

AI- 89904
CC REGULAR AGENDA SPECIAL MTG

Purchasing Department 27.P.1.
Urban County

Meeting Date: 03/07/2023
Submitted For: Benjamin Cortez
Department: PURCHASING DEPT.
Submitted By: Benjamin Cortez, PURCHASING DEPT.

CAPTION

A. Requesting exemption from competitive procurement requirements pursuant to Texas Local Government Code 262.024 (a)(7)(A) for an item that can be obtained from only one source because of the existence of a patent;

B. Acceptance and approval of the Sole Source Declaration [based on the caption above & herein] for bioMérieux, Inc. DBA BioFireDiagnostics, LLC, for the purchase of BioFire@FilmArray@Torch system (PCR testing machine), including any present and future accessories, supplies, support, service, and maintenance, to be used by Hidalgo County Health and Human Services Department in their Health Facilities Bio Safety Lab with said declaration to remain in effect while in place or until revoked by HCCC.

BACKGROUND

Purchasing Project No. 23-0031

Fiscal Impact

CALENDAR YEAR: _____ **ACCT. #:** _____
FUNDS AVAILABLE Y/N?: _____ **MATCHING FUNDS Y/N?:** _____

BUDGETARY IMPACT:

Project is funded by the HC Urban County Program using CDBG-CV Funding

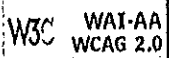
Attachments

- Sole Source Affidavit
- Patent Information from Vendor
- Sole Source Documentation from Vendor
- Technical Specification Sheet
- Sole Source Justification Memorandum

Form Review

Inbox	Reviewed By	Date
Purchasing / Internal	Dina Trevino	03/03/2023 01:51 PM
Budget & Management	Veronica Ortiz	03/03/2023 04:30 PM
Final Approval	Monica Salinas	03/03/2023 08:12 PM
<u>Form Started By:</u> Benjamin Cortez		<u>Started On:</u> 03/01/2023 03:24 PM
<u>Final Approval Date:</u> 03/03/2023		

GO TO PREVIOUS PAGE | **GO TO THE TOP OF THE PAGE**






2812 S. Bus. Hwy 281
Edinburg, Texas 78539
Phone: (956) 318-2626
Fax: (956) 318-2629
www.co.hidalgo.tx.us/purchasing

MEMORANDUM SOLE SOURCE JUSTIFICATION

TO: Hidalgo County Commissioner's Court

FROM: Eduardo Belmarez, MBA, CPM 

DATE: March 07, 2023


RE: Sole Source Justification for bioMérieux, Inc., DBA BioFireDiagnostics, LLC

The Hidalgo County Health and Human Services, in conjunction with the Hidalgo Urban County Program, seeks to procure the purchase of a BioFire®FilmArray®Torch system (PCR testing machine) from bioMérieux, Inc. BioFireDiagnostics, LLC, a wholly owned subsidiary of bioMérieux, Inc., is the sole legal manufacturer of the BioFire®FilmArray®Torch system and bioMérieux, Inc. is the sole sales and service provider of this product.

The United States Patent and Trademark Office has issued U.S. Patent No. 8,394,608 covering the company's FilmArray® system with exclusive right to the patented technology. This patent covers methods for sample preparation and two-step multiplex polymerase chain reaction (PCR) in a sealed container. Further, the BioFire®FilmArray®Torch system utilizes the only multiplex assay cleared by the FDA for twenty-two (22) gastrointestinal pathogen targets. The utility of multiplex gastrointestinal panels will aid the Hidalgo County Health and Human Services Department in epidemiological outbreak investigations.

Texas Local Government Code Chapter 262.024 (a)(7)(A) states, "(a)A contract for the purchase of any of the following items is exempt from the requirement established by section 262.023 if the commissioners court by order grants the exemption: (7)Any item that can be obtained from only one source, including; (A) Items for which competition is precluded because of the existence of patents, copyrights, secret processes, or monopolies."

