

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
Attachment 2: Request for Limited Sources Justification Format >\$150K

LIMITED SOURCES JUSTIFICATION

ORDER >\$150,000

FAR PART 8.405-6

2237 Transaction # or Vista Equipment Transaction #: 506-16-1-1030-0003

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: Beckman Coulter Inc.

Manufacturer/Contractor POC & phone number: Marcia Heminger, Capital Equipment Consultant,
877-888-8643 ext. 421109

Mfgr/Contractor Address: 200 S. Kramer Blvd., P.O. Box 8000, Brea, CA 92822-8000

Dealer/Rep address/phone number: Same as above

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

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs

VA Ann Arbor Healthcare System

2215 Fuller Rd.

Ann Arbor, MI 48105

VISN:

11

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

A Limited Source Justification to provide specialized laboratory reagents, supplies, and equipment needed for patient testing for FY16. Service and maintenance are also a part of the Cost Per Reportable Test Contract# V797P-7090A. This is a VA National Acquisition Center contract. At this time this contract is active through April 16, 2016 with an anticipated renewal prior to that date. The period of performance for the requirement being considered by this Limited Source Justification is October 1, 2015 through September 30, 2016. These items are found on Schedule 66 (III) of the VA National Acquisition Center's catalog and are therefore require mandatory consideration by VA medical centers. The pricing model for this requirement has been established by the VA National Acquisition Center. Total annual cost is estimated based on price per test and historical volume. There are numerous test types in the catalog, and all are priced separately. The government is invoiced only for the tests used.

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

Beckman Coulter, Inc. is the current vendor that provides our DxC880i chemistry analyzers, Contract# V797P-7090A. Chemistry testing for veteran patients includes chemistry profiles, lipid profiles, metabolic profiles, cardiac markers, tumor makers, etc. This contract includes the use of the DxC880i chemistry analyzer, reagents, calibrators, controls, supplies, consumables, and maintenance and service

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to support the two (2) DxC880i analyzers.

(b) ESTIMATED DOLLAR VALUE: \$816,000.00

(c) REQUIRED DELIVERY DATE: 10/1/2015 through 9/30/2016

(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. (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.

The FSS contract# V797P-7090a includes the use of the DxC880i chemistry analyzer, reagents, supplies, consumables/disposables, calibrators, standards, controls, plus maintenance and service coverage. The reagents and supplies used are unique to the Beckman Coulter DxC880i chemistry analyzer. Beckman Coulter Inc. is an excellent company that has been in the chemistry analyzer business for decades. The equipment in question is currently in use at the facility. Installation of such equipment is labor intensive, time consuming and often requires modification of laboratory space.

To change vendors requires several months of work that includes interface connections, correlation studies between new and old analyzers and between analyzers, analytical measurement range studies, linearity studies, assay sensitivity studies, precision studies, reference range validation studies, etc. Both the outgoing and incoming equipment must be run in parallel at the same time, on each sample to ensure corresponding results – this is very costly.

New instruments, especially new vendors, include new training in the operation and analysis of specimens, maintenance procedures, troubleshooting procedures, recoding of instruments and tests associated with the College of American Pathologist (CAP) proficiency programs, and writing of new procedures. Quality control programs for new immunoassay analyzer vendors require new processes to be set up to meet various accreditation agencies requirements; The Joint Commission, CAP, Clinical Laboratory Improvement Amendments (CLIA), etc. All of the above requirements and tasks involve significant cost for various test kits to perform these studies. Additionally, the months of medical technologist labor to perform the above studies is significant. No analyzer can be placed "on-line" until all validation studies, instrument training, and procedure manuals have been written, reviewed, and approved. Every time a new piece of instrumentation enters the laboratory all precautions are taken to provide the necessary training on the analyzers to prevent delay in testing and operator errors that could lead to erroneous results. New instrumentation and new vendors increase the odds of errors due to learning the new system. In summary, the cost associated with changing laboratory equipment and processes is very high and only becomes advantageous when the market offers a solution with clearly defined cost savings at the per-test level. At this time cost savings are not a likely outcome of further competition, even if other sources could meet the need.

