

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A)

For

Other Than Full and Open Competition (>\$150K)

Acquisition Plan Action ID: VA263-15-AP-10709

1. **Contracting Activity:** Department of Veterans Affairs, VISN 23, Fargo VA Medical Center, 474 45th Street South Suite 202, Fargo, ND 58102 (438-16-1-112-0007)
2. **Nature and/or Description of the Action Being Processed:** A firm fixed price blanket purchase agreement with four option years is being contemplated for awarded on a sole source basis.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Opko Health Inc 4K score PSA blood test for prostate cancer risk testing. Each test is estimated to cost \$600.00. The Sioux Falls VA estimates using 625 tests over the next 5 years giving an estimated value of \$375,000.00 to this acquisition (includes options).
4. **Statutory Authority Permitting Other than Full and Open Competition:**

(x) 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):** The 4k score test predicts the risk of prostate cancer using blood tests including the kallikrein test, a digital rectal exam result and a manufacturer developed malignancy risk score system. The 4K score Test combines four prostate-specific kallikrein assay results with clinical information in an algorithm that calculates the individual patient's percent risk for aggressive prostate cancer. The test components, Intact PSA and hK2 are proprietary to Opko. The 4Kscore Test is the only blood test that accurately identifies an individual patient's risk for high-grade, aggressive cancer and is now included in the National Comprehensive Cancer Network 2015 Guidelines for Prostate Cancer Early Detection.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** According to market research results performed in October of 2015 only one vendor was identified that provides the 4k score PSA tests at this time. See box 8 for the description of market research that was conducted to come to this conclusion.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** FAR Part 13.106-3 will be utilized to determine price fair and reasonable. A final price fair and reasonable determination will be made prior to award by comparing previously paid purchase card orders to pricing offered for this BPA.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** GSA advantage, FSS NAC Med-surge catalog, FBO, General Internet searches, FPDS and eCMS have been used for market research. OPKO Health Inc Lab, a full

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
Attachment 3: Request for Sole Source Justification Format >\$150K

service urological testing laboratory, is the provider of the 4Kscore Test. Opko Health Inc. is a small business.

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:** Opko Health Inc is the only vendor available for this requirement. OPKO Health Inc Lab, a full service urological testing laboratory, is the provider of the 4Kscore Test.
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:** Service line will continuously monitor and reassess the market to determine if new prostate exam tests become available.
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: Mary Braley Title: Lab Supervisor Facility: Sioux Falls VA	10-13-15 Date
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13. **Approvals in accordance with the [VHAPM, Volume 6, Chapter VI: OFOC SOP](#).**

- 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: Lance Haman Title: Contract Officer Facility: NCO 23	Date
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- b. **Director of Contracting /Designee (Required \$150K and above):** I certify the justification meets requirements for other than full and open competition.

Name Christopher Volk NCO 23 – Branch Chief Facility: NCO 23	10/14/2015 Date
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