

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA263-17-AP-8738

1. **Contracting Activity:** Department of Veterans Affairs, NCO 23, St Cloud VA Health Care System, St Cloud MN 56303.
 2. **Nature and/or Description of the Action Being Processed:**
This procurement is for a Firm Fixed Price contract for Luminex LapType SSO Beads A, B, C, DRB1, DRB3*4*5, DQA 1 to type for specific locus. Luminex Labscreen single antigen Class I and Class II beads.
 3. **Description of Supplies/Services Required to Meet the Agency's Needs:**
RSSO1A, RSSO1B, RSSO1C, RSSO2B1, RSSO2345, RSSO2Q1, RSSOH1B, RSSOH2B1 beads, and labscreen single antigen Class 1 and Class II beads will be used on the One Lambda LAB Scan 100 Flowanalyzer with Fusion software. The One Lambda Fusion software is compatible with HistoTrac the laboratory's lab management program. Estimated value \$ 471,838.81.
 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;
☐ () (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 by for restricting competition on this procurement via FAR 13.106-1(b)(2).
5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**
 - a. **Only One Responsible Source (FAR 6.302-1) –**
Only One Lambda reagents can be used with the Fusion software that is installed in the VA-owned LABScan 100 Flowanalyzer. Using other reagents will render this equipment unusable. The Iowa Regional Histocompatibility and Immunogenetics Lab is the only tissue typing Human Leukocyte Antigen (HLA) Laboratory in the VA Health Care System and is charged with providing pre and post-transplant testing and antibody screening for the renal and renal & pancreas

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VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP
Attachment 2: Request for Sole Source Justification Format >\$150K

transplant programs at the Iowa City VA Health Care Systems. Accordingly, One Lambda is the only firm capable of providing the supplies and services described in Section III above without the Veteran's Health Administration experiencing substantial duplication of cost that could not be expected to be recovered through competition and 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:

Market research shows intermediate DNA typing reagents from GeneProbe do not currently meet industry standards due to HistoTrac software incompatibility to process patient reports. Future action is to continue to use this product until equipment has reached its life expectancy and replacement is required, at that time, other methods and sources will be researched. A search was conducted on vetbiz and no SDVOSB or VOSB's were found. An inquiry was made to Thermo-Fisher for authorized distributors and One Lambda is the only authorized distributor in North America and they are a large business.

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

The quote received will be compared to current processes and tests being performed at the Iowa City VA HCS as well as other sites throughout VISN 23, which have already been determined to be fair and reasonable IAW FAR 13.106-3.

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

Market research was conducted and shows that only One Lambda reagents are compatible with the Fusion analysis software that is installed and in use of the aforementioned equipment. GSA was searched and no results were found. A general interest search was also performed with no results. Market research on prior purchases and information provided by the mission partner with current procurement package were used.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition: None

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

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:
Once the software being used on the equipment owned by the HLA lab has exhausted its life expectancy, this requirement will be re-competed using full and open competition.