

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval
For
Other Than Full and Open Competition (>\$150K to \$650K)**

1. **Contracting Activity:** Department of Veterans Affairs (VA), VISN 20, located at 5115 NE 82nd Avenue, Suite 203 Vancouver, WA 98662 for the VA Portland Healthcare System (VAPHCS). This requirement shall be funded by (2237) number 648-16-1-066-0018.
2. **Nature and/or Description of the Action Being Processed:**
The proposed action is to add the Immunogenetics and Transplantation lab testing (hereinafter call LIT) to the existing Coagulation and Cancer lab testing contract (VA260-15-P-4894) for its remaining three (3) months (1/01/16 – 3/31/16) while one new contract for lab testing services is being worked on for both services. This modification will be procured in accordance with FAR 13.501, Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.302-1. The proposed action is a Firm Fixed-Price contract modification to the Coagulation and Cancer Testing contract which expires on 31 March 2016. Services for this action are currently provided by the Oregon Health and Science University (OHSU), 3181 Southwest Sam Jackson Park Road Portland, OR 97239.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:**
Prior to a Veteran receiving a kidney transplant in LIT, the patient must have lab tests to ensure the donor kidney matches the Veteran's tissue and blood types. One such test is the kidney biopsy test. A kidney biopsy may be done to check for:
 - Kidney disease when there is blood or protein in the urine or when the kidneys are not working well.
 - Kidney problems seen on an ultrasound or a CT scan.
 - Kidney disease and see if treatment is working. Why a transplanted kidney isn't working well.

A specimen is taken and sent to a lab. These tests help reduce the chances that the body will reject a new kidney. The VAPHCS doesn't have the capability to perform these lab tests. VAPHCS has partnered with OHSU to have these lab tests performed at the OHSU Reference Laboratory.
4. **Statutory Authority Permitting Other than Full and Open Competition:**
The authority restricting competition on this modification is under 41 U.S.C. Code 1901 as implemented by Federal Acquisition Regulation (FAR) 13.106-1(b)(1), for acquisitions of commercial items conducted pursuant to FAR Subpart 13.5.

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

There are several contractors that are capable of providing the required LIT lab testing services, however, one of the VAPHCS's requirements is to have testing start within one (1) hour of specimen collection. There is a sky bridge that connects the VAPHCS with OHSU, and OHSU is the only contractor that could be found that is capable of providing this one (1) hour testing start time requirement. The lab performing these tests is required to be UNOS (United Network for Organ Sharing) certified lab. The UNOS certified lab in this catchment area is at OHSU.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

Market research was conducted for the contract award three (3) months ago via sources sought notices posted to the Government Point of Entry (GPE) and GSA's eBUY. The sources sought notices contained a list of questions asking socio-economic statuses, requests for capability statements, a draft statement of work (SOW), along with a list of the required tests. No responses were received from the sources sought notice posted to the GPE. Three (3) contractors responded to the eBUY sources sought notice.

- Quest Diagnostics state they were not a small business; however, the source sought notice was not restrictive to small business.
- Cedar Diagnostics, LLC. Stated they could not meet the one hour turnaround time.
- LabCorp of America responded with a capability statement. The VAPHCS laboratory personnel reviewed the document and determined LabCorp could not satisfy the one (1) hour requirement.

It is determined that no other sources exist that can currently satisfy this requirement as the three (3) businesses that responded to the eBUY announcement could not provide the required tests within the one (1) hour time frame required by the VA.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:

The costs to the Government will be at a fair and reasonable price based on the prices the Government is currently paying for these required tests. The current contract providing this service to the VAPHCS laboratory is VA260-15-C-0014. The prices under that contract were determined fair and reasonable when compared to similar reference laboratory contract prices and when compared to the Independent Government Cost Estimate (IGCE). The prices will be the same as they have been in Contract VA260-15-C-0014.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:

As stated in section 6, two (2) sources sought notices were posted to GSA's eBUY and the GPE for the original award. None of these efforts yielded additional sources capable of completing the Government's requirements, specifically for the one (1) hour testing start time for collected specimens as required by the VA.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition:

This modification meets the requirements of statutory authority of Title 38 U.S.C. 8153. Title 38 U.S.C. 8153 (a)(1)(A) states:

- a. If the health-care resource required is a commercial service, the use of medical equipment or space, or research, and is acquired from an institution affiliated with the Department in accordance with section 7302 of this title, including medical practice groups and other institution, blood banks, organ banks, ore research centers, the Secretary may make arrangements for the acquisition of the resource without regard to an law or regulation (including an Executive Order, circular, or other administrative policy) that would otherwise require the use of competitive procedures for acquiring the resource.
- b. LIT testing on deceased donor kidneys is an element in the integrated actions that comprise an organ transplant. This is a unique qualification that falls within 38 U.S.C 8153 (a)(1)(A).

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

Quest Diagnostics, Cedar Diagnostics, and LabCorp responded to the GSA eBUY sources sought notice.

11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:

In the event new or unknown medical evidence changes the professional medical opinion of the VAPHCS laboratory regarding specimen testing beginning within one (1) hour of collection, this requirement may be able to be competed if the specimen testing start time is extended from one (1) hour to a time long enough for other laboratories located elsewhere in the country to be able to provide the required reference laboratory services.

12. 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 and belief.

Ed Lyman

Edward Lyman
Administrative Officer

10Dec2015

Date

13. Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP:

- a. **Contracting Specialist Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Andres Arredondo
457612

Andres Arredondo
Contracting Officer
(NCO 20) Service Team 2, Branch Chief

Digitally signed by Andres Arredondo
457612
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Date

- b. **Director of Contracting/Designee (Required > \$150K to \$650K):** I certify the justification meets requirements for other than full and open competition.

Thomas R.
Guyer 901226

Thomas R. Guyer
Chief, Division 2 Contracting
Network Contracting Office 20 (NCO 20)

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11 December 2015

Date