

LIMITED SOURCES JUSTIFICATION

ORDER >SAT

FAR PART 8.405-6

Acquisition Plan Action ID: 36C249-19-AP-1865

- 1. Contracting Activity:** Department of Veterans Affairs, VISN 09, Tennessee Valley Healthcare System (TVHS). The contracting organization making this procurement is Network Contracting Office 9. The applicable purchase requisition number is 626-20-1-097-0004.
- 2. Description of Action:** This acquisition is conducted under the authority of the Multiple-Award Schedule Program (41 U.S.C. 251 and 40 U.S.C. 501). This is a limited sources justification (LSJ) for a new highly specialized cancer testing requirement at TVHS.

Order against: FSS Contract Number: V797D-70053

Name of Proposed Contractor: Genomic Health, Inc. (Genomic)

Street Address: 301 Penobscot Drive

City, State, Zip: Redwood City, CA 94063

Phone: 866-662-6897

3. Description of Supplies or Services:

The total estimated value of the proposed action, inclusive of options, is \$XXXXXX. The base period of performance for this requirement will be from October 1, 2019 to September 30, 2020. The estimated pricing for each period of performance is as follows:

Contract Line Item Numbers	Period of Performance	Estimated Value
0001 - 0002	Base Period October 1, 2019 to September 30, 2020	\$ XXXXX
1001 - 1002	Option Year 1 October 1, 2020 to September 30, 2021	\$XXXXXX
2001 - 2002	Option Year 2 October 1, 2021 to September 30, 2022	\$XXXXXX
3001 - 3002	Option Year 3 October 1, 2022 to September 30, 2023	\$XXXXXX

4001 - 4002	Option Year 4 October 1, 2023 to September 30, 2024	\$XXXXXX
Total		\$XXXXXX

Contractor shall provide all labor, materials, quality assurance, supervision, and testing to perform the following cancer tests on a cost per test basis: Oncotype DX Breast Cancer Assay and the Oncotype DX Prostate Cancer Assay, which are trademarked tests by Genomic Health. The required testing will analyze the activity of a group of genes that can affect how a cancer is likely to behave and respond to treatment. Testing results need to show how complex genes are expressed in cells (what their level of activity is), and the role they play in specific cancers including breast, colon, and prostate.

TVHS requires testing that has been reliable for years and can't afford to risk experimenting with newer specialized cancer tests unless evidence guarantees greater benefits to Veterans. The aforementioned tests are highly specialized and have been proven to predict the likelihood of cancer recurrence, the likelihood of patient survival, and the likelihood of chemotherapy benefit. These unique diagnostic tests can help patients and their doctors make informed, individualized treatment decisions. Results will also help clinicians determine if the patient needs to undergo chemotherapy treatment or not, saving the VA thousands of dollars in treatment costs. Selecting a different type of test could directly and irreparably impact the life of the Veterans TVHS serves.

(4) IDENTIFY THE AUTHORITY AND SUPPORTING RATIONALE (see 8.405-6(a)(1)(i)(A), (B), and (C) or 8.405-6(b)), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE.

- An urgent and compelling need exists, and following the ordering procedures would result in unacceptable delays.
- Only one source is capable of providing the supplies or services required at the level of quality required because the supplies or services are unique or highly specialized;
- In the interest of economy and efficiency, the new work is a logical follow-on to an original Federal Supply Schedule order provided that the original order was placed in accordance with the applicable Federal Supply Schedule ordering procedures. The original order must not have been previously issued under sole source or limited source procedures.
- Items peculiar to one manufacturer:
 - A patent, copyright or proprietary data limits competition. The proprietary data is: (If FAR 8.405-6(a)(2)iii before posting. Do not include specific proprietary data. Only mention the type of equipment, procedure, etc. to show that proprietary supplies or services are being procured.)
 - These are "direct replacements" parts/components for existing equipment.

The material/service must be compatible in all aspects (form, fit and function) with existing systems presently installed/performing. Describe the equipment/function you have now and how the new item/service must coordinate, connect, or interface with the existing system.

(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.404(d) TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION: In accordance with FAR 2.101, “best value” is defined as “...the expected outcome of an acquisition that, in the government’s estimation, provides the greatest overall benefit in response to the requirement.” The reason for this determination is due to the complexity of the tests that are rendered, the potential of the negative outcome if a proven cancer test is not acquired on the Veteran, and the fact that the pricing has already been determined fair and reasonable by the General Services Administration.

(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED: A search was conducted on the Veteran Information Page (VIP) utilizing North American Industry Classification System (NAICS) 621511, Medical Laboratories. All Veteran Owned Small Businesses (VOSB) were sought in the search, and 103 VOSBs were certified to be capable of performing laboratory services not necessarily cancer tests, however. Due to this, it was determined that a Sources Sought Notice (SSN) would need to be issued to gather a clearer perspective on the capabilities of the private sector to perform the required cancer tests.

SSN 36C24920Q0001 was posted to Fed Biz Ops (FBO) on July 16, 2019. The SSN requested capability statements from contractors on whether contractors other than Genomic could provide cancer testing that were equal to or better than Genomic’s testing. The SSN was posted to FBO so that all contractors, regardless of socioeconomic category (i.e. all GSA contractors could see the SSN), could respond to the SSN with their respective capability statement. Responses to the SSN were due July 31, 2019. No contractors provided their capability statements, including GSA contract holders, in response to the SSN.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION: Market research was conducted, details of which are in the market research section of this document. This effort did not yield any additional sources that can meet the government’s requirements. There is no competition anticipated for this acquisition. In accordance with FAR 5.301 and FAR 8.405-6, this action will be synopsisized at award on the Federal Business Opportunities Page (FBO) and the justification will be made publicly available.

(8) A STATEMENT OF THE ACTIONS, IF ANY, THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS THAT LED TO THE RESTRICTED CONSIDERATION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES OR SERVICES IS MADE: 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.

(9) 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. I understand that processing of this limited sources justification restricts consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4.

Shannon L. Skillern Digitally signed by Shannon L.
Skillern 955914
Date: 2019.09.03 10:10:05 -05'00'

9-3-2019

Shannon Skillern
Administrative Officer
Laboratory Service
Tennessee Valley Healthcare System

Date

(10) APPROVALS IN ACCORDANCE WITH THE VHAPM Part 806.3 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.

Stephen A. Clabough Digitally signed by Stephen A.
Clabough 711859
Date: 2019.09.03 10:07:25 -05'00'

9-3-2019

Stephen A. Clabough
Contracting Officer

DATE

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

Thomas N. Allman Digitally signed by Thomas N.
Allman 709696
Date: 2019.09.03 10:41:10 -05'00'

9-3-2019

Thomas N. Allman
Supervisory Contract Specialist

DATE