

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

1. **Contracting Activity:** Department of Veterans Affairs, VISN 16, VA Medical Center- Biloxi, MS
VA Medical Medical Center
400 Veterans Blvd
Biloxi, MS 39531

2. **Nature and/or Description of the Action Being Processed:** The Department of Veterans Affairs proposes to enter into a firm fixed price contract on the basis of other than full and open competition for the purchase of special stains for histological specimens to be used by the NexES Special Stains instrument provided by Ventana Medical Systems

3. **Description of Supplies/Services Required to Meet the Agency's Needs:**
The reagents and supplies for the Ventana instrumentation are intended to standardize the processing of tissue specimens for diagnostic evaluation by pathologists. These reagents are optimized and validated for use on the NexES Special Stains Instrument and are configured specifically for this instrumentation.

Estimated Value: \$

Transaction Number: 520-14-1-077-0046

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):**

α. Only One Responsible Source (FAR 6.302-1) – The staining kits and bulk reagents required by the Ventana NexES Special Stains Platform are equipment specific and no other supplies can be substituted in the processing of histological specimens.

No other staining kits fit on this instrument. Reagents and supplies for the Ventana instrument are designed to standardize the preparation and staining of cells mounted on a microscope slide for examination by pathologist.

A delay in receipt of the required supplies would result in an interruption of processing, and the inability to deliver patient results. The Ventana system and supplies, when used in conjunction, are the only FDA approved solution to be used on the Ventana equipment at VA Medical Center Biloxi. No other contractor is able to provide an FDA approved solution for the **Ventana NexES** equipment.

Reagents and supplies are equipment specific. This is a sole source justification for the requirement to ensure continuation of service for staining kit reagents to support the pathology and laboratory at

Biloxi VAMC. This service recognizes that the interruption in services would severely hinder patient care and treatment. A delay in receiving the required reagents could cause further illness and potentially cause a Veteran's death if the laboratory is not able to analyze the specimens in a timely manner.

The instrument used in histology for the staining of special slides that are specimens obtained typically during a surgical procedure will only accept this particular stain. No other stain is compatible with this equipment.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

The VA Prime Vendor does not manufacture these items nor can they provide these items. Internet search for these particular products do not reveal acceptable alternatives. This vendor, who is a Small Business, is the sole manufacturer and sells direct. As technology becomes available, research will be performed to consider other products that meet or exceed the current requirements. The notice required by FAR 5.201 will be published.

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

Anticipated cost will be considered fair and reasonable and provide the basis for this determination FAR Part 13.106(a). The cost of these supplies is consistent with industry standards for other pathology stains and supplies to be acquired for other machines. One or all Price analysis techniques will be used to verify that the overall price offered is fair and reasonable:

- a. Comparison of previously proposed prices and contract prices with current proposed prices for the same or similar service.
- b. Comparison of proposed prices with independent Government cost estimates.

Comparison of proposed prices with prices obtained for maintenance services on similar medical equipment or prices obtained for other VA contracts for the same equipment.

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

Market research was completed to determine if there is other supplier available that could provide those specific stains and supplies or if other manufacturer's product could be used on the equipment presently used in Biloxi VAMC pathology and laboratory. Ventana Medical Systems Inc., as the manufacturer of the equipment, holds all intellectual/proprietary rights for the equipment and it stains and supplies to be used on this equipment. They do not certify or authorize any third party distributor to sell its products. At this time, there were no other sources available for competition for this unique purchase request.

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

Medical device product and the supplies manufacturing is heavily regulated industry. The Food and Drug Administration (FDA) is the principal healthcare regulatory authority in the United States, having jurisdiction over medical devices, drugs, biologics, and combination products. The paramount objectives driving policy decisions by the FDA are safety and efficacy of healthcare products. For that reason, the manufacturer of the equipment holds all intellectual/proprietary rights to the equipment, associated parts and accessories and its operating system and does not certify or authorize any third party service provider to maintain its products and in many instances to provide the specific stains or chemical components to be used on the equipment.

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

See Section 6 above.

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:

See Section 9 above.

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, M. D.
Chief of Pathology & Laboratory Medicine Service
Gulf Coast Veterans Health Care System

11/14/13

Date

13. Approvals in accordance with FAR 6.304

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

RENATA OTT
CONTRACTING OFFICER
ALEXANDRIA VA HEALTH CARE SYSTEM

Date

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



MICHAEL E. LEWIS
CHIEF, PURCHASING AND CONTRACTING
ALEXANDRIA/VA Health Care System
Network Contracting Office 16

11/14/13

Date