

DEPARTMENT OF VETERANS AFFAIRS
Justification and Approval
For
Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, VISN 08, James A. Haley Medical Center Pathology and Laboratory Services of James A. Haley Veteran's Hospital

Nature and/or Description of the Action Being Processed:

BRAC Analysis diagnostic breast cancer for genetic testing to determine the likelihood of a patient developing breast and/or ovarian cancer. Base (1) one and (4) four option years.

2. **Description of Supplies/Services Required to Meet the Agency's Needs:** BRAC Analysis testing assesses a woman's risk of developing breast or ovarian cancer based on detection of mutations in the *BRCA1* and *BRCA2* genes. BRAC Analysis is the only known method and Myriad Laboratory is the only known source in mutation detection identification of individuals with hereditary breast and ovarian cancer. The positive result allows doctors to take steps to reduce your risk of hereditary cancer by earlier and more frequent screening, and in some cases hereditary cancer risk may be nearly eliminated through preventive drug treatment or preventive surgery. A negative result rules out the most common cause of hereditary breast and ovarian cancers.
3. **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;
4. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**
BRAC Analysis is a patented genetic test that can let you know your risk for hereditary breast and ovarian cancer (HBOC) by identifying a BRCA gene mutation. Myriad Genetics offers the only sophisticated technology available for hereditary cancer syndromes and is the sole source provider for BRAC Analysis diagnostic breast cancer test. BRAC Analysis is used to detect mutations in the BRAC 1 and BRAC 2 genes. Myriad sequences both genes to detect mutations which significantly increase the risk of cancer in mutations carriers. Myriad Laboratories patent rights and copyright method of analysis makes the supplier the only source available to support patients and doctors requirements.
5. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:**
Pathology and Laboratory performed exhausted market research in 2009 and 2011 to locate vendors to support the requirements. Review of online data from contractors and medical trade shows provided negative results for contractors to provide the services.
6. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:**
Pursuant to FAR 13.106-3 (a) (2) (v) prices offered for Mutation gene testing services are fair and reasonable and represents the best value to meet the Government's needs. The fair and reasonable price are comparable against past orders on contract VA248-P-1141 Purchase Orders C20433 3/22/12 \$72,979, C10661 7/1/11 \$38,076.00, C00579 7/1/10 \$109,022.00 and C90602 7/1/09 \$106,704.00. On the basis of the above findings, I hereby determine that it is in the best interest to award a requirements contract to Myriad Laboratories Inc.

Version 1, 6 May 2011

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

Market research revealed that Myriad Laboratory is the only know source that perform mutation detection in genes. Myriad Genetics holds the patent for the mutation genetic tests in the industry.

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

Myriad Genetic Laboratory is the only source that provided mutation genetic testing for BRAC Analysis mutation gene testing.

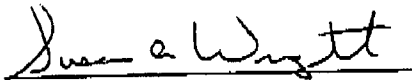
9. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

Special Notice VA-248-09-RQ-0427 resulted in zero responses in June 2009.

10. 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:

The Government shall post a notice on Federal Business Opportunities that permits prospective vendors to submit their respective technical capabilities solely for consideration in future acquisitions for the similar supplies and services.

11. 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.



Susan Wright
Opt Lab Supervisor
JAHVA

10/24/12
10/24/12

12. Approvals in accordance with FAR 6.304 This part is filled out by Contracting Staff as part of the Justification

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



Kella President
Contracting Officer
JAHVA

10/24/2012
10/24/12

- b. Product Line Supervisor (PLS): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.


Ronald Music

24 Oct 2012
10/24/12

- c. DNCM/NCM: (SAT to \$500,000) I certify the justification meets requirements for other than full and open competition.