

LIMITED SOURCES JUSTIFICATION
ORDER >\$3,000
FAR PART 8.405-6

2237 Transaction # or Vista Equipment Transaction #: 528-15-2-4307-0289

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: Abbott Molecular Lab, INC VID#43121
Manufacturer/Contractor POC & phone number: 800-553-7042
Mfgr/Contractor Address: 1300 E. Touhy Ave, Des Plaines, IL 60018
Dealer/Rep address/phone number: Joanie Rinker, Molecular Account Executive, 724-421-9359

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

(1) AGENCY AND CONTRACTING ACTIVITY: Department of Veterans Affairs
Buffalo VA Medical Center
3495 Bailey Ave
Buffalo, NY 14215
VISN: 02

(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:
Testing has been approved by CPRS 2/26/14. Testing is needed for the identification and treatment of non-small cell lung cancer (NSCLC). Abbott Molecular Vysis kits are to only test kits approved by the FDA for this type of NSCLC testing. See attachment for more details. Testing is required by national guidelines.

(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:
All required items for testing are on FSS contract #V797D-40222, which expires August 31, 2019. These items are as follows: Vysis ALK Break Apart FISH Probe Kit (\$3169.01 each), Vysis Paraffin Pretreatment IV & Post Hyb Wash Buffer Kit (\$860 each), Vysis Probechek ALK Negative Control Slides Kit (\$301 each), and Vysis Probechek ALK Positive Control Slides Kit (\$301 each). This is a manual test that does not require any specialized equipment.

(b) ESTIMATED DOLLAR VALUE: \$4,631.01

(c) REQUIRED DELIVERY DATE: 3/13/15

(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.

Abbott's Vysis ALK testing is the only FDA approved test kit for ALK Break Apart FISH to identify NSCLC for treatment. See attachment for more details. This is test is required as per national guidelines. The items required for this test are: Vysis ALK Break Apart FISH Probe Kit, Vysis Paraffin Pretreatment IV & Post Hyb Wash Buffer Kit, Vysis Probechek ALK Negative Control Slides Kit, and Vysis Probechek ALK Positive Control Slides Kit. This is a manual test that does not require any specialized equipment.

A patent, copyright or proprietary data limits competition. The proprietary data is: FDA approval. Abbott Laboratories is the sole known manufacturer and distributor of the Vysis ALK testing kits. The FDA has only approved this test by Abbott Laboratories; no similar tests were found.

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.

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

Test kits are needed urgently to provide testing for current patients at the VA Western New York Healthcare System (VAWNYHCS). There are currently a couple of patients waiting for this test at the VAWNYHCS. This test is the only FDA approved test of its type for the identification of NSCLC and has just received approval for use from CPRS on 2/26/14. Abbott Molecular Vysis kits are to only test kits approved by the FDA for this type of NSCLC testing. See attachment for more details. Testing is required by national guidelines.

(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR [8.404](#)(d) TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:

This test is now available on FSS contract. This test is the only FDA approved test of its type for the identification of NSCLC and has just received approval for use by VA laboratories from CPRS on 2/26/14. In the past, the laboratory utilized send out services for patients requiring this type of test. These send out services take more

time to complete due to the transfer of specimens from one site to another and the delay in receiving/processing the results. Further, the send out test is more costly than completing the test in house. Moreover, Abbott Laboratories, Inc. has a strong history of positive past performance. There are currently no terminations listed in the FAPIIS database and no recorded instances of defective pricing. Additionally, Abbott Laboratories delivery system is highly efficient and therefore is able to provide the supplies for this manual test quickly; this company is able to provide the testing materials to the facility within 2 days of receiving the order for the materials. Finally, when negotiated, the Contracting Officer for the FSS contract sought the best value for these tests. In addition to this, the Contracting Officer for this requirement will seek additional discounts if possible for this requirement.

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

This is the only test of its type approved by the FDA for the identification of NSCLC. See attachment showing FDA approval for this test from Abbott. Additional searches were conducted to see if another company providing this test could be identified on GSA Advantage and on Google. No other company was identified as having this manual test.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

(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:

The Contracting Officer could ask other known Small Businesses and Veteran Owned Small Businesses if they are considering carrying this product. This might encourage these Small Businesses and Veteran Owned Small Businesses to partner with Abbott or to develop their own FDA approved test for identifying NSCLC.

(9) REQUIREMENTS CERTIFICATION: I certify that the requirement outlined in this justification is a bonafide 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.

_____	3/6/2015	_____
SIGNATURE	DATE	
Sharon Machlowski	Medical Technologist, COR	Lab Service-113
NAME	TITLE	SERVICE LINE/SECTION
Western New York Healthcare System at Buffalo		
FACILITY		

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

Service Area Office, East
Department of Veterans Affairs
323 North Shore Drive, Suite 500
Pittsburgh, PA 15212

Memorandum 2011-003
December 28, 2010

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

3/9/15

DATE

Kathleen Ellis

CONTRACTING OFFICER

NCO 2

FACILITY

HIGHER LEVEL APPROVAL (For orders over \$650,000): REQUIRED NOT REQUIRED

b. **ONE LEVEL ABOVE CONTRACTING OFFICER:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief. **This signature may be the VISN NCM if the Contracting Officer and Contracting Supervisor is the same individual.*

SIGNATURE

3/11/15

DATE

Branch Chief, NCO2 Supply Team

NAME AND TITLE

c. **NCM :** 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.

Name

DATE

VISN X NCM

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

JEFFREY RYAN

DATE

Director, SAO East

e. **VHA HCA'S 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

JOSEPH A. WILLIAMS, Jr., RN, BSN, MPM

DATE

Head of Contracting Activity (HCA)

**Service Area Office, East
Department of Veterans Affairs
323 North Shore Drive, Suite 500
Pittsburgh, PA 15212**

**Memorandum 2011-003
December 28, 2010**

f. **VHA Senior Procurement Executive Approval (over \$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 other than full and open competition.

Jan R. Frye
Deputy Assistant Secretary
Office of Acquisition and Logistics
Senior Procurement Executive (SPE)

Date