

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: April 21, 2016

Re: Sole Source Certification Number **SS5029** for **BioFire FilmArray 2.0 System and FilmArray Panel Kits**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5029** for **BioFire FilmArray 2.0 System and FilmArray Panel Kits**, please be advised that UMMC intends to award the purchase of the **BioFire FilmArray 2.0 System and FilmArray Panel Kits** to **BioFire Diagnostics Inc Div bioMerieux SA** as sole source provider of the **BioFire FilmArray 2.0 System and Panel Kits**.

UMMC issues this notice in accordance with Mississippi state law, policy, and procedures for sole source procurements.

Sole Source Criteria

1. Where the compatibility of equipment, accessories, or replacement parts is the paramount consideration (and manufacturer is the sole supplier).
2. Where a sole supplier's item is needed for trial use or testing.
3. Where a sole supplier's item is to be required when no other item will service the needs of UMMC.

Schedule

Task	Date
First Advertisement Date	April 21, 2016
Second Advertisement Date	April 28, 2016
Response Deadline from Objectors	May 5, 2016, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before September 16, 2016

Project Details

1. Describe the commodity that the agency is seeking to procure:

The University of Mississippi Medical Center (UMMC) seeks to purchase BioFire FilmArray 2.0 system to use with the company's Meningitis panel, Blood Culture Identification (BCID) Panel, Respiratory panel, and GI panel. The FilmArray 2.0 platform provides rapid, easy to set up multiplex polymerase chain reaction (PCR) assays for meningitis, blood cultures, respiratory pathogens and gastroenteritis. It is fully automated after initial setup, so that it can be run twenty-four hours per day. The BCID panel will provide a diagnosis in about an hour for 27 of the most likely causes of blood stream infections, including gram positive and gram negative bacteria as well as yeast, together with preliminary susceptibility information. The meningitis panel diagnoses meningitis caused by fourteen of the most likely bacterial, viral and fungal causes. The respiratory panel includes polymerase chain reaction (PCR) for twenty of the most likely bacterial and viral causes of upper respiratory infection. The GI panel diagnoses gastroenteritis from twenty-two of the most common bacterial, viral and parasitic causes.

2. Explain why the commodity is the only one (1) that can meet the needs of the agency:

The BioFire FilmArray 2.0 is currently the only system U.S. Food and Drug Administration (FDA) cleared to provide multiplex molecular meningitis testing and the only FDA cleared platform to provide multiplex rapid blood culture diagnostics that include bacteria as well as yeast in a single panel.

Meningitis

Currently, meningitis diagnostics at UMMC labs are limited to bacterial culture, which has very poor sensitivity. The send out meningitis PCRs have a turnaround time of 2-3 days, and longer on weekends; turnaround time is similar for bacterial culture. Furthermore, empiric meningitis therapy results in multiple intravenous antimicrobial agents, often with substantial toxicity. Being able to reach a positive diagnosis faster has the potential to vastly improve patient care by reducing antibiotic and antiviral use and preventing toxicity. It may also help to identify patients who will be less likely to require admission or continued stay in the hospital.

This empiric therapy often begins before image result for cerebrospinal fluid (CSF) can be obtained for culture, which makes diagnosis by culture less sensitive, and is a shortcoming overcome by multiplex molecular assays.

Other available viral meningitis diagnostics, bacterial antigen testing, either lack both sensitivity and specificity or require selection of individual agents; most also have substantially greater turnaround time requiring batching and complex setup. Because of the severity of the illness and the scarcity of diagnostic CSF fluid, testing for the many possible causes of meningitis in this manner is impractical and often impossible, forcing the lab and clinicians to prioritize their differential diagnosis when in fact the clinical

syndrome caused by these fourteen pathogens is similar. The BioFire FilmArray 2.0 System and FilmArray meningitis panel kit is the only FDA cleared molecular multiplex diagnostic panel for meningitis.

Blood cultures

Currently, blood culture identification and susceptibility require about two days; BioFire FilmArray 2.0 System and FilmArray Panel Kits test turnaround time will be two hours or less. In the setting of potential blood stream infection, this rapid information is critical in allowing tailored antibiotic therapy. Such interventions also greatly improve the rapidity with which we can identify probable contaminants, potentially allowing cessation of unnecessary antibiotic treatment, decreased lengths of stay, and preventing the resulting toxicity from additional drug exposure. There is no other testing solution that provides this information as rapidly or does so for gram positive and gram negative bacteria as well as for yeast in a format suitable to 24 hour testing.

3. Explain why the source is the only person or entity that can provide the required commodity:

The BioFire FilmArray 2.0 system only runs FilmArray Panel Kits; the two are designed exclusively for each other. BioFire Diagnostics, LLC is the manufacturer and exclusive distributor in the acute care 150 bed and larger hospital market for the FilmArray 2.0 System and Panel Kits.

