

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>\$150K)**

Acquisition Plan Action ID: VA259-17-AP-0475

1. **Contracting Activity:** Department of Veterans Affairs, VISN 19, (660) Salt Lake City (SLC) VA Medical Center (2237 TBD).

2. **Nature and/or Description of the Action Being Processed:**

The action under review and submitted for approval is a follow-on requirement for Histocompatibility and Immunogenic laboratory services previously provided under VA259-16-C-0234 for the SLC VA Medical Facility. That award expires March 31st, 2017 and cannot be extended. The new requirement will be awarded as a firm-fixed-price sole-source contract.

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for Histocompatibility and Immunogenic laboratory services in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically 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 6.303-2.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:**

The SLC VA Medical Center requirement is for Histocompatibility and Immunogenic laboratory services. The contractor shall furnish labor, materials, and facilities to provide a complete range of diagnostic testing services used primarily in the field of clinical organ transplantation and, secondarily, for the study of associations between certain diseases and several Human Leukocyte Antigen alloantigens. Services are to be performed following the standards of the College of American Pathologists (CAP) and American Society for Histocompatibility and Immunogenetics (ASHI). Also, the contractor shall be responsible for performing analysis and result interpretation for patient specimens as requested by George E. Wahlen VA SLC Health Care System 500 Foothill Drive, Salt Lake City, Utah 84148. Services shall include the transportation of specimens to the contractor's laboratory, the performance of analytical testing, the reporting of analytical test results and consultative services as required to assimilate the full scope of its laboratory operations to the ordering facility. The contractor shall provide varying levels of support service depending on the unique characteristics presented by the ordering activity. The contractor shall provide STAT (within 60 minutes) on-site pick up of patient specimen samples. The contractor shall provide STAT coverage on a 24-hour basis for clinical consultation and final placement of organs from deceased donors including kidney, pancreas, heart, lung, and liver transplants. Period of performance shall be from April 1, 2017, to March 30, 2018, for the base plus four option years thereafter for a total estimated award of \$967,740.00.

4. **Statutory Authority Permitting Other than Full and Open Competition:**

- (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy
Agency Requirements per FAR 6.302-1;
() (2) Unusual and Compelling Urgency per FAR 6.302-2;

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- () (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- () (4) International Agreement per FAR 6.302-4
- () (5) Authorized or Required by Statute FAR 6.302-5;
- () (6) National Security per FAR 6.302-6;
- () (7) Public Interest per FAR 6.302-7;

FAR13.5 Simplified Procedures for Certain Commercial Items: The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented for restricting competition on this procurement via FAR 13.106-1(b)(2). The service required, while a commercial service, is relatively noncompetitive in the geographical region of the State of Utah. Attempts to locate vendors in addition to the known was via electronic commerce, specifically posting a sources sought on the Federal Business Opportunities (FBO) electronic commerce site, general web search, search of past FBO postings, search for available VOSB and SDVOSB vendors on the Department of Veterans Affairs Office of Small & Disadvantage Business Utilization VOSB/SDVOSB Verification website and email communication with the ASHI accreditation board. Required sources of supply, existing IDIQ and other established contracts are not available. Competition was promoted to the maximum extent practicable.

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

Histocompatibility and Immunogenic Laboratory services is highly specialized service. As per paragraph 4 above, Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1. The Statement of Work (SOW) specifies rigorous accreditation and monitoring requirements as required by regulatory agencies. Specifically that any laboratory utilized for Histocompatibility and Immunogenetics services must be able to perform these services, and be accredited by, the standards of the College of American Pathologists (CAP) and ASHI. They must also be fully licensed as per state and federal statutes and meet the Department of Health and Human Service Clinical Laboratory Improvement Act of 1988 certification. These standards are not negotiable as the organ transplant regulatory agencies, not limited to 42 CFR part 121 - Organ Procurement and Transplantation Network (OPTN), Department of Health and Human Services and the National Organ Transplant Act regulations, determine laboratory requirements, not the Veterans Health Administration. Also, the laboratory must be able to provide on-site pickup of patient specimen samples within 60 minutes to maintain the integrity of the samples. As per the ASHI email dated October 10th 2016, the University of Utah Health Sciences Center is the only accredited laboratory in the State of Utah. They are accredited in the following:

Accreditation: HSC/BM Transplantation: Related Donor, HSC/BM Transplantation: Unrelated Donor, Solid Organ Transplantation: Deceased Donor, Solid Organ Transplantation: Live Donor, Histocompatibility Testing For Other Clinical Purposes, Transfusion Support

Tests: HLA (Human Leukocyte Antigen) Typing Class I: Low-Resolution Molecular

HLA Typing Class II: Low-Resolution Molecular

HLA Antibody Detection: Solid phase

HLA Antibody Identification: Solid phase

Crossmatching: Flow cytometry

Accordingly, the University of Utah is the only firm capable of providing the services described in Section III above without the Veteran's Health Administration experiencing unacceptable delays in fulfilling its requirements.

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

Under the authority of 10 USC 2304(c)(1), only one responsible source has been located, no other source of Histocompatibility and Immunogenetics Laboratory service will satisfy this need. The efforts taken to ensure that any potential sources were located are listed below and in paragraph 8.

