

Attachment 1: Request for Limited Sources Memo Format

**LIMITED SOURCES JUSTIFICATION**

**ORDER >\$3,000**

**FAR PART 8.405-6**

**2237 Transaction # or Vista Equipment Transaction #: 646-15-1-080-0029**

This acquisition is conducted under the authority of the Multiple Award Schedule Program. (VA FSS Contract# V797P-7335A). The 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: Abbott Laboratories \_\_\_\_\_  
Manufacturer/Contractor POC & phone number: Alyssa Pyer – 724-822-9264 \_\_\_\_\_  
Mfgr/Contractor Address: 100 Abbott Park Road, Abbott Park, IL 60064-6095 \_\_\_\_\_  
Dealer/Rep address/phone number: \_\_\_\_\_

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

**(1) AGENCY AND CONTRACTING ACTIVITY:**

Department of Veterans Affairs  
VA Pittsburgh Healthcare System  
Acquisitions, NC04

**VISN:**

1010 Delafield Road  
Pittsburgh, PA 15215

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

Limited Source/Sole Source award, I.A.W. FAR 8.405-6 (a)  
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\_\_\_\_\_  
\_\_\_\_\_

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

Annual Rental of the Abbott Laboratories Architect i2000 Immunoassay Analyzer Equipment;  
Preventative Maintenance; and supply of all required consumables, to conduct Cost Per Test Services,  
For the VA Pittsburgh Healthcare System, Medical Specialty Care Product Line, University Drive Division,  
(2NW120-1-UD-Immuno/Cont., for the period of 10/1/2014 through 09/30/2015.  
\_\_\_\_\_  
\_\_\_\_\_

**(b) ESTIMATED DOLLAR VALUE: \$367,324.08** \_\_\_\_\_

**(c) REQUIRED DELIVERY DATE: 10/1/2014 through 09/30/2015.** \_\_\_\_\_

**(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.

Abbott Laboratories is the sole provider of the rental of their Architect i2000 equipment, as well as, for the preventative maintenance and software, and all required consumables for the Architect i2000 (See attached email from Abbott Laboratories under TP02 of the Procurement Action Briefcase in the Contract File).

The VA Pittsburgh requires a Fully Automated system with the capability of performing the following, and has the features identified with an asterisk (\*), which are unique to only the Abbott Labs Architect i2000 immunoassay analyzer:

\*HIV detecting Antibody and Antigen for earlier detection of HIV infection with the ability to also perform the following tests; Hepatitis markers (ie: Hepatitis B Surface Antigen, Hepatitis B Antibody, Hepatitis Core, Hepatitis Core IgM, Hepatitis A IgM, Hepatitis A IgG, HCV) on a single random access instrument.

\*For current plans of instrument consolidation the system must also have the ability to perform the following testing: Vitamin D and Immunosuppressants (Tacrolimus, Cyclosporine, Sirolimus).

In addition to the above menu requirements, the selected vendor must also satisfy all of the following:

- \*This system should have the ability to perform these assays individually or together with clinically insignificant carry over.
- The system should have liquid, ready-to-use reagents and calibrators requiring no preparation by the Technologists at VA Pittsburgh.
- \*Due to the high mutation rate of Hepatitis B, the Surface Antigen assay must be able to detect mutations in the "a" determinant.
- \*The methodology will specifically contain 4<sup>th</sup> generation HIV Antigen/Antibody detecting capabilities.
- \*The HIV Antigen/Antibody combination assay must not require bracketed controls.
- \*For HCV, reflex supplemental testing shall be limited to only those samples falling below a 5 s/co value.

- For Hep B Antibody- must have the ability to provide quantitative or qualitative results.
- \*The system should track the on board stability of the reagent with the option to remove reagents to extend the stability and useful life of the reagent.
- The methodology selected will require only 2 controls per run.
- The analyzer will provide automated testing.
- The methodology selected will only require a 1ml sample volume.
- The system should have minimal maintenance required by the technologists at VA Pittsburgh requiring less than 5 minutes "technician hands on" per day.
- The vendor chosen for this contract will provide Field Service and resolve all issues within 24 hours, Mon-Fri.

The vendor chosen will offer all of the above special considerations. A methodology that includes all of the special considerations will provide State of the Art technology for our veterans and reduce time to result significantly

The only system that can meet the criteria is the Abbott ARCHITECT i2000.

☐

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.)

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These are "direct replacements" parts/components for existing equipment.

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☐ 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.

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☐ 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.

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

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**(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:**

Per FAR .8.404 (d), placing an Order against a schedule contract using the procedures at FAR 8.405, the ordering office has concluded that the Order represents the best value, and results in the lowest overall cost alternative to meet the Government's needs. The VAPHS Contracting is using procedures at FAR 8.405. This is an Order off a VA Federal Supply Schedule Contract.

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

The items are available on a VA FSS Contract, therefore deemed commercial items, so no Market Research was required to determine if the items were Commercial Items. A Google Search was conducted using the words Abbott Laboratories Rental Architect i2000, and no other companies came up. A query was done in GSA Advantage using the words Architect i2000 Rental and no other companies came up. As mentioned above, an email was obtained from Abbott Laboratories, stating they are the Sole Provider of the needed rental equipment, preventative maintenance, software, and consumables for the needed rental equipment. (See email from Abbott Laboratories under TP02 of the Procurement Action Briefcase in the Contract File).

All vendors inquiring as to our automated Hepatitis/HIV needs were informed of our desire to continue automated Hepatitis/HIV testing in FY 2013. All were asked to submit proposals if FDA approved and could provide testing on available platforms. Abbott was the clear winner

being solely able to supply 4<sup>th</sup> generation HIV testing kits.

Per FAR Part 8, no Synopsis is required to be posted to e-Buy or Fedbizopps for a Limited Source/Sole Source action, prior to award.

**(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:**

NA

**(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.)*

Birte Schupay  
SIGNATURE

9.16.14  
DATE

Birte Schupay

Lab Manager

Medical Specialty Care Product Line

NAME

TITLE

SERVICE LINE/SECTION

University Drive

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.

ronald.mazzei@va.gov

Digitally signed by ronald.mazzei@va.gov  
DN: cn=ronald.mazzei@va.gov  
Date: 2014.09.16 15:55:04 -04'00'

CONTRACTING OFFICER'S SIGNATURE

DATE

Ronald Mazzei

H.J. Heinz

NAME AND TITLE

FACILITY

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

herbert.byrns@va.gov

Digitally signed by herbert.byrns@va.gov  
DN: cn=herbert.byrns@va.gov  
Date: 2014.09.16 17:28:53 -04'00'

SIGNATURE

DATE

Herbert F. Byrns

Deputy Director for Contracting, NC04.

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

e. **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.

SIGNATURE

DATE

NAME

DIRECTOR, SAO X

f. **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

NAME

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

DATE

g. **VA Deputy Senior Procurement Executive Approval (\$12.5 million not to exceed \$50 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