4. Explain why the amount to be expended for the commodity is reasonable:

The estimated amount to be expended is for the purchase of the **BioFire FilmArray 2.0 System and FilmArray Panel Kits:**

FilmArray 2.0 – Quantity 4	\$120,000.00
FilmArray Panel Kits 12 month spend	\$800,000.00

This amount is within the expected price range for these products.

5. Describe the efforts that the agency went through to obtain the best possible price for the commodity:

Through market intelligence, UMMC was able to negotiate best pricing for these products. All applicable discounts were explored and applied.

Submission Instructions and Format of Response from Objecting Parties

Interested parties who have reason to believe that the **BioFire FilmArray 2.0 System and FilmArray Panel Kits** (hereafter, “Products”) should not be certified as a sole source should provide information in the Vendor Form for the State to use in determining whether or not to proceed with awarding the sole source to **BioFire Diagnostics Inc Div bioMerieux SA**. The Vendor Form may be found at <http://www.dfa.state.ms.us/Purchasing/documents/ObjectiontoSoleSourceDetermination.pdf>.

Objections must include the certification in Attachment B.

Comments will be accepted at any time prior to May 5, 2016, at 3:00 p.m. (Central Time) to solesource@umc.edu. Responses may be delivered via email to solesource@umc.edu. UMMC WILL NOT BE RESPONSIBLE FOR DELAYS IN THE DELIVERY OF RESPONSES. It is solely the responsibility of the Interested Parties that responses reach UMMC on time. Responses received after the deadline and responses that lack all required information will be rejected. UMMC reserves the right to inspect Interested Party’s commodity for comparison purposes.

If you have any questions concerning the information above or if we can be of further assistance, please contact solesource@umc.edu.

Attachment A-D: Vendor Correspondences

Attachment E: Objection Certification

Attachment A

March 31, 2016

Re: FilmArray® Meningitis/Encephalitis (ME) Panel Kit Sole Source Justification

To Whom It May Concern:

The Meningitis/Encephalitis (ME) Panel kit that runs on the FilmArray System is the only FDA-cleared sample-to-answer test capable of simultaneously testing for fourteen of the most common causes of community-acquired Central Nervous System (CNS) infections from a single patient sample consisting of cerebrospinal fluid (CSF). These targets include bacteria, viruses and fungi. The FilmArray is the latest in user-friendly automated multiplex PCR that integrates sample preparation, amplification, detection, and analysis into one easy-to-use system with a test turn-around time of about one hour. The FilmArray System:

1. Can perform DNA/RNA extraction, purification and highly multiplexed PCR.
2. Can generate, detect and analyze PCR melting curves. The analysis includes a meta-analysis of all applicable controls and gene targets required for determination of a single result for each organism included in the multiplex reaction.
3. Is compatible with 200µl CSF samples.
4. Sensitivity and specificity of the System is comparable to that of common commercially available real-time PCR instruments.
5. Requires less than five minutes for set up and completes a run in about one hour.
6. Ships with Windows® and analysis software.
7. Is capable of reading bar codes.
8. Is fully automated following initial run set-up.
9. Contains all necessary reagents for sample prep, PCR, and detection and reagents can be stored at room temperature.

BioFire Diagnostics, LLC is the manufacturer and exclusive distributor in the acute care 150 bed and larger hospital market for the FilmArray System and the FilmArray Meningitis/Encephalitis (ME) Panel, Respiratory Panel (RP), Blood Culture Identification (BCID) Panel, and Gastrointestinal (GI) Panel.

Please feel free to contact me if you require any further information ((801) 736-6354 x463).

Sincerely,



Wade Stevenson
Senior Vice President of Sales and Marketing



390 Wakara Way • Salt Lake City, Utah 84106, USA • 001 736 6354 (usa) • 1 800 736 6354 (toll free) • 001 508 5037 (int'l)
BioFireDX.com

Attachment B

July 28, 2014

Re: FilmArray® BCID Kit Sole Source Justification

To Whom It May Concern:

The FilmArray System is the latest in user-friendly automated multiplex PCR. The FilmArray integrates sample preparation, amplification, detection, and analysis into one easy-to-use system. Capable of detecting 27 Blood Culture Identification (BCID) targets in one sample in approximately one hour, the FilmArray System:

1. Can perform DNA/RNA extraction, purification and highly multiplexed PCR.
2. Can generate, detect and analyze PCR melting curves. The analysis includes a meta-analysis of all applicable controls and gene targets required for determination of a single result for each organism included in the multiplex reaction.
3. Can support fluorescence acquisition LED excitation.
4. Is capable of simultaneous detection and identification of multiple bacterial and yeast nucleic acids and select genetic determinants of antimicrobial resistance.
5. Sensitivity and specificity of the system is comparable to that of common commercially available real-time PCR instruments.
6. Is 10 x 15.5 x 6.5 inches and weighs 20 pounds.
7. Requires less than five minutes for set up and completes a run in about one hour.
8. Ships with a Windows®-based computer and analysis software.
9. Is capable of reading bar codes.
10. Is fully automated following initial run set-up.
11. Contains all necessary reagents for sample prep, PCR, and detection.
12. Is only available through BioFire Diagnostics, LLC, in the USA.

