LIMITED SOURCES JUSTIFICATION

ORDER >SAT

FAR PART 8.405-6

Acquisition Plan Action ID: 36C252-18-AP-0528

1. **Contracting Activity:** Department of Veterans Affairs, Great Lakes Acquisition Center (GLAC) on behalf of the Edward Hines VA Hospital, Pathology & Laboratory Medicine Service, Hines, IL, VISN 12.

   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 for a delivery order against FSS V797D-30085 with Biofire Diagnostics, LLC for the purchase of laboratory instruments for pathogen detection for VISN 12 PLMS locations at Edward Hines Jr. VA Hospital, Hines, IL, James Lovell Federal Health Care Center, North Chicago, IL, Clement J. Zablocki VA Hospital, Milwaukee, WI, William Middleton VA Hospital, Madison, and Illiana Health Care Center, Danville, IL.

   Order against: ☒ FSS Contract Number: _V797D-30085___

Name of Proposed Contractor:	Biofire Diagnostics, LLC
Street Address:	515 Colorow Drive
City, State, Zip:	Salt Lake City, UT 84018-1214
Phone:	801-736-6354 x1348

2. **Description of Supplies or Services:**

The estimated value of the proposed action is $ 321,101.02

VISN 12 PLMS requires the ability to conduct automated multiplex polymerase chain reaction (PCR) for rapid identification of microorganisms in patient samples via Food and Drug Administration (FDA) approved panels. The platform for tests will provide rapid identification for diagnosis and treatment of respiratory, gastrointestinal, blood, and cerebrospinal fluid pathogens. In addition to the purchase of the Film Array instrumentation, each location will receive ancillary equipment and verification packages of reagents. Included in this initial purchase is the manufacturer's warranty. VA will purchase ten (10) instruments capable of conducting pathogen identification of positive blood culture, respiratory samples, and meningitis/encephalitis via cerebrospinal samples. Biofire Diagnostics, LLC is the sole provider of the Film Array platform and associated supplies.

(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;

Biofire is the only known FDA approved testing platform with FDA approved panels that detect bacteria, viruses, parasites, yeast and antimicrobial resistance genes via multiplex utilizing patient samples in nasopharyngeal swab, positive blood culture, stool in cary-blair, and cerebrospinal fluid (CSF). Multiplexing allows for multiple analytes to be run simultaneously in one run of the instrument to identify if any of the system detectable pathogens are present, producing a result typically in 60-90 minutes. This reduction in testing time by the Biofire platform utilizing multiplexing allows for faster diagnosis and subsequent treatment of potentially life-threatening pathogens.

Biofire offers Respiratory panels that detect 20 viral and bacterial pathogens, Blood Culture panels that detect 27 targets, three of which are antibiotic resistance genes, Gastrointestinal panels that detect 22 pathogens, and Meningitis/Encephalitis panels that detects 14 targets. With the addition of meningitis and encephalitis panels, the system available from Biofire offers a comprehensive system with testing capabilities for a broad array of common pathogens all in one system decreasing the need for multiple, separate systems at the facilities. There is no other platform with all the above capabilities.

☐ 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 <u>"direct replacements" parts/components</u> 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 the contractors NAC FSS schedule, discounts from the contractor are as follows: Up to 5% on the first instrument, up to 20% on the second instrument, up to 30% on the third instrument and 4th and subsequent instruments are maximum of 40%. Based on the volume being purchased by VISN 12 the contractor has provided an additional discount on the first instrument for a total of 20% off, the second instrument for a total of 30% off and the third through 10th instruments there is a total discount of 40% off for each instrument. For ancillary equipment and supplies VISN 12 is receiving a 0.5% to 0.61% discount off the contract price.

(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED:

In accordance with the Vets First Contracting Program, 38 U.S.C. 8127 & 8128 Implementation Policy and Procedures, a search was conducted on the Vendor Information Pages using NAICS 334516 and yielded 92 results. A search of keyword pathogen yielded 6 contractors, however, the contractors capabilities do not include information on capabilities to provide the required type of testing. A search using NAICS 334516 and pathogen yielded one result, however, the contractor's capabilities do not include information on capabilities to provide the required type of testing. Additional searches on VIP for keywords PCR, multiplex, polymerase, and syndromic either yielded no responses or no capabilities in contractors yielded. A search on Dynamic Small Business Search (DSBS) for NAICS 334516 and pathogen, PCR, syndromic separately did not yield results of contractors with capabilities to provide the required testing. A search of Unicor and AbilityOne did not yield capabilities. A search on GSA did not yield capabilities. There are no known sources on NAC FSS, namely schedule 66III. A general search on the internet yielded contractors with some capabilities but no contractors yielded panels for positive blood culture, respiratory, gastrointestinal, and meningitis/encephalitis. Some competitive contractors have one or two of the required testing panels but do not currently possess the capability to provide blood culture, respiratory, gastrointestinal, and meningitis/encephalitis.

Sources sought notice 9350 was posted to Federal Business Opportunities (FBO) on January 25, 2018 to challenge the previous assumption. It returned one response from industry, however, upon discussion with the end users and the contractor it was determined the panels are not FDA approved. Without FDA approved panels, results from a contractor's system would have to be offered for non-clinical purposes and could not be used in clinical diagnosis or patient management, therefore, this system did not meet the minimum requirements of VISN 12.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION: None**.**

(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:

There are no known actions the agency can take to remove or overcome barriers to competition. This will be dependent on other contractors to develop a competitive comprehensive system that meets the VISN 12 testing needs.

(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.

Donna M. Wray 394473

Digitally signed by Donna M. Wray 394473
Date: 2018.08.08 07:00:57 -05'00'

DONNA WRAY, BUSINESS MANAGER, PLMS — DATE
BUSINESS MANAGER
PLMS

(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.

jessica l. Rasmussen 303871

Digitally signed by jessica l. Rasmussen 303871
Date: 2018.08.08 10:10:49 -05'00'

JESSICA RASMUSSEN — DATE
CONTRACTING OFFICER
NCO 12

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.

David J Picchi 1428405

Digitally signed by David J Picchi 1428405
Date: 2018.08.08 10:34:32 -05'00'

DAVID PICCHI — DATE
BRANCH CHIEF, SUPPLY TEAM
NCO 12