

LIMITED SOURCES JUSTIFICATION

ORDER >\$150,000

FAR PART 8.405-6

Acquisition Plan Action ID: VA241-16-AP-0504

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: Oxford Immunotec Inc

Manufacturer/Contractor POC & phone number: _____

Mfgr/Contractor Address: 700 Nickerson Road, Suite 200, Marlborough, MA

01752 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

NCO1

830 Chalkstone Avenue

Providence, RI 02908

VISN1

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

Obtain TSPOT TB laboratory testing services for a 12 month base plus 4 option year BPA from Oxford Immunotec, a GSA FSS contract reference laboratory testing contractor, for VISN 1 patients and employees using the contractor's proprietary test methodology that does not require pre-analytical special handling.

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

T- SPOT TB testing is required for the diagnosis of both latent and active TB infection by measuring T cells that have been specifically activated by Mycobacterium tuberculosis (MTB) antigens. Annual test quantity usage is estimated to be 1,926 tests.

The Oxford Immunotec proprietary T-SPOT.TB test:

Removes background interferon gamma to maximize sensitivity

Utilizes a standard number of PBMCs to correct for a patient's immune status

Uses a standard green top collection tube

Does not require special phlebotomy

(b) ESTIMATED DOLLAR VALUE: _____

(c) REQUIRED DELIVERY DATE: 6/1/2016

(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.

This is the only contractor laboratory that is able to offer this testing methodology on blood samples without requiring special handling pre-assay. Oxford Immunotech is the sole source provider for the proprietary T-SPOT test.

1. TB test with both sensitivity and specificity greater than 95%.
2. Collection of the blood specimen in a standard green top collection tube.
3. No special phlebotomy; i.e. shaking of tubes or incubation within 16 hours.
4. Blood specimen stability up to 32 hours.
5. TB test that provides a Borderline test result which is recommended by the CDC.
6. Shipping containers that have been validated to maintain the blood specimens at room temperature.

☐ 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.

☐ 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:

Tuberculosis testing using the TSPOT TB method will provide accurate TB results to our clinicians in a short turnaround time. No specialized specimen tubes or incubators will be needed in the performance of this proprietary test. The specimen is collected similarly to most other blood samples and will not need special pre-assay handling as compared to the Quantiferon testing – the current methodology being utilized.

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

An extensive internet search was conducted to evaluate sources for this alternative TB testing method. No other laboratories offer this specific TSPOT test due to the contractor's proprietary technology. Assays for the same purpose require pre-assay handling. Although both Quest and LabCorp USA GSA Contracts, on behalf of the manufacturer Qiagen, offer an assay that tests for TB on blood samples, Quantiferon, they require special handling procedures which are time consuming and delay transporting the specimen to the contractor. This also delays delivering the test result to the provider and diagnosis for patients.

According to the Center for Disease Control, T-SPOT TB is one of (3) blood tests for tuberculosis that are called interferon gamma release assays (IGRAs). The (3) commercially available IGRAs that are approved by the FDA include TSPOT TB, Quantiferon-TB Gold and Quantiferon-TB Gold In Tube. TSPOT TB, manufactured by Oxford, is the only test that does not require special handling procedures or equipment.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

Oxford Immunotec, Inc. is a small business NAC FSS contract holder that provides the proprietary TSPOT TB testing on their GSA contract V797P-2025D under Schedule 621 II, Category 621-209. Their GSA Terms and Conditions indicate they will provide volume quantity discounts.

(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:

An annual review of performance will be completed prior to exercising the renewal option. If the Contractor does not meet the Government standards, the Contracting Officer will be notified prior to renewal.

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

Before subsequent acquisitions are made for these services, market research will be conducted to identify any new vendors or technologies made available for this type of testing.

(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.)*

Mary-Ann

Bridgwood 150466

SIGNATURE

Mary-Ann Bridgwood

NAME

Program Manager

TITLE

April 12, 2016

DATE

Facility VISN1 Network Consolidated Laboratory

SERVICE LINE/SECTION

VA Brockton

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.

Valerie J. DeAngelis

908087

CONTRACTING OFFICER'S SIGNATURE

Valerie J. DeAngelis

Contracting Officer

4/12/2016

DATE

Providence

FACILITY

b. QA Review:

Gary W Dilk 231297

Gary W. Dilk
Procurement Analyst

Digitally signed by Gary W Dilk 231297
DN: dc=gov, dc=va, o=internal, ou=people,
0.9.2342.19200300.100.1.1=gary.dilk@va.gov, cn=Gary W
Dilk 231297
Date: 2016.04.15 12:47:34 -04'00'

DATE

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

Heather L.

Simpson 410637

SIGNATURE

OFOC SOP Revision 04

Original Date: 03/22/11

Revision 04 Date: 10/01/2015

Digitally signed by Heather L. Simpson
410637
DN: dc=gov, dc=va, o=internal, ou=people,
0.9.2342.19200300.100.1.1=heather.simpson
@va.gov, cn=Heather L. Simpson 410637
Date: 2016.04.15 13:41:16 -04'00'

DATE

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
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Heather L. Simpson

For Gerald F. Jacobs

Director Network Contracts Office 1 (Acting)