
Date