

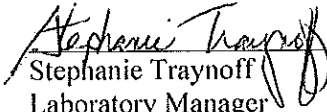
## DEPARTMENT OF VETERANS AFFAIRS

### Justification and Approval (J&A) For Other Than Full and Open Competition (>\$150K)

Acquisition Plan Action ID: VA69D-16-AP-7030

1. **Contracting Activity:** Department of Veterans Affairs, VISN 12, Federal Health Care Center (FHCC) and Great Lakes Acquisition Center (GLAC). Contract Request 556-17-1-2948-0001.
2. **Nature and/or Description of the Action Being Processed:** Justification and approval for a Contact to provide Myriad Prolaris Test Results in accordance with FAR 13.5, Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Provide Prolaris Test Kits for sending specimens to Myriad Genetic to generate test results for patients of FHCC. FHCC estimates needing 36 test results per year, at an estimated value of \$107,712.00 per year, and an estimate of \$538,560.00 for a 5 year ordering period.
4. **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;  
  
The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).
5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** Prolaris is a genomic test developed to aid healthcare professionals in predicting prostate cancer aggressiveness in conjunction with clinical parameters such as Gleason score and PSA. Prolaris is the first prognostic test that offers a direct measure of the molecular biology of an individual patient's prostate cancer. By measuring the expression levels of genes involved in cancer cell proliferation, Prolaris is able to more accurately predict disease aggressiveness. Prolaris has been shown to be the single most clinically significant prognostic parameter of outcomes at the time of diagnosis. The test provides unique additional information that can be combined with standard clinical factors to make the most accurate prediction of a patient's prostate cancer aggressiveness. Prolaris has been extensively validated across multiple patient cohorts in both pre- and post-treatment scenarios.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Prolaris is a registered trademark of Myriad Genetic Inc, Salt Lake City, Utah and no other source can provide us these test results at this time.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The current list price for this test is \$3400.00. The anticipated cost per test for the Government will be approximately \$2992.00 per test. Based on this comparison the Contracting Officer has determined this cost to be fair and reasonable.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** A search of Vetbiz for "Prolaris" resulted in no responses. Unicor and Ability One do not provide medical test results. A search of GSA and FSS for "Prolaris" resulted in no responses or records. A search of Google for "Prolaris" resulted in several options all taking you to the Prolaris.com site, which confirmed this test is proprietary to Myriad Genetic in Utah.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** None.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** None.
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:**  
Since new testing is being developed daily for all types of cancer, this agency will continue to look for the best options to take care of our patients.
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.

  
Stephanie Traynoff  
Laboratory Manager  
Lovell FHCC

10-25-16  
Date

13. **Approvals in accordance with the**

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

\_\_\_\_\_  
Teresa Beers-Wesolowski  
Contracting Officer  
GLAC

\_\_\_\_\_  
Date

- b. **Director of Contracting /Designee (Required over \$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

\_\_\_\_\_  
Andrea L. Morris  
Operations Division Manager  
NCO 12

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Date