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:** Ventana is a sole source vendor of anatomic pathology/histology supplies. The purpose is to produce immunohistochemistry/insitu hybridization antibodiesfor histological specimens. The intended use of these antibodiesis is to aid in the diagnosis of pathological disease such as cancer. The Benchmark XT IHC/ISH instrument requires specific pre-dilute, ready to use antibodies provided through Ventana in order to process patient samples.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:**
   The antibodies required for the Ventana instrumentation are intended to standardize the processing of tissue specimens for diagnostic evaluation by pathologists. The antibodies required are equipment specific and no other supplies can be substituted.

   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):**

   Only One Responsible Source (FAR 6.302-1) – The antibodies required are equipment specific and no other supplies can be substituted. This is a sole source justification for the requirement to ensure continuation of service of 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.

   i. The pre-dilute, ready to use IVD antibodies for the Ventana instrumentation are intended to standardize the processing of tissue specimens for diagnostic evaluation by pathologists. The following antibodies used in this histological process are required, based on vendor availability or clone availability, to be purchased through Ventana Medical Systems. The CINtec p16 antibody is an

IHC assay used for the qualitative detection of the p16 protein in cervical biopsies. This product is intended for in vitro diagnostic use (IVD) and should be evaluated by a qualified pathologist. This antibody is only offered through Ventana. No other vendor offers this product.

ii. The antibodies utilized by VA Biloxi are only offered through Ventana Medical Systems based on the *specific species and clone* of that antibody. The following clones have been optimized and validated for use on the Benchmark XT Staining Platform, and these Rabbit Monoclonal Primary Antibody clones are only available through Ventana Medical Systems.

i. ***H.Pylori***- Clone SP48
ii. ***BCL***-2- Clone SP66
iii. **Calretinin**- Clone SP56
iv. **KI67**- Clone 30-9
v. **CD10**- Clone SP67
vi. **CD79a**- Clone SP18
vii. **Synaptophysin**- Clone SP11
viii. **CD23**- Clone SP23
ix. **CD3**- Clone 2GV6
x. **TTF1**- Clone SP141
xi. **Cytokeratin 20**- Clone SP33
xii. **Cytokeratin 7**- Clone SP52
xiii. **CD5**- Clone SP19

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 an FDA approved solution for the clinical diagnosis of patient samples at VA Medical Center Biloxi.

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 antibodiesand 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 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 ad 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 antibodies 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. — Date: 11/14/13
Chief of Pathology & Laboratory Medicine Service
Gulf Coast Veterans Health Care System

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.

Digitally signed by renata.ott@va.gov
Date: 2013.11.22 09:46:08 -06'00'

RENATA OTT — Date
CONTRACTING OFFICER
ALEXANDRIA VA HEALTCH CARE SYSTEM

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

11/14/2013

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

Date