DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID:___36C256-19-AP-3611___

1. **Contracting Activity:**

   Department of Veterans Affairs,
   VISN 16 Jackson VA Medical Center Medical Center

   2237 – 586-20-1-042-0022

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

   Jackson VA Medical Center has a requirement to purchase reagents and supplies for its Roche Ventana IHC system. The reagents and supplies are needed to perform immunohistochemistry, in-situ hybridization, fluorescent in-situ hybridization, and immunofluorescence in the Path and Laboratory Medicine Service, located at 1500 E. Woodrow Wilson, Jackson, Mississippi.
   Reagents and supplies must be compatible with existing Roche Ventana IHC Stain Instrumentation without any instrument modifications. Ventana/Roche supplies are the sole source supplies that meet the histology department's needs because the instrument is proprietary and already being utilized on site. Currently, the medical centerl owns the equipment. The Government intents to make an award for a firm fixed contract for 1 base year and 3-1 year options.

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

   The estimated value of the proposed action is $629,654.50 which includes 1 base year and 3 1 year options.

   Jackson VAMC is primarily dependent on Ventana/Roche reagent staining kits as well as an investment was made to purchase and install the equipment required to run the test. The purchase is inclusive with ROCHE Tissue primary and advanced staining instrumentation which serves as a component that interfaces with the existing primary and advanced staining instrumentation for interchangeability. ROCHE IHC reagent and supplies allows for high medical value diagnostics, companion diagnostics, and fully FDA approved PMA and IVD diagnostic testing. The ROCHE reagent and supplies integrates fully with the existing ROCHE Tissue solutions without any need for instrument modifications that are usually required by other systems. The challenges of limited space and small numbers of staff does not allow for any changes in the system or any major deviations because this usually will require a lot of manual labor which will possibly hinder performance of other time sensitive duties

Brief Description of Service*		Period of Performance	Estimated Amount
Base Year:	October 1, 2019 thru September 30, 2020		$ 125,930.90
Option Year 1:	October 1, 2020 thru September 30, 2021		$ 125,930.90
Option Year 2:	October 1, 2021 thru September 30, 2022		$ 125,930.90
Option Year 3	October 1, 2021 thru September 30, 2023		$ 125,930.90
	TOTAL		**$ 629,654.50**

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;

ROCHE IHC reagent and supplies are unique and only allow for high medical value diagnostics, companion diagnostics, and fully FDA approved PMA and IVD diagnostic testing. Currently, the ROCHE reagents and supplies integrates fully with the existing ROCHE Tissue solutions without any need for instrument modifications. Also, Ventana's reagents are leaders in automate tissue processing and slide staining for cancer diagnostics and are successful in identifing patients most likely to respond favorably to specific therapies.
Last, The products which make up the RTD portfolio are subject to FDA approval and regulation. Roche IHC obligations with respect to their RTD consumables include ensuring the products are properly temperature controlled throughout the entire shipping and storage process in route to a customer site. Failure to comply with these regulations could create potential patient safety issues. Because of potential patient safety issues and other factors, RTD has made the business decision to only sell these products directly to the end-users.

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 requested reagents and supplies are manufactured by Roche and Ventana is the subdivision of Roche. The proprietary equipment and supplies are currently installed and reside on site therefore, changing to a different vendor is not prudent nor cost effective and will potentially

create a backlog for surgical samples requiring immediate processing for diagnostic testing of patient's samples. The associated reagent and supplies for use with the Roche Ventana IHC Stainer will enable the Medical Center's Pathology department to continue processing urgent and critical testing with little or no delay, therefore allowing for faster turn-around time and consistent and accurate diagnosis. Also,Ventanas' intuitive, integrated staining, workflow management platforms, and digital pathology solutions optimize laboratory efficiencies reduce errors, support diagnosis and inform treatment decisions for anatomic pathology professionals.
Accordingly, Roche is the only firm capable of providing the supplies that were described above in Section III as well as the Veteran's Health Administration not experiencing substantial duplication of cost that could not be expected to be recovered through competition.

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

A sources sought synopsis was posted on FBO on 8/9/19 and ROCHE was the only company that responded and confirmed that the products are proprietary to Roche Diagnostics Corporation (RDC) and only available for purchase in the United States directly from RDC.

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

The contracting officer has deemed the price to be fair and reasonable from the review and comparison of historical purchases in IFCAP that were deemed to be of the same value and quality of the products that are to be procured in this procurement.

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

The Jackson VA Medical Center has a requirement for a service agreement for a Ventana/Roche IHC system of supplies and reagents for a Base Year and three (3) additional One (1) Year options (exercisable at the discretion of the Government). The supplies and reagents shall be used to perform immunohistochemistry, in-situ hybridization, fluorescent in-situ hybridization, and immunofluorescence in the Path and Laboratory Medicine Service, located at 1500 E. Woodrow Wilson, Jackson, Mississippi. The contracting officer has determined that the market does not support the VA Rule of Two because SDVOSB's and VOSB's did not respond to the RFI that was posted, however, market research revealed that the sought reagents are proprietary to Roche Diagnostics Corporation (RDC) and only available for purchase in the United States directly from RDC. The market research findings show that this procurement action should be awarded as a sole source procurement due to proprietary rights of the supplies and reagents.

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

Currently the market shows that the products are proprietary to Roche Diagnostics Corporation (RDC) and only available for purchase in the United States directly from RDC.

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

Roche Diagnostics Corporation (RDC) expressed in writing that they are the only company that can provide the reagents because the products are proprietary to Roche Diagnostics Corporations.

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:

Contracting staff will be required to practice their due diligence of market research of ensuring that the market for finding competitive contractors that can provide pathology reagents for detecting cancer, etc has not changed by looking at current innovative researchers, historical data, previous awards, etc. to ensure that the Government is getting a fair and reasonable price and best value for the supplies that are required.

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.
(This signature is the requestor's supervisor, fund control point official, chief of service, someone with responsibility and accountability)

_____ _____
Name Date
Title
Facility

13. Approvals in accordance with the VHAPM Part 806.3 OFOC SOP: *This part if filled out by Contracting Staff as part of the Justification*

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.

[redacted]

b. **<u>One Level Above the Contracting Officer (Required over SAT but not exceeding $700K):</u>** I certify the justification meets requirements for other than full and open competition.

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