

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, VISN 4, Michael J. Crescenz Medical Center is proposing justification for other than full and open competition for the Roche Amliprep Instrument equipment rental and reagents for two months. This is an emergency order to hold us over until a larger contract can be completed.
2. **Nature and/or Description of the Action Being Processed:** The Microbiology department has been using this equipment for 10 years. Testing for HIV and HCV Viral Loads are done on this instrumentation.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The equipment is a fully automated, real time PCR. This equipment is necessary for the testing of HIV and HCV viral loads.
4. **Statutory Authority Permitting Other than Full and Open Competition:** There are other vendor's that offer this testing but we already have the equipment.

- (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;

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

Viral load testing is used to monitor the patient's response to the new therapeutic regimens now available for both of these viruses. Maintaining consistency in viral load testing is critical to timely and appropriate therapies. The equipment is the only equipment that can be used because the patients are based lined using these results. Their viral loads are monitored during the course of treatment for HCV. A change in testing would create an issue because patients would need to be retested and restarted on HCV medication. This would interfere with their treatment.

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

Replacing this equipment would create an immediate patient care problem because all patient's currently being followed through Viral Load testing would need to be re-baselined. Their treatment for HCV is dependent on these results.

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

The cost of this equipment and reagents is considered fair and reasonable. We are asking for 45 HCV viral Load Kits and 24 HIV viral load kits which come to a total of \$259,858.00. This is to hold us over for 2 months of testing.

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

There are other vendor's that offer this testing but will not satisfy the need of the department. Current operation using Roche reagents has been validated and patients are currently being monitored and medicated based upon the results of this vendor's testing matrix. Any potential change to testing equipment would need to be phased in over an extended time period.

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

Patients are monitored based upon the results produced by the reagents on the equipment. The reagents and equipment go hand and hand. Reagents can't be tested unless the equipment is compatible. This equipment is the only one compatible to do this testing with these reagents.

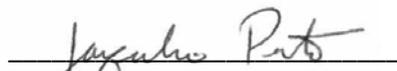
10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

N/A

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:

Agency is conducting continuous market research and exploring the possibility of a competitive procurement for the long term acquisition package.

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.


Name Jacqueline Pento
Title Microbiology Supervisor
Facility PVAMC

Date: 1/11/16

13. Approvals in accordance with FAR 6.304

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

_____	1/11/2017
Ronald Kline	_____
Contracting Officer	Date
NCO4	

- 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.

_____	1/11/2017
Jonathan Taliani	_____
Acting Branch Chief, Hybrid 2	Date
NCO4	