

LIMITED SOURCES JUSTIFICATION

ORDER >SAT

FAR PART 8.405-6

Acquisition Plan Action ID: 36C249-19-AP-1863

(1) CONTRACTING ACTIVITY: Department of Veterans Affairs, VISN 09, Tennessee Valley Healthcare System (TVHS) Nashville and Alvin C. York VA Medical Centers, Robley Rex VA Medical Center, Lexington VA Medical Center, and Memphis VA Medical Center, 596-20-1-030-0020, 603-20-1-068-0006, 614-20-1-025-0025, 626-20-1-066-0013

(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 source justification to establish a new firm-fixed-price (FFP) base plus three (3) one (1) year options against FSS contract V797D-30085 with BioFire Diagnostics, LLC for reagent panels and additional test equipment. The panels and equipment will be used in conjunction with the BioFire FilmArray Torch and FilmArray 2.0 that supports testing at the VISN 09 hospitals microbiology labs.

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

(3) DESCRIPTION OF SUPPLIES OR SERVICES:

The estimated value of the proposed action is \$2,571,524.88; break down of total value listed below:

VAMC	BASE YEAR	OPTION YEAR 1	OPTION YEAR 2	OPTION YEAR 3	STATION SUBTOTALS
TVHS	\$193,630.00	\$193,041.60	\$193,041.60	\$193,041.60	\$772,754.80
ROBLEY REX	\$55,854.00	\$55,854.00	\$55,854.00	\$55,854.00	\$223,416.00
MEMPHIS	\$347,398.52	\$347,398.52	\$347,398.52	\$347,398.52	\$1,389,594.08
LEXINGTON	\$46,440.00	\$46,440.00	\$46,440.00	\$46,440.00	\$185,760.00
TOTAL ESTIMATED VALUE					\$2,571,524.88

The BioFire FilmArray Torch – HFTA-ASY-0003

The Torch system is a fully integrated, random access syndromic infectious disease testing system designed to meet the microbiology labs needs and provides quick, comprehensive, and accurate result. It is compatible with all existing BioFire testing panels.

Respiratory Panel Kit (RP) - RFIT-ASY-0124

The RP kits are used for the rapid identification by polymerase chain reaction (PCR) of bacterial, viral,

yeast and parasite pathogens, and antimicrobial resistance genes in laboratory samples from critically ill patients. The RP identifies the most common viral and bacterial pathogens that cause respiratory tract infections that present with nearly indistinguishable symptoms. The rapid and accurate identification of the causative agent helps determine upper respiratory tract infection treatment options for a healthcare provider to choose.

Blood Culture Identification (BCID) Panels Kit - RFIT-ASY-0126

The BCID panel kits are used for the rapid detection of 27 BCID targets in one sample in approximately one (1) hour. The BCID Panel detects and identifies the most common causes of bloodstream infections. Quickly identifying the cause of sepsis helps clinicians more rapidly and appropriately manage septic patient therapy. Rapid identification of bloodstream pathogens may help reduce the time to appropriate antimicrobial therapy and positively impact patient survival.

Meningitis / Encephalitis (ME) Panel Kit - RFIT-ASY-0118

The BioFire ME Panel tests for a comprehensive set of 14 of the most common bacterial, viral, and fungal pathogens associated with central nervous system (CNS) infections in about one hour using only 0.2 mL of cerebrospinal fluid (CSF). The ME testing is currently sent out to other labs and performing in-house will significantly decrease turn-around time so that patients can begin treatment.

(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) that can be used with FilmArray 2.0 and Torch systems currently in place at the hospitals. 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.

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 are no other platforms/testing panels with all the above capabilities that can work with the FilmArray 2.0, Torch systems, and BioFire software currently in place at the hospitals.

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 8.404(d) prices have already been determined fair & reasonable. In accordance with 8.405-4 ‘Price Reductions’ additional discounts were sought by Network Contracting Office 9 (NCO 9); BioFire Diagnostics, LLC provided an additional 20% discount on all reagents along with 20% on the Torch systems being added to the Memphis VA Medical Center. BioFire is allowing the VA to buy the equipment currently being leased at Memphis for a prorated rate adding up to a 48.76% discount. The following awards have been placed against BioFire Diagnostics, LLC FSS contract and were determined fair & reasonable:

Award #	PO #	Awarded Amount	Effective Date
36C24919P0009	603A90003	\$75,762.00	10/01/2018
36C24919N0024	626A90006	\$115,458.30	10/01/2018

The new individual panel kit pricing is less due to the quantity being ordered and discounts received. The following table shows the past price the VISN 09 VA Medical Centers received compared to the prices quoted for this new requirement:

