

LIMITED SOURCES JUSTIFICATION

ORDER >\$150,000

FAR PART 8.405-6

Acquisition Plan Action ID: VA259-17-AP-10977

- 1. Contracting Activity:** Department of Veterans Affairs, VISN 19, Oklahoma VA Medical Center
- 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).

This requirement is for the purchase of Roche brand reagents and supplies to be utilized with the Roche96 Instrument at the Oklahoma City VA Medical Center.

This will provide HIV, HCV, and HBV test reagents and consumables for performance of molecular virological testing on the Roche96 COBAS AmpliPrep/COBAS TaqMan system in compliance with VHA Directives 1300.01 "National Viral Hepatitis Program" and 2009-063 "Reflex Confirmatory Testing for Chronic Hepatitis C Virus Infection".

Order against: ☒ FSS Contract Number: V797D-70105

Name of Proposed Contractor: Roche Diagnostic

Street Address: 9115 Hague Rd

City, State, Zip: Indianapolis, IN 46250

Phone: 317-521-3086

3. Description of Supplies or Services:

The estimated value of the proposed action is \$ 393,913.92

Roche brand reagents and supplies:

ITEM NUMBER	DESCRIPTION OF SUPPLIES/SERVICES	QUANTITY	UNIT
0001	MagNa Pure reagent tub, large	3.00	BX
0002	MagNa Pure reagent tub, 20mL	5.00	BX

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0003	MagNa Pure sample cartridge	4.00	BX
0004	MagNa Pure processing cartridge	3.00	BX
0005	MagNa Pure tip stands	3.00	BX
0006	MagNa Pure Rxn tips, large (30x32)	8.00	CS
0007	AmpliPrep Output Tube (12x24)	4.00	BX
0008	MagNa Pure LC TNAI (192 rxn)	10.00	EA
0009	AmpliPrep Input Tube-S w/barcode clips 12x24	35.00	BX
0010	Tube-K box of 12x96/COB.TaqMan	10.00	BX
0011	AmpliPrep Tip-K 1.2 mm ID 12x36	20.00	BX
0012	AmpliPrep SPU flapless box of 12x24	35.00	BX
0013	KIT CAP-G/CTM wash reagent 5.1 L IVD	85.00	EA
0014	Kit CAP-G/CTM HIV-1, 48 tests US-IVD	30.00	EA
0015	Kit CAP-G/CTM HCV, 72 tests US-IVD	85.00	EA
0016	Kit CAP-g/CTM HBV, 72 tests	10.00	EA
0017	O-ring gripper set of 10 AmpliPrep	2.00	EA
0018	Reagent tip AmpliPrep	6.00	EA
0019	Fan Filter	12.00	EA
0020	WASTE BAGS	1.00	PG
0021	POWER SUPPLY FILTER	6.00	EA
0022	Cartridge seals (MagNA Pure)	1.00	PG
0023	TaqMan Halogen Lamp, 120V	2.00	EA
0024	MagNA Pure Greasing Set	1.00	EA
0025	MagNA Pure O-ring Maintenance Kit	1.00	EA
0026	SYRINGE, 2.5mL	4.00	EA

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(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;

Roche Diagnostics is the manufacturer of these items and they do not provide these items for distribution. No other products can be substituted as the instrument requires Roche brand reagents and supplies. Utilizing substitute items risks damaging the instruments and invalidates all test results produced. Roche COBAS AmpliPrep/COBAS TaqMan Assays are the sole, proprietary test kits compatible with equipment installed.

☐ 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:

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The Roche COBAS AmpliPrep/COBAS TaqMan system is already in place within the laboratory, method validation studies and correlations required by accreditation have already been completed, policies are written, staff is trained and competency has been assessed for medical technologists using equipment, test files are already set up in the lab package for reporting of patient results into the electronic medical record. Selecting another manufacturer's reagents would require replacement of the existing instrument, retraining staff on the new instrument and all the costs required to perform method validation studies and correlations, and drafting of new policies to be put in place. Replacing the instrument is cost prohibitive.

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

As this is a brand name specific requirement extensive market research is not possible. The internet was searched to see what supply items were available online (list prices) but none were found. GSA Advantage was also searched but limited similar items were found listed. Previous contract pricing was used to compare to list pricing provided by Roche Diagnostic.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

The Roche96 COBAS AmpliPrep/COBAS TaqMan system is currently installed in OKC VA HCS clinical laboratory for performance of highly specialized molecular virological testing mandated by VHA National Viral Hepatitis Program. Roche COBAS AmpliPrep/COBAS TaqMan Assays are the sole, proprietary test kits compatible with this equipment.

(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:

This requirement will be reassessed when possible to see if there have been equipment changes and changes in supply requirements.

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

<u>Joseph D Legault</u>		<u>10/13/17</u>
SIGNATURE		DATE
<u>Joseph D Legault</u>	<u>Supv. med Technologist</u>	<u>Molecular</u>
NAME	TITLE	SERVICE LINE/SECTION
<u>OKC VA HCS</u>		
FACILITY		

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(10) APPROVALS IN ACCORDANCE WITH THE VHAPM Part 806.3 OFOC SOP: *This part is filled out by Contracting Staff as part of the Justification*

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



CONTRACTING OFFICER

10-16-2017

DATE

Edward Marshburn, Contracting Officer

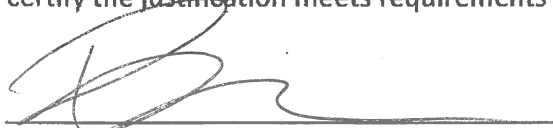
NAME AND TITLE

NCO 19

FACILITY

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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.


SIGNATURE

10/16/2017
DATE

Bai Perney
NCO 19 Services 2, Branch Chief