

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval Under Simplified Acquisition Procedures (SAP) Simplified Acquisition Threshold (\$3K to \$150K) For Restricting Competition under FAR 13.106-1(b)(1) "Single Source"

1. Contracting Activity:

Department of Veterans Affairs, NCO 20, Spokane Medical Center for Portland VA hospital. Funded by 2237# 648-13-1-066-0017 and purchase request # VA260-13-P-1143.

2. Nature of the Action Being Processed:

Request a new one year plus four option year contract be established.

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

Oncotype X Interpretation of laboratory tests results are a required diagnostic tool. This type of test quantifies the likelihood of disease recurrence in women with early stage hormone estrogen receptor (ER) positive only breast cancer (prognostic significance) and assesses the likely benefit from certain types of chemotherapy (predictive significance). Estimated cost is \$136,640 over five years starting 1 Oct 2012-30 Sep 2017.

4. Statutory Authority Permitting Restriction in Competition:

Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;

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

Only One Responsible Source (FAR 6.302-1) Genomic Health owns the patent on Oncotype DX and no other laboratory performs this test. No one can legally perform this test under copyright law, and the Government cannot perform a comparable test in house nor can it develop one without substantial increase in cost, relative to what Genomic can already provide today.

6. Description of Efforts Made to Ensure that Offers are Solicited from As Many Potential Sources as Deemed Practicable IAW FAR 13.104:

Market research shows Genomic owns the patent so no other vendor can provide this service.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable – IAW FAR 13.106-3:

Previous contract VA260-12-P-1246 for six months listed each test at \$4,300 as reasonable. The contracting officer anticipates garnering a discount per test by writing a five year contract.

8. Description of the Market Research Conducted and the Results, or Statement of Reasons Market Research was not Conducted (FAR 10):

Market research shows Genomic owns the patent so no other vendor can provide this service.

9. Any Other Facts Supporting the Restriction of Competition:

None

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


None

11. Statement of 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:

Market research shows Genomic owns the patent so no other vendor can provide this service.

12. Requirements Certification - IAW FAR 6.303-2(c):

I certify that the requirement outlined in this justification is a bonafide 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: *Edward Lynn*
Position: *Lab Business Manager*
PVAMC

9/18/12
Date

13. Approvals IAW VHA SOP 3.22.11:

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



Name:

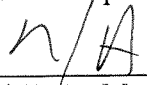


Date

Contracting Officer

NCO 20 (Services) Acquisitions Team

- b. **NCM/PCM/DESIGNEE:** 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 for other than full and open competition.



NCO 20 (...) Team Manager

Date