

4/30/14

14-101-NC08- Nucleic Acid Processor
(CE)
KPN

LIMITED SOURCES JUSTIFICATION

ORDER >\$3,000

FAR PART 8.405-6

2237 Transaction # or Vista Equipment Transaction #: 675-14-2-2637-0365

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: Abbott Laboratories, Inc

Manufacturer/Contractor: Abbott Laboratories, Inc

Manufacturer/Contractor POC & phone number: Laura Pfantz / 224-361-7674

Mfg. /Contractor Address: 1300 E. Touhy Avenue, Des Plaines, IL 60018

Dealer/Rep address/phone number: None

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

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs

Orlando VAMC

5201 Raymond St.

Orlando, FL 32803

VISN:

08

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

Nucleic Acid Processor Molecular System (M2000) was purchased by the Orlando VAMC on January 10, 2013. There are no other manufactures that produce FDA-Approved reagents, supplies and services for use on the Abbott M2000 Analyzer. The reagents are used to test Human Immunodeficiency and Hepatitis C Viruses.

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

The Orlando VAMC needs to purchase reagents consumables and services to perform a cost per test. The estimated volume required to meet the needs are 1,458 HIV tests and 1804 HCV tests for a total of 3,262 tests/year, including tests with controls and calibrators.

(b) ESTIMATED DOLLAR VALUE: \$180,776.04 base year / \$903,880.20 four (4) option period

(c) REQUIRED DELIVERY DATE: May 15, 2014

(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)

☐ 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 order represents best value because the FSS schedule reflects significant savings to the government. When compared to the open market pricing, the FSS pricing is \$336,993.96 less. The open market price for the reagents is \$517,770.00 per year and the FSS contract price is \$180,776.04 per year providing a \$336,993.96 per year savings to the government

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

A request for information (RFI) was issued under VA248-14-I-0625, SIN 605-6a Clinical Analyzers, Laboratory and Cost-Per-Test on GSA Advantage for reagents, supplies and services. Received responses from Abbott Laboratories and Roche Diagnostics. Roche Diagnostics states "As such, the only reagents FDA approved for use on the M2000 instrument are the Abbott Real-Time Tests. Therefore, in this case, Abbott is the only vendor than can reply to your RFI.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

Nucleic Acid Processor Molecular System (M2000) was purchased by the Orlando VAMC on January 10, 2013, under contract # VA248-13-C-0080 / 675A30051. There are no other manufactures that produce FDA-Approved reagents, supplies and services for use on the Abbott M2000 Analyzer.

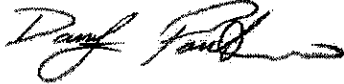
(8) A STATEMENT OF THE ACTIONS, IF ANY, THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS THAT LED TO THE RESTRICTED CONSIDERATION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES OR SERVICES IS MADE:

(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.)

ESTHER W. MURPHY 3-28-2014
SIGNATURE DATE
ESTHER W. MURPHY MO/acting CHIEF MT P&LMS
NAME TITLE SERVICE LINE/SECTION
ORLANDO VAMC
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.



CONTRACTING OFFICER'S SIGNATURE

Daniel Pontoriero

Daniel Pontoriero

Contracting Officer

Orlando VAMC, Activation

22 April 2014

DATE

Orlando VAMC

FACILITY

- b. **NCM/PCM/DESIGNEE:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

MITCHELL

SIGNATURE

J. THOMAS

132545

Digitally signed by MITCHELL J.

THOMAS 132545

DN: dc=gov, dc=va, o=internal,

ou=people,

0.9.2342.19200300.100.1.1=mitch

ell:thomas2@va.gov,

cn=MITCHELL J. THOMAS

132545

Date: 2014.04.23 08:54:39 -04'00'

DATE

Mitchell Thomas

Network Contract Manager

VISN 08, NCM/PCM

HIGHER LEVEL APPROVAL (Required For orders over \$650,000):

- c. **SAO:** I certify the justification meets requirements for restricting consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4.

nancy.bailey@va.gov

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DN: cn=nancy.bailey@va.gov

Date: 2014.04.30 09:19:53 -04'00'

SIGNATURE

DATE

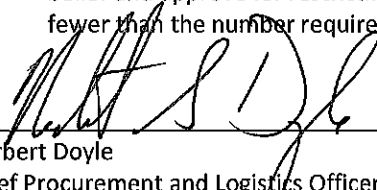
Jeffrey R. Ryan

Network Contract Manager

Director

Service Area Office, East

- d. **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



Norbert Doyle
Chief Procurement and Logistics Officer
VHA Head of Contracting Activity (HCA)

5/1/14

DATE