

LIMITED SOURCES JUSTIFICATION

ORDER >\$150,000

FAR PART 8.405-6

Acquisition Plan Action ID: VA263-17-AP-11706

- 1. Contracting Activity:** Department of Veterans Affairs, VISN 23, Minneapolis VA Medical Center, Molecular Laboratory, One Veterans Drive, Minneapolis MN 55417. Network Contracting Office (NCO) 23, St. Cloud Minnesota
Delivery Location: BB-141, Molecular Laboratory

2237: 618-18-3-106-0034

- 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 establish an FSS BPA (Blanket Purchase Agreement) for the Minneapolis VA HCS Molecular Laboratory at the Minneapolis VA Health Care System for a base period and four (4) one-year option periods.

BPA against: ☒ FSS Contract Number: V797D-70105, effective March 16, 2017 – March 15, 2022

Name of Proposed Contractor: Roche Diagnostics

Street Address: 9115 Hague Road, PO Box 50457

City, State, Zip: Indianapolis IN 46250-0457

Phone: 303-248-6862

3. Description of Supplies or Services:

Delivery date: Start/Effective date: 04/01/2018

Base Period:	04/01/2018 – 09/30/2018
Option Year No. 1:	10/01/2018 – 09/30/2019
Option Year No. 2:	10/01/2019 – 09/30/2020
Option Year No. 3:	10/01/2020 – 09/30/2021
Option Year No. 4:	10/01/2021 – 09/30/2022
Option Period No. 5:	10/01/2022 – 03/31/2023

To establish an FSS BPA (Blanket Purchase Agreement) with Roche Diagnostics on a sole source basis for reagents, controls, calibrators, and expendable supplies needed by the molecular laboratory at the Minneapolis VA Health Care system. These supplies are for HIV, HCV, and DNA extraction, which have been found acceptable for use with the Roche COBAS Taqma, Ampliprep, and Roche Magna Pure instrumentation. These products are sold exclusively by Roche Diagnostics. All of these products are proprietary Roche products and procured exclusively on a direct basis. These materials are consumed on Roche platforms and require specific shipping and handling protocols. To ensure product integrity and the best possible customer experience, Roche ships directly to their customers and do not leverage any distribution partners.

Estimated Quantities:

Item #	Description/Part Number*	Qty
1	Kit Cap-G CTM HIV-1 V2.0 US-IVD	20
2	System Wash Reagent (5.1L)	85
3	LightCycler Factor II (Prothrombin) G20210A Kit v2.0	7
4	LightCycler Factor V Leiden kit v2.0	9
5	Capillaries, 20 uL (5x96)	10
6	K-tube, (12x96)	10
7	Specimen processing units (SPU's)	26
8	Sample input Tubes with Barcode Clips (12x24)	25
9	Racks of Output Tubes (12x36)	2
10	K-tips Rack (12x36)	16
11	COBAS AmpliPrep/COBAS Taqman HCV v2.0 (includes sample prep reagent)	64
12	COBAS z 480 Mircowell Plate and sealing Film	4

(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.

☐ 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.

Roche Diagnostics is the sole distributor of the required reagents, controls, calibrators, and expendable supply items needed by the Minneapolis VA HCS Molecular Laboratory

to use with the highly specialized Minneapolis VA HCS owned Roche COBAS Taqman, COBAS Ampliprep, and Roche Magna pure instrumentation. All of the products listed above are proprietary Roche products and procured exclusively on a direct basis. These materials are consumed on Roche platforms and require specific shipping and handling protocols. To ensure product integrity and the best possible customer experience, Roche ships directly to their customers and do not leverage any distribution partners. Roche Diagnostics does not have any SDVOSB/VOSB authorized distributors.

☐ 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.

Only Roche reagents can be utilized with the Minneapolis VA HCS Molecular laboratory owned COBAS Taqman, COBAS Ampliprep, and Roche Magna Pure instrumentation. All of the products listed above are proprietary Roche products and procured exclusively on a direct basis. These materials are consumed on Roche platforms and require specific shipping and handling protocols. To ensure product integrity and the best possible customer experience, Roche ships directly to their customers and do not leverage any distribution partners.

Procuring reagents from another company would force the Minneapolis VA laboratory into purchasing new instrumentation that correlated with the new vendor's reagents. Not only would this be a large expense for the VA, it is also very labor intensive and time consuming. New instrumentation must undergo an intensive validation study that would take a minimum of a month of a laboratory technicians time to complete. There is rigorous testing that must be completed before instruments can be utilized on actual patient samples. During that validation time, patient testing would be interrupted.

(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:

Only Roche reagents can be utilized with the Minneapolis VA HCS's Molecular Laboratory owned Roche COBAS Taqman, COBAS Ampliprep, and Roche Magna Pure instrumentation. These Roche products are found on the Roche FSS Contract No. V797D-70105. Purchasing reagents from an alternate vendor would force the Minneapolis VA HCS Molecular laboratory into purchasing new instrumentation that correlated with the new vendor's reagents. Not only would this be a large expense for the Minneapolis VA HCS, it is also very labor intensive and time consuming. New instrumentation must undergo an intensive validation study that will take a minimum of a month of laboratory technician's time to complete. During that validation time, patient testing would be interrupted. These reagents are found to be acceptable for use by the Minneapolis VA HCS Molecular laboratory. Before they are put into use, laboratory instruments they must go through an extensive validation process, and each year CAP (College of American Pathologists) samples are analyzed to ensure acceptable use from these reagents.

Pricing quoted by the vendor will be reviewed against the most recent Roche purchases to ensure pricing is fair and reasonable. In accordance with FAR 8.404 (d), GSA has already determined the price to be fair and reasonable. Due to the estimated value of this BPA and in accordance with FAR 8.405-4, the Contracting Officer will be asking for discount from FSS pricing when the BPA pricing is offered.

(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED:

Items are available via Roche Diagnostics' s FSS Contract No. V797D-70105. Roche does not have any authorized SDVOSB/VOSB authorized distributors. A Vetbiz search for NAICS '325413' along with the term 'roche' yielded no matches. When I contacted the vendor, they stated that they do not have any authorized SDVOSB/VOSB distributors. A Notice of Intent to Sole Source to Roche was posted on FBO for 10 days and the only reply received was from Roche Diagnostics.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION: None

(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:

If the Minneapolis VA requires procurement of new instrumentation that allows multiple vendor's expendables, this will become a competed action. In the future, if Roche allows distributors, this will be competed amongst those vendors.

(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.

(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.

b. One Level Above the Contracting Officer (Required over \$150K but not exceeding \$700K): I certify the justification meets requirements for other than full and open competition.

Date

HIGHER LEVEL APPROVAL (Required for orders over \$700,000):

c. VHA SAO HCA REVIEW AND APPROVAL (over \$700,000 to \$68 million): I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for restricting consideration of the Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4.

Date