

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

1. **Contracting Activity:** Department of Veterans Affairs, VISN 8, Bay Pines VA Healthcare System.  
This is a request for justification for other than full and open competition for purchase request #516-14-1-037-0008.
2. **Nature and/or Description of the Action Being Processed:** This request is for the procurement BRACAnalysis® testing which assesses a woman's risk of developing hereditary breast or ovarian cancer based on detection of mutations in the BRAC1 and BRAC2 genes. This is a new contract that will be awarded at a firm fixed price with a base and four option years. The anticipated price for the base year is \_\_\_\_\_ The total anticipated amount of the contract for the five year period is \_\_\_\_\_ The period of performance will be from October 1, 2013 – September 30, 2018.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Provide technical and professional services for BRACAnalysis Testing. Provide a test request form with a statement of medical necessity. Provide at no additional cost to the patient or physician: transport containers; telephone counseling/consultation with reference laboratory's pathologist when deemed appropriate. All reports must include comments that reflect clinical application. This test has become the standard of care in identification of individuals with hereditary breast and ovarian cancer. Bay Pines is required by VHA Directive 1330.01 to perform genetic testing for breast oncology when needed to make diagnostic, management, and secondary prevention decisions.
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;
  - (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):** Myriad Genetic Laboratories is the only laboratory that performs the BRACAnalysis testing at this time. BRCA mutations are responsible for the majority of hereditary breast and ovarian cancer. Patients with a mutation in either the BRAC1 or BRAC2 gene have risks of up to 87% for breast cancer and up to 44% for ovarian cancer by age 70. This acquisition is essential to the Government's requirements according to the VA Directive mentioned in #3 above and currently only one company provides this service as explained in #8 below. Accordingly, Myriad Genetic Laboratories is the only firm capable of providing the services described in Section III above without the Veteran's Health Administration experiencing 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:** No other potential sources are currently available. A sources sought synopsis was issued July 18-25, 2013 under solicitation # VA248-13-Q-2205 seeking vendors who could perform these tests within the 14-day turnaround time that Myriad currently provides. No responses were received. No other action will be planned to facilitate competition for this acquisition as market research (#8 below) explains the Myriad Genetic Laboratories is the only laboratory that performs this BRACAnalysis testing at this time.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** This test is a highly specialized test and due to the specificity and cost to perform. This test is performed by this reference laboratory only. As stated in #8 below, other companies perform one or both of these tests; however, their costs and turn-around times are currently unacceptable. The anticipated cost is considered fair and reasonable to the government.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:**  
No other vendors provide this test as requested by the patient's provider. The attached article dated July 12, 2013

mentions that two weeks prior to the release of the article, the U.S. Supreme Court struck down Myriad Genetics' central patent claims to the BRAC1 and BRAC2 genes and that several U.S. genetic testing laboratories have been gearing up to snatch a piece of the BRCA testing market in this country, previously Myriad's monopoly. The new market players are Ambry Genetics, Ethigen and DNA Traits, a division of Gene by Gene. The article goes on to explain that these new players just gearing up since the U.S. Supreme Court's decision. Myriad's turn-around time is 14 days; these companies have turn-around times from two weeks to four months. They also charging more and some of them don't provide both tests at this time. They expect that within the few years, many other labs providing such tests will become well-known for the benefit of the general public.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** The BRACAnalysis was developed by Myriad Genetic Laboratories. Currently, the market does not present any other vendor with this profile or a recognized equal.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** None, Myriad Genetic Laboratories is the only laboratory that offers this test. See section #6 above.
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:** Competition will be sought in the future knowing that other companies will be competitively entering this market within the next two to three years.
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 Date 6/5/2013  
Title: PAS Technical Specialist  
Facility: Bay Pines VAHCS

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.

\_\_\_\_\_  
Name Date  
Contracting Officer  
Facility

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

\_\_\_\_\_  
Name Date 7/30/13  
Contracting Supervisor  
Facility