

## LIMITED SOURCES JUSTIFICATION

ORDER >SAT

FAR PART 8.405-6

Acquisition Plan Action ID: 36C244-19-AP-2894

- 1. Contracting Activity:** Department of Veterans Affairs, VISN 04, VA Pittsburgh Healthcare System, University Drive Campus, University Drive, Pittsburgh, PA 15240. PR: 646-20-1-080-0013
- 2. Description of Action:** This acquisition is conducted under the authority of the Multiple-Award Schedule Program ([41 U.S.C. 251](#) and [40 U.S.C. 501](#)) to acquire .

Order against: ☒ FSS Contract Number: V797D-70105

Name of Proposed Contractor: Roche Diagnostics Corporation

Street Address: 9115 Hague Road, P.O. Box 50457

City, State, Zip: Indianapolis, IN 46250

Phone: 800-428-5076

**3. Description of Supplies or Services:**

The estimated value of the proposed action is: Base Year \$117,501.00, Option Year 1 \$117,501.00, Option Year 2 \$117,501.00, Option Year 3 \$117,501.00, Option Year 4 \$117,501.00, and the total base plus 4 one-year options is \$587,505.00.

This new request includes the following required reagent/supplies.

HPV Amplification/Detection Kit	05235880190	16
HPV Controls Kit	05235855190	16
System Sample Preparation Kit	0523578219	16
System Liquid Cytology Preparation Kit	05235812190	16
System Wash Buffer Kit	05235863190	16
CO-RE Tips, 1,000 µl	04639642001	10
System Extraction Plate	05232716001	4
Reagent Reservoir, 50 mL	05232732001	4
Reagent Reservoir, 200 mL	05232759001	2
Sarstedt Tubes	063950023001	8

These supplies are utilized on the Roche Cobas 4800 instrument to perform automated Human Papilloma Virus (HPV) testing.

**(4) IDENTIFY THE AUTHORITY AND SUPPORTING RATIONALE (see 8.405-6(a)(1)(i)(A), (B), and (C) or 8.405-6(b)), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE. (CHECK ALL THAT APPLY AND COMPLETE)**

- ☐ An urgent and compelling need exists and following the ordering procedures would result in unacceptable delays.
- ☒ Only one source is capable of providing the supplies or services required at the level of quality required because the supplies or services are unique or highly specialized.
- ☐ In the interest of economy and efficiency, the new work is a logical follow-on to an original Federal Supply Schedule order provided that the original order was placed in accordance with the applicable Federal Supply Schedule ordering procedures. The original order must not have been previously issued under sole source or limited source procedures.
- ☐ Items peculiar to one manufacturer:
- ☐ A patent, copyright or proprietary data limits competition. The proprietary data is: (If FAR 8.405-6(a)(2) iii before posting. Do not include specific proprietary data. Only mention the type of equipment, procedure, etc. to show that proprietary supplies or services are being procured.)
- ☐ These are "direct replacements" parts/components for existing equipment.
- ☐ The material/service must be compatible in all aspects (form, fit and function) with existing systems presently installed/performing. Describe the equipment/function you have now and how the new item/service must coordinate, connect, or interface with the existing system.

**(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.404(d) TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:**

This sole source new request is only available through Roche Diagnostics Corporation (Roche). The requested reagents/supplies are FDA approved and are authorized to be used on the Roche Cobas 4800 instrument that is already in place at the Pittsburgh VA. Product substitutions are not FDA approved and would be considered a laboratory modified test. Any attempt to purchase from a different vendor will result in the immediate removal of the Roche 4800 instrument and cause a cease in patient testing and may cost the VA Medical Center additional

money to replace. Roche Diagnostics Corporation is sole manufacturer and exclusive provider of the Roche Cobas 4800 products and support services for this equipment. Roche has been used in previous years as a supplier for automated HPV testing supplies. During those times, the cost was deemed fair and reasonable.


**(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED:** Market research was conducted to include searches of General Services Administration (GSA), the National Acquisition Center (NAC), the Strategic Acquisition Center (SAC), and Federal Business Opportunities (FBO). Market research has determined Roche is the sole distributor of the requested reagents and supplies. Furthermore, an email from Roche Diagnostics Corporation stating Roche is the sole manufacturer and distributor of the Cobas 4800 is uploaded to the briefcase file for reference.

**(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:**  
The Pittsburgh VA currently utilizes the Roche Cobas 4800 instrument and staff are fully educated and proficient in its use.

**(8) A STATEMENT OF THE ACTIONS, IF ANY, THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS THAT LED TO THE RESTRICTED CONSIDERATION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES OR SERVICES IS MADE:** Currently, the Cobas 4800 is considered state of the art testing. As technology continues to improve and other vendors develop new testing methodologies, this procurement can be competed in the future. At this moment, there are no barriers that the agency is capable of removing to allow full competition.

**(9) 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. I understand that processing of this limited sources justification restricts consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4.

JASON C.  
TEDROW 214979



Digitally signed by JASON  
C. TEDROW 214979  
Date: 2019.08.29 13:25:37  
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Jason Tedrow  
Lead medical Technologist  
Pittsburgh VA Healthcare System

**(10) APPROVALS IN ACCORDANCE WITH THE [VHAPM Part 806.3 OFOC SOP](#):**

**a. CONTRACTING OFFICER'S CERTIFICATION (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

RONALD J.  
KLINE 152627

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RONALD J. KLINE 152627  
Date: 2019.09.03 08:16:44  
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Ronald J. Kline  
Contracting Officer  
NCO4-Commodities 2

**b. One Level Above the Contracting Officer (Required over the SAT but not exceeding \$700K):**

I certify the justification meets requirements for other than full and open competition.

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Darlene Seminko,  
Branch Chief  
NCO4- Commodities 2