

LIMITED SOURCES JUSTIFICATION

ORDER >\$150,000

FAR PART 8.405-6

Acquisition Plan ID No: VA263-17-AP-5589

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in par. 3 below is sole source, therefore, consideration of the number of contractors required by FAR Subpart 8.4 – Federal Supply Schedules, is precluded for the reasons indicated below.

Restricted to the following source: Provide original manufacturer's name for material or contractor's name for service. (If a sole source manufacturer distributes via dealers, ALSO provide dealer information.)

Manufacturer/Contractor: BioFire Diagnostics, LLC
Manufacturer POC & Phone No: 385-228-5625
Mfgr/Contractor Address: 390 S. Wakara Way, Salt Lake City, UT 84108
Dealer/Rep address/phone number: 801-736-6354 ext 250

☒ The requested material or service represents the minimum requirements of the Government.

(1) AGENCY AND CONTRACTING ACTIVITY: Department of Veterans Affairs
Network Contracting Office, NCO 23
2101 Elm Street North, Building 30
Fargo, ND 58102
VISN: 23

(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:

The VA Midwest Healthcare Network (VISN 23) has a requirement for detection instrumentation systems which will test for common gastrointestinal (GI) pathogens including viruses, bacteria, and parasites. This "Brand Name Only" request is for the FilmArray manufactured by BioFire Diagnostics, LLC. These detection products are available via a delivery order through NAC FSS Contract No. V797D-30085.

The "FilmArray" brand name by BioFire Diagnostics, LLC has an automated multiplex polymerase chain reaction (PCR) system which integrates sample preparation, nucleic acid amplification, detection, and analysis into one walk-away testing platform capable of performing separate assay panels for multiple pathogenic organism targets. Those targets include bacteria, viruses, fungi, and parasites, for gastrointestinal, respiratory, blood culture, and meningitis specimen types.

(3)(a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:

The instrumentation must utilize a multiplex PCR (polymerase chain reaction) method. The detection system must have FDA-cleared assays for GI pathogens from stool samples, have very little hands-on time (2 minutes or less) and have results for all 3 categories of pathogens (annotated above) in 1 hour. The detection system must include all hardware components to perform the assay method: processor, computer, printer, cables, and software. In addition to the instrumentation, verification packages and reagents are required. The verification package includes all materials needed to test and ensure the instrumentation is certified for use. The reagents are required during the performance of the test, using the instrumentation.

The quantities required to meet the agency's need in the first year of the BPA are estimates that will vary in accordance with ordering. Included in the start-up package is the complete FilmArray System which includes a testing module, a Windows-based computer, analysis software and a myriad of peripheral items. Although usage will vary dependent on ordering, it is estimated that the cases of test kits (30 test panels/kit) for the base year are as follows: Gastrointestinal (GI) – 86; Respiratory – 0; Blood Culture (BCID) – 0; Meningitis (ME) – 0. It is anticipated that Biofire testing for Respiratory, Blood Culture, and Meningitis will not begin until Option Year 1.

To meet the agency's needs, the instrumentation must be FDA-approved and contain PCR methodology. The instrumentation must be capable of a 1-hour turn around in a single test and must be capable of testing for an array of (22) common potential pathogen targets for gastrointestinal specimens to include bacteria, viruses, and parasites. The instrumentation must be capable of testing for (20) respiratory pathogen targets including both viruses and bacteria. The instrumentation must be capable of testing 27 blood culture targets, including both Gram-positive and Gram-negative bacteria and yeast, plus detect the presence of several major antibiotic resistance genes. A meningitis/encephalitis panel requires detection capability of at least 16 potential pathogen targets, including bacteria, viruses, and yeast species.

The "FilmArray" brand name from BioFire Diagnostics, LLC is the only FDA approved system that possesses multiplex PCR technology in a single test format with a 1 hour turn-around time to final result with multiple targets tailored to each specimen type.

The Midwest Healthcare Network (VISN 23) needs instrumentation that will test for common gastrointestinal (GI) pathogens including viruses, bacteria, and parasites. The required instrument must utilize a multiplex PCR (polymerase chain reaction) method, have FDA-cleared assays for GI pathogens from stool samples, have very little hands-on time (2 minutes or less) and have results for all 3 categories of pathogens (listed above) in 1 hour.

The detection system must include all hardware components to perform their assay method, including the processor, computer, printer, cables, and software. In addition to the instrumentation, verification packages and reagents are required. The verification package includes all materials needed to test and ensure the instrumentation is certified for use. The reagents are required to perform tests in conjunction with the instrumentation.

(b) ESTIMATED DOLLAR VALUE: Base Year: \$819,923.08
Total Contract Value (Base and four options): \$6,491,064.18

(c) REQUIRED DELIVERY DATE: 9/1/2017

(4) IDENTIFICATION OF THE JUSTIFICATION RATIONALE (SEE FAR 8.405-6), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE.

☒ Specific characteristics of the material or service that limit the availability to a sole source (unique features, function of the item, etc.). Describe in detail why only this suggested source can furnish the requirements to the exclusion of other sources.