Based on the information provided herein, we humbly request that the Hidalgo County Commissioners Court declare bioMérieux, Inc., DBA BioFireDiagnostics, LLC, a Sole Source Vendor, for the purpose of procuring the purchase of a BioFire®FilmArray®Torch system. This sole source declaration will remain in effect through the life term of BioFire®FilmArray®Torch system and any supplemental service agreements, unless otherwise revoked by the Hidalgo County Commissioners Court.


Eduardo Belmarez, MBA, CPM
Hidalgo County Purchasing Director

BioFire® FilmArray® Torch Specification Sheet

**TECHNICAL
::: NOTE**

1. BioFire Torch Overview

The BioFire Torch is an automated in vitro diagnostic (IVD) device intended for use with FDA cleared or approved IVD BioFire® FilmArray® Panels. The BioFire Torch is intended for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The BioFire Torch interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR (nmPCR) in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The BioFire Torch software automatically determines the results and provides a test report.

The BioFire Torch is a modification of BioFire® FilmArray® 2.0 and is composed of two to twelve BioFire® FilmArray® Torch Modules connected to a BioFire® FilmArray® Torch System Base running BioFire® FilmArray® Torch software. The BioFire Torch System Base houses two BioFire Torch Modules. Up to five Duplex Module enclosures, each capable of housing two additional BioFire Torch Modules, may be added on top of the BioFire Torch System Base. Each BioFire Torch Module can be randomly and independently accessed to run a reagent pouch. The BioFire Torch software controls the function of each BioFire Torch Module and collects, analyzes, and stores data generated by each BioFire Torch Module.

2. BioFire® FilmArray® System Specifications

Sample Description	• One sample capacity per BioFire Torch Module (with up to 12 samples per BioFire Torch)
Run Time	• Sample run time about one hour
User Interface	• System Base with touch screen and barcode scanner
Data Output	• Automatic analysis with end-of-run interpretive reports
Fluorescence Acquisition	• Single color optics module: 475nm excitation, 545nm emission, and sensor imaging
Temperature Control	• Operating temperature 15°C to 30°C • Peltier devices: • Ambient to 100°C • Ramp rate from 0.1–0.5°C /sec on melt
Operations Specification	• 15°C to 30°C @ 20 to 80% relative humidity (non-condensing) • -16m to 3048m • Indoor use only

Shipping Specifications	<ul style="list-style-type: none"> -30°C to 38°C @ 5 to 85% relative humidity (non-condensing) -16m to 10,600m 				
Power Requirements	Qty. of Modules	Voltage	Frequency	AC Current at 120 V	AC Current at 240 V
	2	100-240 VAC	50-60 Hz	3.2 A	1.7 A
	4			5.0 A	2.8 A
	6			6.9 A	3.8 A
	8			8.8 A	4.8 A
	10			10.6 A	5.8 A
12	12.5 A			6.9 A	
Fuse	<ul style="list-style-type: none"> • 250V 3.15A Type T (Modules) • 250V 10A Type T (System Base) 				
Dimensions and Weight	<ul style="list-style-type: none"> • 18 x 29 x 11.5 in (45.8 x 73.7 x 29.2 cm) (W x D x H; System Base only) <ul style="list-style-type: none"> • 4.5 in (11.4 cm) (H; Modules only) • 34 in (86.4 cm) max height (12 Modules) • Weight: Approximately 268 lbs (121.6 kg) maximum: <ul style="list-style-type: none"> • System Base – 36 lbs (16.3 kg) • Modules – 15 lbs (6.8 kg) each • Duplex (Module enclosure) – 6.5 lbs (~3 kg) each 				
EMC Requirements	<ul style="list-style-type: none"> • The BioFire® FilmArray® Torch complies with the emission and immunity requirements in IEC 61326: Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements. 				
Safety Requirements	<ul style="list-style-type: none"> • The BioFire Torch complies with IEC 61010-2-101: Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment. 				
CPU	<ul style="list-style-type: none"> • Intel® 				
Storage and Memory	<ul style="list-style-type: none"> • 512 GB hard drive or greater • 16 GB RAM or greater 				
Interface and Peripherals	System Base <ul style="list-style-type: none"> • 12+1 Ethernet network interfaces • 4 USB connections or more Module <ul style="list-style-type: none"> • One Ethernet network interface 				
Display	<ul style="list-style-type: none"> • LCD • 10.6" diagonal (26.9 cm) • 1280 x 768 resolution • Capacitive touch screen interface 				
Operating System	<ul style="list-style-type: none"> • Microsoft® Windows® OS as released with the BioFire® FilmArray® System 				

