

**DEPARTMENT OF VETERANS AFFAIRS**

**Justification and Approval**

**For**

**Other Than Full and Open Competition**

1. **Contracting Activity:** Department of Veterans Affairs, VISN 04, Louis A. Johnson VA Healthcare System (540)

Transaction Number: 540-12-4-032-0062

2. **Nature and/or Description of the Action Being Processed:** This request is for genomic-based laboratory services.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Genomic Health, Inc. provides specialized Oncotype DX testing that is patented and can only be provided by this vendor. This assay provides Oncology providers with valuable information regarding optimal Chemotherapy treatments for colon and breast cancer patients.

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

- ( ) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;  
(X) (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):** An urgent and compelling need exists at this time. This medical center currently has a patient with known cancer awaiting treatment. The requested testing will direct the next step in the treatment program. Therefore, the outcome of the test will directly impact the treatment of this cancer patient and cannot be postponed.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Not applicable; urgent and compelling need

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** This test can only be completed by Genomic Health, as they hold the patent for Oncotype DX breast cancer assay testing.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** A brief internet search turned up the laboratory Genomic Health. Genomic

Health owns a patent on the Oncotype DX testing and is the only lab in the United States who can perform the test. Several websites were found attesting to the ownership of the patent.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** No other facts than what has already been stated, the results of this testing directly impact the treatment of this cancer patient and, therefore, necessitate an urgent and compelling situation.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Not applicable
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:** Until Genomic Health no longer solely holds the patent on this testing, then there will be no 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.



YVONNE FREEDMAN  
Administrative Officer  
Louis A. Johnson VA Healthcare System (540)

9/12/2012  
Date

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.



Kristina Weir  
Contract Specialist  
540

09/12/2012

Date

- b. **Supervisory Contract Specialist for NCM/PCM:** I certify that the foregoing justification meets the requirements for other than full and open competition.

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Brent Burns  
Supervisory Contract Specialist  
VISN4/PCA 540

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Date