

**DEPARTMENT OF VETERANS AFFAIRS**

**Justification and Approval (J&A)  
For  
Other Than Full and Open Competition (>SAT)**

**Acquisition Plan Action ID:** 36C263-19-AP-1676

1. **Contracting Activity:** Department of Veterans Affairs, Network 23 Contracting Office, 4801 Veterans Drive, St. Cloud, MN 56303

**Organizational Activity:** Department of Veterans Affairs, Minneapolis VA Health Care System, One Veterans Drive, Minneapolis MN 55417

**2237 Number:** 618-20-1-106-0009

2. **Nature and/or Description of the Action Being Processed:** firm-fixed price requirements contract to provide Hepatitis C Virus Genotyping (HCVg) Test Kits (Research Use Only) and the associated instrumentation for the Minneapolis VA Health Care System's Molecular Diagnostic Laboratory.

Period of Performance: 10/01/2019 to 9/30/2020 with four one-year option periods



**FAR13.5 Simplified Procedures for Certain Commercial Items:** *This procurement is for Hepatitis C Virus Genotyping (HCVg) Test Kits 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:** The Minneapolis VA Health Care System's Molecular Diagnostic Laboratory requires eSensor Hepatitis C Virus Genotyping (HCVg) Direct Test Kits (Item Number: MT008102)
4. **Statutory Authority Permitting Other than Full and Open Competition:** *41 USC §3304(a)(1), as implemented by FAR 6.302-1.*

- (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;

**FAR13.5 Simplified Procedures for Certain Commercial Items:** *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):** These direct kits are the only kits that can be utilized for the highly specialized, and highly specific testing need in the molecular diagnostics laboratory. This test is a laboratory developed tests, and in order to meet the regulations in place for laboratory developed tests using Research Use Only (RUO) a significant amount of testing and validation would need to occur prior to patient testing. This testing and validation could take a year or longer due to the fact the genotypes of hepatitis are not common, and each of the genotypes would have to be tested multiple times to meet the regulations in place. It would be next to impossible to find all the genotypes in a shorter amount of time, as they have such a low occurrence rate. If we would switch to a different product would mean that either testing would need to halt patient testing until a new laboratory developed test could be developed, tested, and validated. To halt testing for a year would have an unacceptable effect on patient care.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** GenMark is the manufacturer of the eSensor Hepatitis C Virus Genotyping (HCVg) Direct Test Kits. GenMark has no authorized distributors or resellers.
7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** The government believes the anticipated cost will be considered fair and reasonable IAW FAR 13.106-3(a)(2)(ii), based upon Comparison of Proposed Prices with Prices Found Reasonable on Previous Purchases.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** In accordance with VA Procurement Policy Memorandum 2016-05 -Implementation of the Veterans First Contracting Program, U.S.C. §§ 8127, Market Research was conducted on Vetbiz.gov using 325413, with 25 results returned. However GenMark is the exclusive manufacturer and distributor of the eSensor Hepatitis C Virus Genotyping (HCVg) Direct Test Kits. There are no other sources of these supplies.
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:** The Government will continue to conduct market research to ascertain if there are changes in the market place that would enable future actions to be competed for these reagents, calibrators and controls.
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,

VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP  
Attachment 2: Request for Sole Source Justification Format >SAT

which are included in the justification, are accurate and complete to the best of my knowledge and belief.



Amy Colbaugh  
Laboratory Contract Liason  
Minneapolis VA Health Care System

Date

13. Approvals in accordance with the [VHAPM Part 806.3 OFOC SOP](#):

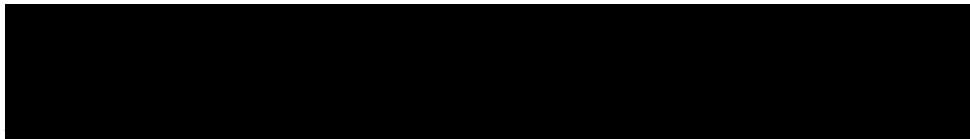
- a. **Contracting Officer or Designee's Certification (required)**: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



Andrea Harter  
Contracting Officer  
NCO 23

Date

- b. **One Level Above the Contracting Officer (Required over SAT but not exceeding \$700K)**: I certify the justification meets requirements for other than full and open competition.



Jameson Schwartz  
Branch Chief  
NCO 23  
Department of Veterans Affairs

Date