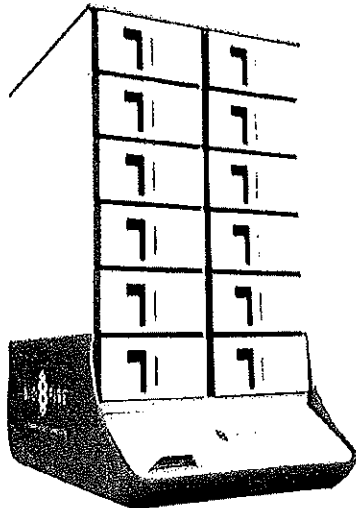
TECHNICAL ::: NOTE

3. BioFire® FilmArray® System Specifications

Select a clean, well-ventilated area that is large enough to fit the BioFire® FilmArray® Torch.

- There must be at least 1 Inch (2.6 cm) between the rear panels and any other surface (such as the wall) to allow for proper air flow.
- The depth of the bench-top space should be at least 30 in (77 cm).
- The width of the bench-top space should be at least 19 in (49 cm).
- The height of the space required depends on the number of Modules installed:
 - System Base – 11.5 in (30 cm)
 - System Base + 1 Duplex – 16 in (41 cm)
 - System Base + 2 Duplexes – 20.5 in (53 cm)
 - System Base + 3 Duplexes – 25 in (64 cm)
 - System Base + 4 Duplexes – 29.5 in (75 cm)
 - System Base + 5 Duplexes – 34 in (87 cm)

The BioFire Torch complies with the emission and immunity requirements in IEC 61326. It is advisable to evaluate the electromagnetic environment prior to operating the device. CAUTION: Do not use this device in close proximity to sources of strong electromagnetic radiation (unshielded intentional radio frequency sources, for example) because these may interfere with the operation of the BioFire Torch.



TECHNICAL ::: NOTE

Technical Support Contact Information

BioFire is dedicated to providing the best customer support available. If you have any questions or concerns about this process, please contact the FilmArray Technical Support team for assistance.

Customer and Technical Support for U.S. Customers	
Reach Us on the Web www.biofiredx.com	Reach Us by Phone 1-800-735-6544 –Toll Free (801) 736-6354, select Option 5 - Utah
Reach Us by E-mail support@biofiredx.com	Reach Us by Fax (801) 588-0507
Reach Us by Mail 515 Colorow Drive Salt Lake City, UT 84108 USA	
Customer and Technical Support Outside of the U.S.	
For International FilmArray technical assistance and support, please contact your local bioMérieux representative or authorized distributor.	

**TECHNICAL
::: NOTE**



To Whom It May Concern:

This letter is to confirm that bioMérieux, Inc. is the sole source manufacturer and service provider of the systems and software listed below with exception of BIOFIRE products. bioMérieux's wholly owned subsidiary, BioFire Diagnostics, LLC, is the sole legal manufacturer of the BIOFIRE products listed below and bioMérieux, Inc. is the sole sales and service provider of these products. All bioMérieux Field Service Engineers are certified and qualified with extensive factory training and experience in working on the entire range of bioMérieux products. If any unauthorized third-party repairs, alters or modifies a bioMérieux instrument or the operative software, bioMérieux is not responsible for defects arising from such repair or modifications.

