

LIMITED SOURCES JUSTIFICATION

ORDER >\$3,000

FAR PART 8.405-6

2237 Transaction # or Vista Equipment Transaction #: 618-17-1-106-0003

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: Provide original manufacturer's name for material or contractor's name for service. (If a sole source manufacturer distributes via dealers, ALSO provide dealer information.)

Manufacturer/Contractor: Roche Diagnostic Corp

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

Mfgr/Contractor Address: 3115 Hague Rd, PO Box 50457 Indianapolis, IN 46250-0457

Dealer/Rep address/phone number: Jordan Bendal, address same, (608) 632-2431

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

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs

NCO 23-St. Cloud Minnesota

4801 Veterans Drive

St. Cloud Minnesota

56301

VISN:

23

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

This action is to establish a BPA (Blanket Purchase Agreement) for a base period plus four (4) one year option periods for the purchase of an expendable supply/reagents for assays to run on existing/Minneapolis VAHCS's owned Roche instrumentation located at the Minneapolis VA Health Care System, Minneapolis Minnesota. The assays include HCV viral load, HIV viral load, Factor 2, Factor 5, EGFR, and KRAS. The disposables must be compatible with the following instrumentation: COBAS AmpliPrep, Taqman, MagNA Pure, Roche Light Cycler.

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

Assay kits compatible with instrumentation currently owned by the VA. The assay kits needed are only available through Roche Diagnostics, because only their kits will run on the Roche Instruments.

(b) ESTIMATED DOLLAR VALUE: _____

(c) REQUIRED DELIVERY DATE: 10/01/2016

(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.

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.

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.

X 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.

Assay kits compatible with instrumentation currently owned by the VA. The assay kits needed are only available through Roche Diagnostics, because only their kits will run on the instruments. The items under this BPA are consumables (reagents) to be used with instruments currently owned by the Minneapolis VA HCS. If a different vendor other than Roche was selected, new instrumentation to accommodate a change would cost the facility at least \$500,000.

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:

These products are available through Roche's FSS contract number V797P-7037A. In accordance with FAR 8.404 (d), GSA has already determined the prices to be 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 determined that only one vendor (Roche) can provide the kits needed for existing Minneapolis owned laboratory instrumentation. These disposables for specimen testing via Federal Supply Schedule contract No. V797P-7037A, SIN #605-6B.

(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:

Whenever new assays are needed by the Minneapolis laboratory and there are no pre-owned instrumentation to run the new assays on, thus saving funding, there will be a competitive acquisition for replacement equipment at that time.

(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.)*

John J. Holter

May 26, 2016

SIGNATURE

DATE

John Holter

Micro/Molecular Lab super

PALMS/Micro-Molecular Lab

NAME

TITLE

SERVICE LINE/SECTION

Minneapolis VA Medical Center

FACILITY

(10) APPROVALS IN ACCORDANCE WITH FAR 8.405-6(d):

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

**MELANIE A
STOCKMAN 197716**

Digitally signed by MELANIE A STOCKMAN
197716
DN: dc=gov, dc=va, o=internal, ou=people,
0.9.2342.19200300.100.1.1=melanie.stockman
@va.gov, cn=MELANIE A STOCKMAN 197716
Date: 2016.05.26 08:22:39 -05'00'

5/26/2016

Melanie Stockman
Contracting Officer
NCO 23- St. Cloud Minnesota

Date

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

**BENEDICT A.
SEITZ 253829**

Digitally signed by BENEDICT A. SEITZ
253829
DN: dc=gov, dc=va, o=internal, ou=people,
0.9.2342.19200300.100.1.1=ben.seitz@va.g
ov, cn=BENEDICT A. SEITZ 253829
Date: 2016.06.01 15:22:43 -05'00'

6/01/2016

Daryl Berg
Director Contracting
NCO 23

Date

c. VHA HCA REVIEW AND APPROVAL (over \$650,000 to \$12.5 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

Randy L. Hays 534204

Digitally signed by Randy L. Hays 534204
DN: dc=gov, dc=va, o=internal, ou=people,
0.9.2342.19200300.100.1.1=randy.hays@va.gov, cn=Randy L. Hays 534204
Date: 2016.07.20 10:24:13 -07'00'

Randy L Hays
Acting Director, SAO Central Region
SAO Central Head of Contracting Activity (HCA)

Date