

LIMITED SOURCES JUSTIFICATION

ORDER >\$150,000

FAR PART 8.405-6

Acquisition Plan Action ID: VA69d-16-AP-6118

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in par. 3 below is sole source, therefore, consideration of the number of contractors required by FAR Subpart 8.4 – Federal Supply Schedules, is precluded for the reasons indicated below.

Restricted to the following source:

Manufacturer/Contractor: Roche Diagnostics Corporation

Manufacturer/Contractor POC & phone number: Angie Cope, 317-521-3086

Mfgr/Contractor Address: 9115 Hague Rd, P.O. Box 50457, Indianapolis, IN 46250-0457

☒ The requested material or service represents the minimum requirements of the Government.

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs

Great Lakes Acquisition Center (GLAC)

Hines VA Medical Center

5000 S. 5th Ave

Hines, IL 60141-3030

VISN:

12

(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:

Only one source is capable of providing the supplies required at the level of quality required because the supplies are unique or highly specialized; (FAR 8.405-6(a)(1)(i)(B)).

(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:

Molecular Pathology Reagents for the COBAS c4800.

(b) ESTIMATED DOLLAR VALUE: \$656,757.00

(c) REQUIRED DELIVERY DATE: ASAP

(4) IDENTIFICATION OF THE JUSTIFICATION RATIONALE (SEE FAR 8.405-6), 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)

☒ Specific characteristics of the material or service that limit the availability to a sole source (unique features, function of the item, etc.). Describe in detail why only this suggested source can furnish the requirements to the exclusion of other sources.

Roche is the sole manufacturer and distributor for all assays, including reagents and assay materials, performed on this system in the United States. The assays that will be performed on the COBAS c4800 test for the Human Papillomavirus (HPV), Chlamydia trachomatis / Neisseria gonorrhoeae (CT/NG) DNA, BRAF V600 Mutation and Epidermal Growth Factor Receptor (EGFR) mutation.

☐ 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.
Roche is the sole manufacturer and distributor for all assays, including reagents and assay materials, performed on this system in the United States. The assays that will be performed on the COBAS c4800 test for the Human Papillomavirus (HPV), Chlamydia trachomatis / Neisseria gonorrhoeae (CT/NG) DNA, BRAF V600 Mutation and Epidermal Growth Factor Receptor (EGFR) mutation.

☐ 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.

☐ An urgent and compelling need exists, and following the ordering procedures would result in unacceptable delays.

(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.4 TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:

The current equipment is only 3 years old, and it would not be cost effective to replace this equipment. The best value at this time is to purchase the reagents from Roche. Current Reagents for this equipment is available on FSS contract V797D-70105

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

A search of Federal Prison Industries website utilizing the keywords “Reagents” produced no matches. A search of Ability One website utilizing the keywords “Reagents” produced no matches. A search of Vetbiz using NAICS 325413 and “Reagents” resulted in 3 potential SDVOSB vendors. CO reviewed the information included in Vetbiz for each potential SDVOSB. One response manufactured generic reagents, another provided everything from Landscaping to pharmaceutical preparation, and the final one’s service area did not cover the state of IL. A copy of each is included in my contract folder. These results did not satisfy the rule of 2. Our current equipment was purchased from Roche in 2014, and only Roche reagents can be used on this equipment. A search of FSS provided the new contract V797D-70105, POP: 3/16/17 to 3/15/22.

(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:

When the current equipment is no longer viable, the agency will post a solicitation for new equipment or processes to meet their needs.

(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.)*

SIGNATURE

DATE

Donna Wray

Business Manager

PLMS – VISN 12

NAME

TITLE

SERVICE LINE/SECTION

VISN 12 - PLMS

FACILITY

(10) APPROVALS IN ACCORDANCE WITH THE [VHAPM, Volume 6, Chapter VI: 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.

CONTRACTING OFFICER/DESIGNEE'S SIGNATURE

DATE

Teresa Beers-Wesolowski

GLAC

NAME AND TITLE

FACILITY

b. Director of Contracting/DESIGNEE: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

SIGNATURE

13 April 2017

DATE

David Picchi

NAME

NCO 12 / Branch Chief, Supply Team