**LIMITED SOURCES JUSTIFICATION**
**ORDER > $150,000**
**FAR PART 8.405-6**

**2237 Transaction # or Vista Equipment Transaction #: 618-16-1-106-0039**

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 V797D-30085
Manufacturer/Contractor POC & phone number: Rob Bednarik
Mfgr/Contractor Address: 390 S. Wakara Way
Salt Lake City, UT 84108
tel: 801-736-6354
email: rob.bednarik@biofiredx.com

Dealer/Rep address/phone number: same as above

☒ 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
4801 Veterans Drive
St. Cloud MN 56303-2099

**VISN:** 23

**(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:**
The Minneapolis VA Healthcare System (MVAHCS) has a need for a contractor to provide consumables that will test for common gastrointestinal (GI) pathogens including viruses, bacteria, and parasites using the Film Array assay on the BioFire instrumentation. The assay consumables 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. Product number RFIT-ASY-0116 (BioFire GI Panel kit) is the only assay kit to fulfill this requirement.

The VA is requesting a Blanket Purchase Agreement (BPA) for a base year period with four one year option years. Estimated period of performance is January 1, 2016 through December 31, 2016, with four one (1) year option periods.

(3) (a) **A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:**
The assay consumables being sought need to identify:
-Parasites (e.g. Cryptosporidium, Entamoeba histolytica, Giardia lamblia, and Cyclospora cayetanensis)
-Gastrointestinal pathogenic bacteria and viruses.
-All from one set of consumables/reagents
-Need just 2 minutes of hands-on time to run the assay, and be completed in one hour.
-Must be compatible with the FilmArray instrument by BioFire

(b) **ESTIMATED DOLLAR VALUE:** $304,453.38 per year ($1,522,266.90 for base + option years)

(c) **REQUIRED DELIVERY DATE:** January 1, 2016

**(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.**

X 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.

No other vendor but Biofire detects all 3 categories of pathogens: parasites, gastrointestinal pathogenic bacteria, and viruses in one assay. The BioFire system only accepts the FilmArray Pouch, so no other reagent products may be used. There is specific equipment these consumables (pouches) must work with. The government already owns the instrument for these consumables. The instrument is the FilmArray PCR instrument, made by BioFire, and the model is FilmArray 2.0.

☐ 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.

X 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 Minneapolis VA HCS currently owns the FilmArray 2.0 instrument by BioFire, which will only operate with the BioFire assay kits to perform the required laboratory testings. A different vendor would cost the Minneapolis VA HCS an additional $60,000 to purchase new instrumentation, plus the cost of the consumables. Also, only BioFire's technicians are allowed to service the equipment. BioFire will detect all categories of gastrointestinal pathogens from one processing step.

☐ 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:**

These consumables are available via Federal Supply Schedule (FSS) contract number V797D-30085, and in accordance with FAR (Federal Acquisition Regulation) 8.404 (d), GSA has already determined the price to be fair and reasonable.

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

Market research was conducted and investigating done by on-line searches and literature searches of Nanosphere and BioFire, with followup in-house vendor presentations by both companies. The chart below shows how the FilmArray compares to other molecular assays:

| | FilmArray | Luminex | Hologic | BD MAX | Nanosphere |
|---|---|---|---|---|---|
| Specimen to Result? | Yes | No | No | Yes | No |
| Comprehensive panel? | Yes | Yes | No | No | No |
| Hands-on-time: | 2 minutes | 45 minutes | <30 minutes | 1.5 minutes | ~5 minutes |
| Total time to result: | 1 hour | 5 hours | 4 hours | <3 hours | ~2 hours |
| Detects Bacteria: | 14 | 7 | 5 | 4 | 7 |
| Detects Viruses: | 5 | 2 | 0 | 0 | 0 |
| Detects Parasites: | 4 | 2 | 0 | 0 | 0 |

Specimen to result means no intermediate steps after the reagents and specimen are loaded into the assay consumable. Comprehensive panel means can the assay detect enteric pathogens that are bacterial, viruses, and parasites (all 3 categories). The "detects" rows mean how many different pathogens in that category does each assay detect and report. Even though FilmArray was clearly the best in these categories, I had FilmArray and Nanosphere follow up with on-site presentations of their assays. The other assays were eliminated because they were too labor intensive (hands-on-time) which means the tech time was too much (this needs to be done quickly), or took too long to get a result to be practical, or they lacked the ability to detect viruses and parasites—both of which are important enteric pathogens. The in-house presentations of FilmArray and Nanosphere served to compare assays, and confirmed that between the 2 companies, only FilmArray detects a multitude of bacteria, viruses, and parasites in a short time (1 hour) with very little prep time (2 minutes). FilmArray is the best assay for our laboratory to use.

**(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:**

Whenever new assays are needed by the Minneapolis laboratory, and there are no pre-owned instrumentations to run the new assays on, thus saving funding , there will be a competitive acquisition for replacement equipment at that time.

**(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.)*

John J. Holter — 10-22-2015

SIGNATURE — DATE

| John Holter | Supervisor | PALMS/Microbiology & Molecular Diagnostics Laboratory |
|---|---|---|
| NAME | TITLE | SERVICE LINE/SECTION |

Minneapolis Veterans Affairs health Care System
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.

MELANIE A STOCKMAN 197716

Digitally signed by MELANIE A STOCKMAN 197716
DN: dc=gov, dc=va, o=internal, ou=people, 0.9.2342.19200300.100.1.1=melanie.stockman@va.gov, cn=MELANIE A STOCKMAN 197716
Reason: I agree to specified portions of this document.
Date: 2015.10.22 12:53:34 -05'00'

Melanie Stockman — Date
Contracting Officer
NCO 23-St. Cloud MN

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

Daryl A. Berg 429170 Digitally signed by Daryl A. Berg 429170 DN: dc=gov, dc=va, o=internal, ou=people, 0.9.2342.19200300.100.1.1=daryl.berg@va.gov, cn=Daryl A. Berg 429170 Date: 2015.10.29 15:57:45 -05'00'

Daryl Berg
Director of Contracting
NCO 23

10/29/2015
Date

d. **VHA HCA REVIEW AND APPROVAL (over $650,000 to $12.5 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

Ricky L. Lemmon
Director, SAO Central Region
SAO Central Head of Contracting Activity (HCA)

11/3/15
Date