DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Activity:** The agency responsible for this acquisition is the Veterans Health Administration (VHA), Eastern Colorado Health Care System (ECHCS). The contracting activity is the VHA SAO West, Network Contracting Office 19, and 4100 E. Mississippi Avenue, Ste 900, Glendale, CO 80246. The Purchase Request Number is 554-12-1-023-0296

2. **Nature and/or Description of the Action Being Processed:** On the basis of other than full and open competition under the authority of FAR 6-302-1, the Department of Veteran Affairs proposes to award a sole source procurement (base plus four 1 year options) to Ventana Medical Systems, Inc. for the purchase of Reagents, Test Kits, Antigens and Antibodies for use in diagnosing patient care cases. ECHCS now owns Ventana's Benchmark LT Full Analyzer System (N750-BMKLT-FS), used to conduct testing for the processing and complete immunohistochemical work-up of Cytology, Autopsy and Surgical specimens in the diagnosis of disease in patients. The life of the Ventana Benchmark Analyzer is approximately 15 years and was purchased in July 2007. All the supplies with this equipment are proprietary. This procurement and the award contemplated will be a firm-fixed price, with delivery of reagents and supplies from Ventana Medical Systems located at 1910 Innovation Park Drive, Tucson, AZ 85755.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The procurement is to provide reagents and other supplies to the Pathology and Laboratory Medicine Services (P&LMS) of the ECHCS (base plus four 1 year options) at the estimated total annual price of $94,000.00 each year for a total proposed award of $470,000.00. The P&LMS section utilizes the Ventana Benchmark LT Full Analyzer System, designed to use proprietary fitted vials of antibodies and other reagents that snap into the equipment. These reagents and supplies include the following: Ultraview Universal Dab Detection Kits, Liquid Cover slip High Temperature, Ez Prep (10x), Ssc (10x), Reaction Buffer (10x), Cell Conditioning (Cc1), Ebar Printer Ribbon, Ebar Label Kit, Temperature Verifier Slides, Confirm Negative Rabbit Control Ig, Negative Control Mouse Ig, Ema (Epithelia Membrane Antigen), Bel-6, Confirm Vimetin, Confirm Cd30, Actin, A-Smooth Muscle, Psa (Prostatic Specific Antigen), Confirm Ki67, Confirm Bcl-2, Confirm Desmin, Cyclin Dl, Cd138 (Syndecan-1), Confirm Cd34, Confirm Kappa, Confirm Cd15, Cd45 (Lca), Confirm Lambda, Confirm Cd79a, Cytokeratin (Pan), Cd10, Confirm Cd56, Confirm Thyroid Transcriptionfactor 1 (Ttf-1), Confirm Cd3, Confirm Cd5, Confirm S100, Confirm Cd20, And Confirm Cytokeratin. Procurement of the reagents and supplies is in support of testing and complete immunohistochemical work-up of Cytology, Autopsy and Surgical specimen diagnosis of disease in patients. This supports the mission of the VA to provide timely, accurate and appropriate pathology services in support of patient care.

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:** The harm to the government in not using these supplies is that each time P&LMS changes manufacturers, the service is required, per accreditation, to perform complete patient and quality control correlations. These correlations require the duplicate testing of each immunostain/reagent to be used on 100 patients each. To accomplish duplicate testing, P&LMS would perform the stain in-house using the new vendor's stains, and also would have to send the sample to a reference lab. This would not only cost approximately $134,400.00, but would delay diagnosis of multiple diseases for patients.

   The proposed vendor has provided written assurance that the supplies required are proprietary to the manufacturer and analyzer. Moreover, the contractor, Ventana Medical Systems, is the only source of specialized immunohistochemical reagents that come in prepackaged, self-contained, pre-diluted reagents that are configured to communicate, via electronic chips the date in use, the expiration date of the reagent and the volume of reagent to the Ventana Benchmark Immunostainer. The proposed vendor can also supply reagents that have at least a 1 year expiration date upon delivery, and provide liquid cover slips compatible with the Benchmark Immunostainer.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Direct inquiries and request for vendor capabilities were made to NAICS 325413 In-Vitro Diagnostic Substance Manufacturers to determine if their reagents were compatible. Neither the Contracting Office and/or P&LMS received affirmative confirmation that these companies had reagents that were compatible. Mandatory sources of supply via GSA website (http://www.gsaelibrary.gsa.gov/ElibMain/ElibHome) were also reviewed to determine if there were any reagents and supplies listed that were compatible with the Ventana Benchmark Analyzer. P&LMS indicates the reagents and supplies listed were either manual tests or were not compatible with the Ventana Benchmark Analyzer.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated total dollar amount of the proposed acquisition is $470,000.00. Past procurement data and market research described in this document support the determination of price reasonableness.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Direct inquiries were made to NAICS

325413 In-Vitro Diagnostic Substance Manufacturers to determine if their reagents were compatible. Neither the Contracting Office and/or P&LMS received affirmative confirmation that these companies had reagents that were compatible. Mandatory sources of supply via GSA website (http://www.gsaelibrary.gsa.gov/ElibMain/ElibHome) were also reviewed to determine if there were any reagents and supplies listed that were compatible with the Ventana Benchmark Analyzer. P&LMS indicates the reagents and supplies listed were either manual tests or were not compatible with the Ventana Benchmark Analyzer. P&LM conducted an Internet query of suppliers of immunohistochemical stains and found several available, but only as manual kits. Ventana Medical Systems has provided written assurance that the supplies required are proprietary, and a review of https://www.fbo.gov Government procurements made to this vendor supports the same as all reviewed have been done on a Sole Source basis.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** The estimated cost for a complete purchase of another analyzer and correlation studies to meet accreditation requirements and ensure correct diagnosis will be $194400.00 and would result in the delay of diagnosis.

10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** No other vendor has expressed written interest in the acquisition.

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**: ECHCS does anticipate that there will be subsequent procurements for immunostain reagents and supplies in the future if the Ventana Benchmark Analyzer requires replacement. To the maximum extent practicable competitive procurement practices will be used to acquire such diagnostic equipment and the follow-on reagents and supplies. ECHCS is continually performing market research and ongoing evaluation of vendors and equipment through vendor visits and displays.

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.

Shirley M Nelson — 2/24/12

Name: Shirley Nelson — Date
Title: Laboratory Manager
Facility: VA ECHCS

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.

Name Heather Voyt — Date 2/24/12
Title Contracting Officer
Facility VISN 19

b. **VISN/Designee:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Sarilynn Thomas — 24 Feb 12

Name Sarilynn Thomas — Date
Title Commodities Supervisor
Facility VISN 19