- BIOFIRE® FILMARRAY® TORCH System and the BIOFIRE® FILMARRAY® 2.0 System and associated reagents:
 - BIOFIRE® Respiratory 2.1 Panel
 - BIOFIRE® FILMARRAY® Gastrointestinal Panel †
 - BIOFIRE® Blood Culture Identification 2 Panel †
 - BIOFIRE® FILMARRAY® Meningitis/Encephalitis Panel †
 - BIOFIRE® FILMARRAY® Pneumonia Panel †
 - BIOFIRE® Joint Infection Panel †

- BIOFIRE® FILMARRAY® 2.0 EZ
 - This system configuration runs the BIOFIRE® Respiratory 2.1-EZ Panel (EUA)†

- MYLA® middleware solution
 - Connects to bioMérieux microbiology equipment to consolidate the data into one location and is only intended to be used with VITEK® MS, VITEK® 2, BACT/ALERT® VIRTUO®, and BACT/ALERT® 3D.

- VITEK® MS PRIME and VITEK® MS
 - A mass spectrometry system using matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF MS) for the identification of microorganisms cultured from human specimens. The system is comprised of the VITEK MS analyzer, MYLA microbiology middleware, and reagent consumables.

- VITEK® 2 XL, VITEK® 2 60, VITEK® 2 60, VITEK® 2 COMPACT 60, VITEK® 2 COMPACT 30, and VITEK® 2 COMPACT 15
 - A reliable, rapid, and easy automated system for providing bacterial identification and/or antimicrobial susceptibility testing when used with the following associated reagents:

□ VITEK® 2 GN Card	□ VITEK® 2 ANC Card
□ VITEK® 2 GP Card	□ VITEK® 2 YST Card
□ VITEK® 2 NH Card	□ VITEK® 2 AST Cards

- ETEST[®]
 - A quantitative technique for determining the antimicrobial susceptibility of Gram-negative bacteria, Gram positive bacteria, fastidious bacteria, and yeasts. The system is comprised of a predefined antibiotic gradient that is used to determine the Minimum Inhibitory Concentration (MIC), in µg/mL, of different antimicrobial agents against microorganisms as tested on agar media using overnight incubation.

- API[®]
 - A method for microorganism identification to the species level. The test kits contain strips with microtubes of biochemical tests. During incubation, organism metabolism produces color changes in the microtubes. The reactions are interpreted according to the reading tables and an identification is obtained using APIWEB[™]. APIWEB is an Internet-based platform containing all API databases for a reliable interpretation of API strip results.

- NUCLISENS[®] EMAG[®]/easyMAG[®] Instruments
 - Automated nucleic acid extraction systems capable of processing various sample types and volumes within the same run using a single standardized workflow.

- EPISEQ[®]
 - EPISEQ is a cloud based, software as a service (SaaS) with a fully automated bio-informatics pipeline for the analysis of next generation sequencing (NGS) data. Current applications of EPISEQ include whole genome analysis for bacterial strain typing and variant calling for SARS-CoV-2 viral sequences. The software is comprised of an intuitive user interface and pre-paid credits for data uploads.

- BACT/ALERT[®] VIRTUO[®] and BACT/ALERT[®] 3D and BACT/ALERT[®] culture bottles
 - BACT/ALERT is a continuous monitoring blood culture system to be used with BACT/ALERT culture bottles. These bottles contain liquid culture media for recovery of microorganisms from blood and/or sterile body fluids. The BACT/ALERT MP Reagent System provides a microbial detection system and culture media for the recovery of mycobacterial species commonly isolated from patient specimens other than blood.

- CHROMID[®] Chromogenic Culture Media
 - CHROMID is an extensive range of chromogenic media for the simultaneous culture and identification of microorganisms in clinical specimens. Specific chromogenic substrates are included in the agar along with peptones and, if needed, antibiotics. The substrate is hydrolyzed when it comes in contact with the bacteria or yeast, resulting in specific coloration for clear identification. The intensity and specificity of the colors of CHROMID make results clear to see.

- PREVI[®] COLOR GRAM
 - PREVI COLOR GRAM is an automated Gram staining system that utilizes patented spray technology to provide rapid, standardized results for all types of specimens while adding efficiency to the microbiology process species commonly isolated from patient specimens other than blood.