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Furthermore, VA Ann Arbor laboratory staff concluded that the Beckman Coulter DxC880i chemistry analyzer is the only vendor that provides the closed-tube sampling system and is therefore the only responsible source.

☐ 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.

☒ 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.

Beckman Coulter, Inc. equipment is currently installed in our laboratory. Several months are required to execute a competitive procurement and several more months are required to transition from one vendor to another. The transition process is time consuming, requires at least thirty (30) days of parallel testing and would involve notable cost.

☐ 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:

In accordance with 8.404 (d), GSA and the VA National Acquisition Center [FSS] has already determined the prices of supplies, fixed-price services, and rates for services offered at hourly rates, under schedule contracts to be fair and reasonable. High complexity laboratory analyzers represent the state-of-the-art in medical technology and provide little relative comparison for determining price reasonableness. It is for this reason that the VA NAC center conducts price reasonable activities for the VA community.

Market research is an ongoing process. VA Ann Arbor Laboratory staff reviewed offerings from several available sources. Due to the nature of high tech laboratory equipment the pool of possible contractors is limited to the few conducting relevant research and development in these areas. The sources included in the market research are Beckman Coulter DxC880i, Siemens Vista, and Ortho Clinical Diagnosis Fusion. VA Ann Arbor laboratory staff concluded that the Beckman Coulter DxC880i chemistry analyzer is the only vendor that provides the closed-tube sampling system, offers the best value regarding quality of results and test menu, turnaround time, and maintenance. The Beckman Coulter reagents and supplies are unique to the Beckman Coulter DxC880i systems. After market research was conducted, Beckman Coulter was determined the only contractor that could practicably meet the needs of the laboratory. Initially selected in 2011, Beckman Coulter is the only vendor that provides a vast test menu, ease of operation, and high throughput of patient test results for its value.

(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 is a continuous process to evaluate other vendors on the FSS that offer chemistry/immunochemistry platforms. Market research consisted of site visits, FSS and GSA searches, as well as internet searches. At the time of market research, other sources could not provide the specific requirements requested for a chemistry/immunochemistry platform. Laboratory staff engage industry on a regular basis to determine if the needs of the VA can be better met by emerging or recently established technology.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

None

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(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 method of awarding "follow-on" contract is not considered a barrier competition. Laboratory analyzers in current use represent the state-of-the-art in medical technology. The VA National Acquisition Center seeks contract vehicles with contractors as new technologies become available. As such, laboratory personnel utilize and review offerings available under the VA National Acquisition catalog.

(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.)*

Joseph Masson
Digitally signed by Joseph Masson
DN: cn=Joseph Masson, ou=VAAAHS, ou=PALMS,
email=joseph.masson@va.gov, c=US
Date: 2015.08.25 10:14:07 -04'00'
8/25/2015
SIGNATURE DATE
Joseph Masson Technical Specialist PALMS - 113
NAME TITLE SERVICE LINE/SECTION
VAAAHS
FACILITY

(10) APPROVALS IN ACCORDANCE WITH THE VHAPM, Volume 6, Chapter VI: OFOC SOP: *This part if 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.

Roy W. Samsel
Digitally signed by Roy W. Samsel 230337
DN: dc=gov, dc=va, o=internal, ou=people,
0.9.2342.19200300.100.1.1=roy.samsel@va.
gov, cn=Roy W. Samsel 230337
Date: 2015.08.25 10:19:35 -04'00'
230337
CONTRACTING OFFICER'S SIGNATURE DATE
Roy Samsel, Contracting Officer NCO 11
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 DATE
8/25/2015

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Donald R. King

Name

Director of Contracting

Network Contracting Office 11

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.

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=andy.hays@va.gov, cn=Randy L. Hays 534204
Reason: I agree to specified portions of this document.
Date: 2015.08.25 14:40:17 -0700

SIGNATURE

DATE

Ricky L. Lemmon

NAME

Director, Service Area Office Central Region

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 S. Doyle

NAME

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

DATE

9/3/15