Sources Sought Synopsis: A sources sought synopsis was issued on FBO, VA259-17-N-0033, on the 20th of October 2016 and closed the 26th of October 2016. The scope was stated as "Contractor shall furnish labor, materials, and facilities to provide a complete range of diagnostic testing services used primarily in the field of clinical organ transplantation and, secondarily, for the study of associations between certain diseases and several HLA alloantigens. Services are to be performed per the standards of the College of American Pathologists (CAP) and American Society for Histocompatibility and Immunogenetics (ASHI)." Further detail was provided in General, and Mandatory requirements sections of the sources sought posting. Specifically, there were details of the on-site pickup of patient specimen samples with response time requirements. No responses were received from any potential sources.

Other Actions: Multiple attempts to locate additional sources have been attempted over the last five years, these were: FBO sources sought postings, FBO posted solicitations, and contacting the accreditation agencies for any accredited sources in the State of Utah. Also, attempts to contact any other professional organizations were considered but this was not pursued as contacting the ASHI fulfilled this. No other sources were located, and the University of Utah is the only accredited laboratory in the State of Utah.

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

The anticipated cost will be determined for fair and reasonableness via comparison of previously proposed prices and previous Government contract prices with current proposed prices during the source selection process. Certified cost or pricing data is not applicable to this acquisition. According to acquisition history, the Independent Government Cost Estimate is estimated to be \$967,927.50 for a base plus-four award.

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

In preparation for the new Histocompatibility and Immunogenetics Laboratory Services requirement, the Contract Specialist (CS) conducted market research pursuant to FAR Part 10 with the following results. An examination of the acquisition history was conducted, finding that these services have been procured successfully in the past, and there is a current contract with the University of Utah for these services. While there are multiple vendors capable of performing this service in the contiguous United States, only the University of Utah has been found to meet the onsite pickup requirement due to geographic and time limitations. Multiple attempts over the last five years have been attempted to locate other sources without success. When doing a general web search for Histocompatibility and the State of Utah only the University of Utah was a result (other results were received, but they were for Texas and Tennessee for example). A search of FBO's current and archived postings for Histocompatibility requirements in the State of Utah did find results, but the results returned were not specifically for the State of Utah and were not for this specific requirement, for example, results were returned for Histocompatibility equipment testing or animal requirements. A search of the Department of Veterans Affairs Office of Small & Disadvantage Business Utilization VOSB/SDVOSB Verification website also did not find any results meeting requirements. When searching for "Histocompatibility" there were no results, and when searching for "Utah" and NAICS "6251511" there were five matches but none of these companies provide Histocompatibility and

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Immunogenic laboratory services. Additionally, the CS contacted ASHI, who is the accreditor for Histocompatibility and Immunogenetics Laboratories, requesting the names for any accredited labs in the State of Utah. They responded that they have only one accredited lab, which is the University of Utah. As described in Section VI above, additional market research, in accordance with FAR Part 10, was conducted by posting a synopsis of the proposed acquisition on FBO, advising industry of the pending acquisition and soliciting inquiries from interested parties. No responses were received from any potential sources. Due to the complexity of the requirement and nature of organ transplants utilizing a non-accredited laboratory for laboratory services would endanger patient safety and make any organs ineligible for transplant.

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

After review of the SOW, there was no way to modify the requirements to meet full and open competition and still meet the transplant requirements. Utilizing a laboratory that is not accredited is not a possible alternative. Utilizing express shipping or courier was also considered, but due to the tissue samples delicate nature, this was not deemed a feasible solution (these methods would exceed the hour transportation time limit).

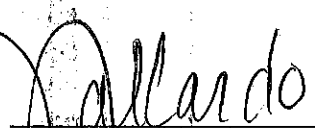
10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

No additional sources have expressed interest in this Acquisition.

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:

For any future acquisition, attempts will be made to locate alternate accredited laboratories that can meet the requirements. As there are no plans for the SLC VA Medical Center to gain these capabilities and no known plans for other laboratories opening in the region in the near future it is in the best interest of the Government to pursue a contract with four option years. This method will be more advantageous and cost effective to the Government in lieu of re-competing the requirement every year. Before enacting the option years, contracting staff will conduct a market survey in an attempt to discover any changes (to include contacting the ASHI for the listing of accredited labs in the State of Utah). Due to the accreditation and OPTN regulatory requirements, there are no other possible actions that can be taken to remove barriers to competition.

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.



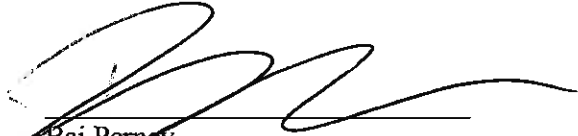
Terry Gallardo
Health Systems Specialist
SLC Pathology & Laboratory Medicine Service

Date

12/5/2016

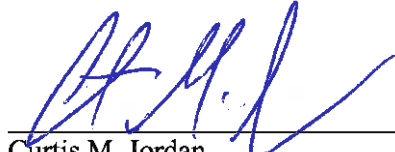
13. Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP (Part 806.3).

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


Bai Perney
Contracting Officer / Branch Chief, Services II

12/5/2016
Date

- b. **Director of Contracting /Designee (Required over\$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.


Curtis M. Jordan
Director of Contracting, NCO 19

12/5/2016
Date

- c. **VHA SAO HCA Review and Approval:** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and recommend approval (if over \$13.5 million) or approve (\$700K to 13.5 million) for other than full and open competition.

Delia A. Adams, MBA, CPCM
VHA Head of Contracting Activity (HCA)

12/07/16
Date