Award #	BCID Kit Price	RP Kit	ME Kit	GI Kit	Pneumonia
36C24919N0024 (TVHS)	\$3,848.61 EA	\$3,848.61 EA	N/A	N/A	N/A
36C24918Q9681 (Louisville)	N/A	\$4,009.50 EA	N/A	N/A	N/A
Purchase Card (Lexington)	\$3,870.00 EA	N/A	N/A	N/A	N/A
36C24918N3689 (Memphis)	\$4,142.52 EA	N/A	N/A	\$4,860.12 EA	N/A
Average Past Prices / FSS	\$3,953.71 EA	\$3,929.06 EA	\$4,650.00 EA	\$4,860.12	\$5,850.00 EA
New Requirement	\$3,720.00 EA	\$3,618.45 EA	\$4,632.00 EA	\$3,720.00 EA	\$5,850.00 EA

Given the current prices compared to average past prices the Government is estimated to save \$11,568.65 a year on the BCID Panel Kits, \$11,802.99 a year on the RP Kits, and \$34,203.60 a year on GI Panel Kits. When comparing the new pricing to NAC FSS contract pricing the Government will save an estimate of \$2,316.00 on the ME Kits. The total estimated savings on panels over four (4) years is \$232,616.96 and \$46,942.00 on equipment for a total amount of \$279,558.96.

The ME, BCID, RP, GI, and Pneumonia Panels, ME Verification Kit, and testing equipment are proprietary to BioFire Diagnostics, and they have no authorized distributors. No other testing panels can be used with BioFire equipment currently in place at the VISN 9 Medical Centers. Without additional panels to replenish a depleting stock, the laboratory will not be able to test patients for sicknesses and will affect patient-care.

(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 GSA advantage using catalog number FLM1-ASY-0124, and it revealed one (1) business with the capabilities of providing this supply.

A search using the same criteria on the National Acquisition Center (NAC) Medsurge Catalog revealed no other businesses capable of providing this supply.

Results

BioFire is the sole provider of its products on GSA and NAC.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

The following market research was conducted outside of the schedule holders in an effort to obtain additional competition:

Vendor Information Pages (VIP)

A search conducted on VIP using NAICS code 325413 and keyword BioFire it returned zero (0) Service-disabled Veteran-owned Small Businesses/Veteran-owned Small Businesses (SDVOSB/VOSB, respectively). A separate search using keyword BioFire returned zero (0) SDVOSB/VOSBs.

Manufacturer

The contract specialist reached out to the manufacturer via email requesting a list of authorized distributors to the VA. They responded with a propriety letter stating they are the sole distributor for BioFire equipment and testing panels.

Sources Sought Notice (FBO)

An “unrestricted” source sought notice was posted May 29, 2019 to June 2, 2019 under 36C24919Q0301 with zero (0) responses from any businesses with the capabilities of providing this supply.

Federal Procurement Data System (FPDS)

Two searches conducted on FPDS using keyword BioFire and BCID Panel revealed two (2) businesses with awards since 2017.

Vendor	DUNS	Business Type
Biofire Diagnostic, LLC	0792802626	Large

Government Scientific Source, Inc.	785807611	Small
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After verifying on the Government Scientific Source website, BioFire is not listed as one of their suppliers (<https://www.govsci.com/products-suppliers/>).

Recent Market Research Conducted

Market research conducted for two identical buys for the BioFire testing panels revealed that all equipment and testing panels used on BioFire equipment are proprietary and solely manufactured/distributed through BioFire Diagnostics, LLC.

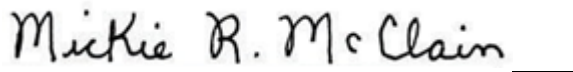
Reagent/Equipment Compatibility

The reagents are only compatible with the BioFire equipment and software currently being used at the VISN 09 hospitals. It would be cost prohibitive to procure other equipment that would not be recouped through competition; the current equipment has not neared its end of life date.

(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 without adding cost to the Government. This will be dependent on other contractors to develop a competitive comprehensive system that meets the VISN 09 testing needs upon the end of the useable life of the current testing equipment and test. The agency will seek additional competition, if possible, on future procurements and verify if BioFire has added any authorized distributors/resellers.

(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.



MICKIE R. MCCLAIN

VISN 9 Program Manager, P&LMS

(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.

MONICA E
THOMPSON 110287

Digitally signed by MONICA E
THOMPSON 110287
Date: 2019.08.20 12:07:15
-05'00'

MONICA E. THOMPSON
NCO 9 Contracting Officer

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.

Robert M Kellner 184085

Digitally signed by Robert M Kellner
184085
Date: 2019.08.20 12:33:49 -05'00'

ROBERT (BOBBY) M. KELLNER
NCO 9, Division Chief II (Supplies, Services, & Prosthetics)
VISN 9

c. Director of Contracting Recommendation:

LINDA S. GREAVES
NCO 9, Director of Contracting
VISN 9

d. VHA SAO HCA REVIEW AND APPROVAL (over \$700,000 to \$68 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.

TERRY L. SPITZMILLER
Executive Director
Regional Procurement Office Central (VHA)