- VIDAS[®]
 - The VIDAS family instruments, including VIDAS 3, MINI VIDAS, and VIDAS, are automated benchtop immunoassay systems that utilize proven enzyme-linked fluorescent assay (ELFA) technology, for high quality on-demand test results. There is a specialty menu available of single-test read-to-use reagents.

For all United States Department of Veterans Affairs and State Public Health Laboratory customers as well as all other customers which are not part of the United States Government including, without limitation, the Department of Defense and its agencies; the Departments of State, Commerce, Treasury, Transportation, Interior, Agriculture, Labor, Justice, Education, Health and Human Services, and Homeland Security; the National Aeronautics and Space Administration; the General Services Administration; the Small Business Administration; the National Science Foundation; the Environmental Protection Agency; the United States Agency for International Development; the Federal Reserve System; the Nuclear Regulatory Commission; the United States International Trade Commission; the United States Trade Representative; the Federal Communications Commission; and the Government Accountability Office U.S., the BIOFIRE® System is only available through bioMérieux, Inc. in the USA.

If you need additional information, please feel free to email us at us.servicecontracts@biomerieux.com.

Sincerely,



Dawn Rossin
Vice President of Clinical Marketing, North America

US FDA cleared | *CE₂₇₉₇ | †CE

*This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.

*This product has been authorized only for the detection and differentiation of nucleic acid of SARS-CoV-2 from multiple respiratory viral and bacterial organisms; and,

*The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

BioFire Diagnostics, Inc. Announces Issuance of U.S. Patent for the FilmArray® System

SALT LAKE CITY, Utah, (March 13, 2013) – BioFire Diagnostics, Inc., today announced that the United States Patent and Trademark Office has Issued U.S. Patent No. 8,394,608 covering the company's FilmArray system.

FilmArray's proprietary technology represents a significant advancement in user-friendliness and multiplex infectious disease testing capability for hospital clinical labs. This is the first U.S. patent issued to cover the FilmArray system, and BioFire has exclusive rights to the patented technology. Specifically, the patent covers methods for sample preparation and two-step multiplex polymerase chain reaction (PCR) in a sealed container.

As part of the FilmArray system, BioFire has developed the FilmArray Respiratory Panel (RP), which rapidly detects nucleic acids in nasopharyngeal swabs obtained from individuals suspected of respiratory tract infections. Requiring only two minutes of hands-on time, FilmArray RP has about a one-hour turnaround time, and simultaneously tests for 20 viral and bacterial targets.

Additionally, BioFire is continuing to develop a broader test menu for its FilmArray system, including a Blood Culture ID Panel, Gastrointestinal Panel and a Meningitis Panel, with more patents expected in the future.

"BioFire is excited to broaden its already extensive intellectual property portfolio," said Kirk Ririe, CEO of BioFire Diagnostics. "We are confident this newest patent will provide exclusivity for our FilmArray system and methods."

For more information, visit www.BioFireDx.com.

About BioFire Diagnostics, Inc.

BioFire Diagnostics, Inc., formerly Idaho Technology, Inc., is a privately held clinical diagnostics company based in Salt Lake City, Utah. The Company manufactures and distributes the FilmArray RP, which operates on the user-friendly FilmArray system, to hospital-based clinical laboratories across the U.S. and EU. With the FilmArray RP, BioFire provides the only FDA-cleared clinical diagnostic test for eight of the 20 organisms in its panel. In addition, BioFire continues to broaden its FilmArray test menu, and is currently developing a Blood Culture ID Panel, a Gastrointestinal Panel, and a Meningitis Panel.

BioFire holds over 70 patents related to polymerase chain reaction (PCR), and it has used its extensive patent portfolio to successfully market nearly 200 products to the clinical, research, and military markets. BioFire customers include the Department of Health and Human Services, the Department of Defense, state and local law enforcement, and researchers and medical technicians across a spectrum of fields and industries.

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Contact:

BioFire Diagnostics, Inc.
Jill Powlick
801-736-6354 x423
Jill.Powlick@biofiredx.com

Idaho Technology is now

