

## DEPARTMENT OF VETERANS AFFAIRS

### Justification and Approval (J&A) for Other Than Full and Open Competition (>SAT)

**Acquisition Plan Action ID: 36C249-19-AP-1768**

1. **Contracting Activity:** Department of Veterans Affairs, VISN 09, 626 Nashville VA Medical Center  
PR# 626-20-1-066-0004

2. **Nature and/or Description of the Action Being Processed:**

This is a Justification and Approval for a Sole Source contract to Roche Diagnostics Corp IAW all applicable FAR and VAAR regulations. This will be a new contract for Ventana Stain Kits for the requisite Veterans Affairs Medical Center (VAMC). This will be a firm fixed price contract for the medical supplies described herein.

**FAR13.5 Simplified Procedures for Certain Commercial Items:**

This procurement is for Roche Ventana Stain Kits IAW FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures (SAP) are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2. Estimated Value: \$690,616.30

3. **Description of Supplies/Services Required to Meet the Agency's Needs:**

The Nashville VAMC has a new requirement for Ventana Stain kits for diagnosing and treating patients. Ventana innovates and manufactures instruments and reagents that automate tissue processing and slide staining for cancer diagnostics. The Ventana solutions are intuitive, integrated staining, workflow management platforms, and digital pathology solutions optimize laboratory efficiencies to reduce errors, support diagnosis and inform treatment decisions for anatomic pathology professionals. This requirement is for a base year (12-months) plus four (4) option years. Each period of performance will cost an estimated \$1138,123.26 with a total overall estimated cost of \$690,616.30.

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):**

Roche Diagnostics Corp is the sole manufacturer of the Ventana Stain kits and accompanying equipment. The Nashville currently owns the Ventana stain testing equipment and has utilized this equipment for the past 15 years. Staff are already trained and knowledgeable on the operation of this equipment. As the sole source, Roche Diagnostics Corp is the only vendor that can provide the Ventana Stain Kits. Roche Diagnostics has provided a sole source letter documenting their proprietorship of the Ventana testing platform.

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

Market research was conducted to determine potential vendors that can fulfill this requirement. Through searches of FBO, FDA, FPDS, NAC, and VIP no other vendors were discovered that can potentially fulfill this requirement. A sole source letter has been provided from the vendor and is included in the contract file.

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

The CO has determined that the anticipated cost is fair and reasonable based on the ICGE and comparisons with acquisitions from other Veterans Affairs located through a search of FPDS for Ventana stain kits. Costs listed for those requirement were consistent with pricing provided for this requirement.

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

Market Research was conducted IAW FAR Part 10. Databases were queried to include VIP, GSA, FPDS, but due to the sole source nature of this procurement no other vendors were found. The VA's Rule of Two in association with Veteran's First Contracting initiative could not be satisfied in conjunction with this requirement. An open market procurement utilizing the authority of FAR 13.5 is being contemplated. Full analysis of Market Research is available in the Market Research Report located in the eCMS Briefcase and is a part of the contract file.

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

Roche Diagnostics Corp has provided a sole source letter explaining that Ventana Stain Kits are proprietary to Roche and there are no authorized vendors or distributors.

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

Roche Diagnostics Corp, 9115 Hague Rd., Indianapolis, IN 46256

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:**

Market research will be conducted on future acquisitions to obtain other potential vendors to solicit in order to obtain maximum competition and resultant pricing that represents a best value to the government.

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.

\_\_\_\_\_  
Vanessa Dailey  
Nashville VA Medical Center

\_\_\_\_\_  
Date

13. **Approvals in accordance with the [VHAPM Part 806.3 OFOC SOP](#):**

- a. **Contracting Officer or Designee'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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MONICA THOMPSON  
Supply West Branch  
Chief NCO 9

\_\_\_\_\_  
Date

- b. **Division Chief's Concurrence:**

☐ Concur    ☐ Non-concur

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ROBERT (BOBBY) KELLNER  
NCO 9, Division Chief (Supplies,  
Services, & Prosthetics)

\_\_\_\_\_  
Date