The FilmArray system (including the testing module) is the only equipment that has the capability to work with test panels which include gastrointestinal panels. The FilmArray is more comprehensive than

their competitor, Nanosphere because Nanosphere does not include detection of parasites. The blood culture panel is the most comprehensive one in a single test including Gram negative and Gram positive bacteria and yeast. Neither competitor (Nanosphere or Luminix) offers yeast identification. With Nanosphere and Luminix, different panels are required after determining whether a Gram positive or Gram negative panel is required following microscopy and observation of a Gram stain. This procedure adds at least another hour to the testing process. In addition, Polymicrobial infections could be missed using this system with these requirements.

The meningitis panel is the only complete panel that is FDA-approved for spinal fluid. The FilmArray system provides this testing. Nanosphere and Luminix would have to have a separate test done which would take at least one hour of additional preparation and testing. No other system can provide all the tests (to include meningitis testing) that the FilmArray system can do. Because Nanosphere and Luminix cannot provide the tests in a single process, the lab would have to conduct additional tests, which take additional resources of personnel and time.

Furthermore, any delay on getting the results back in the shortest time may negatively impact the well-being of patients and their treatment. The sooner physicians know the test results, the sooner they can start the patient's treatment and prescribe medication that will help the patient feel better. Market research was conducted, and there is only one source that allows for the detection of all three gastrointestinal pathogens; a) parasites b) bacteria and c) viruses. The Film Array instrumentation is able to identify parasites such as:

Cryptosporidium, Entamoeba histolytica, Giardia lamblia, and Cyclospora cayetanensis), as well as gastrointestinal pathogenic bacteria and viruses.

☒ **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.)

The FilmArray manufactured by BioFire is instrumentation that is capable of testing for Virus, Bacteria and Parasites.

☐ 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.

☐ 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.

☐ An urgent and compelling need exists, and following the ordering procedures would result in unacceptable delays.

(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.4 TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:

This requirement is on VA FSS Contract No. V797D-30085. Per FAR Part 8.404(d), GSA has already determined the prices of supplies under schedule contracts to be fair and reasonable. Therefore, ordering activities are not required to make a separate determination of fair and reasonable pricing. Since this instrumentation is offered on a VA FSS schedule, the NAC determined the prices and those publicized prices are firm-fixed. A price evaluation will be conducted, per FAR 8.405-2(d). Government has concluded that the FilmArray by BioFire Diagnostics represents the best value when price and special features are combined.

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

On March 21, 2017, a "Sources Sought Notice" was publicized to Federal Business Opportunities in an attempt to search for Veteran Owned, Small Businesses. The "Sources Sought Notice" invited feedback from any interested competitor. Salient Characteristics accompanied the "Sources Sought Notice". No one replied to the "Sources Sought Notice". A second "Sources Sought" was publicized to GSA eBuy using the Category 66-100. The results of this market research enforced the Contracting Officer's assumptions. When the FilmArray system by BioFire Diagnostics, LLC was compared to its competition; the competitions shortcomings became very evident. The most detrimental element is that the competitions instrumentation does not allow for the detection of all three gastrointestinal pathogens: parasites, bacteria and viruses.

Market research was conducted, and the FilmArray System is the one source that allows for the detection of all three gastrointestinal pathogens – parasite, bacteria and viruses. The Film Array instrumentation is able to identify a myriad of parasites (e.g. Cryptosporidium, Entamoeba histolytica, Giardia lamblia, and Cyclospora cayetanensis), as well as gastrointestinal pathogenic bacteria and viruses. None of the competitors have instrumentation on an FSS contract and none allow for the detection of all three gastrointestinal pathogens; parasite, bacteria, and viruses.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION: N/A

(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:

Currently within VISN 23, the FilmArray System is in use at two VA laboratories. In the future, when the need arises for new pathogen testing, lab personnel and contracting will conduct extensive market research to determine if the market has changed and to determine whether superior instrumentation became available that can provide testing as efficiently as the FilmArray System by BioFire Diagnostics, LLC. Furthermore, contracting will continue to determine whether any SDVOSB contractor has entered the market and can provide this parasite detection system.

(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. *(This signature is the requestor's supervisor, fund control point official, chief of service or someone with responsibility and accountability.)*

<hr/>		6/28/2017
SIGNATURE		DATE
<u>Angela Mulinix</u>	<u>Biomedical Engineer</u>	<u>VISN 23/Biomedical Engineering</u>
(NAME)	(TITLE)	(SERVICE LINE/SECTION)
<u>VISN 23</u>		
(FACILITY)		

(10) 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.

<hr/>	06/28/2017
Jan M. Lang	DATE
Contracting Officer	
NCO 23	

b. Director of Contracting/DESIGNEE: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

<hr/>	06/30/2017
Daryl A. Berg	DATE
NCO 23 Director of Contracting	

HIGHER LEVEL APPROVAL (Required *For orders over \$700,000*):

c. VHA SAO HCA REVIEW AND APPROVAL (over \$700,000 to \$13.5 million): I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for restricting consideration of the Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4

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Linda S. Greaves	DATE
Acting Director, SAO Central Region	
SAO Central Head of Contracting (HCA)	