BioFire Diagnostics, LLC is the manufacturer and exclusive distributor in the acute care 150 bed and larger hospital market for the FilmArray System and the FilmArray Meningitis/Encephalitis (ME) Panel, Respiratory Panel (RP), Blood Culture Identification (BCID) Panel, and Gastrointestinal (GI) Panel.

Please feel free to contact me if you require any further information ((801) 736-6354 x463).

Sincerely,



Wade Stevenson
Vice President of Sales and Marketing



A BIOMÉRIEX COMPANY

390 Wakarusa Way • Salt Lake City, Utah 84108, USA • 801 736-6354 local • 1 800 735-6644 toll free • 801 590-0007 fax
BioFireDX.com

Attachment C

May 12, 2014

Re: FilmArray® Gastrointestinal (GI) Panel Kit Sole Source Justification

To Whom It May Concern:

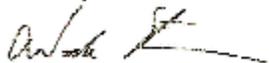
The FilmArray System is the latest in user-friendly automated multiplex PCR. The FilmArray integrates sample preparation, amplification, detection, and analysis into one easy-to-use system. Capable of detecting 23 Gastrointestinal targets inclusive of bacteria, viruses and parasites in one sample in approximately one hour, the FilmArray System:

1. Can perform DNA/RNA extraction, purification and highly multiplexed PCR.
2. Can generate, detect and analyze PCR melting curves. The analysis includes a meta-analysis of all applicable controls and gene targets required for determination of a single result for each organism included in the multiplex reaction.
3. Can support fluorescence acquisition LED excitation.
4. Is compatible with up to 200ul samples.
5. Sensitivity and specificity of the system is comparable to that of common commercially available real-time PCR instruments.
6. Is 10 x 15.5 x 6.5 inches and weighs 20 pounds.
7. Requires less than five minutes for set up and completes a run in about one hour.
8. Ships with a Windows® based computer and analysis software.
9. Is capable of reading bar codes.
10. Is fully automated following initial run set-up.
11. Contains all necessary reagents for sample prep, PCR, and detection
12. Is only available through BioFire Diagnostics, LLC in the USA.

BioFire Diagnostics, LLC is the manufacturer and exclusive distributor in the acute care 150 bed and larger hospital market for the FilmArray System and the FilmArray Meningitis/Encephalitis (ME) Panel, Respiratory Panel (RP), Blood Culture Identification (BCID) Panel, and Gastrointestinal (GI) Panel.

Please feel free to contact me if you require any further information ((801) 736-6354 x463).

Sincerely,



Wade Stevenson
Vice President of Sales and Marketing



A SIGMA AIDU COMPANY

390 Walnut Way • Salt Lake City, Utah 84108 USA • 801 736 6354 ext 463 • 1 800 733 6344 toll free • 801 396 0867 fax
BioFireDX.com

Attachment D

July 28, 2014

Re: FilmArray® Respiratory Pathogen Panel Kit Sole Source Justification

To Whom It May Concern:

The FilmArray System is the latest in user-friendly automated multiplex PCR. The FilmArray integrates sample preparation, amplification, detection, and analysis into one easy-to-use system. Capable of detecting 20 Respiratory Pathogen Panel (RP) targets in one sample in approximately one hour, the FilmArray System:

1. Can perform DNA/RNA extraction, purification and highly multiplexed PCR.
 2. Can generate, detect and analyze PCR melting curves. The analysis includes a meta-analysis of all applicable controls and gene targets required for determination of a single result for each organism included in the multiplex reaction.
 3. Can support fluorescence acquisition LED excitation.
 4. Can process Nasopharyngeal Swab.
 5. Is compatible with up to 250ul samples.
 6. Sensitivity and specificity of the system is comparable to that of common commercially available real-time PCR instruments.
 7. Is 10 x 15.5 x 6.5 inches and weighs 20 pounds.
 8. Requires less than five minutes for set up and completes a run in about one hour.
 9. Ships with a Windows®-based computer and analysis software.
 10. Is capable of reading bar codes.
 11. Is fully automated following initial run set-up.
 12. Contains all necessary reagents for sample prep, PCR, and detection
 13. Is only available through BioFire Diagnostics, LLC in the USA.
- BioFire Diagnostics, LLC is the manufacturer and exclusive distributor in the acute care 150 bed and larger hospital market for the FilmArray System and the FilmArray Meningitis/Encephalitis (ME) Panel, Respiratory Panel (RP), Blood Culture Identification (BCID) Panel, and Gastrointestinal (GI) Panel

Please feel free to contact me if you require any further information ((801) 736-6354 x163).

Sincerely,



Wade Stevenson
Vice President of Sales and Marketing



A BIOMERIEUX COMPANY

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BioFireDX.com

Attachment E

**SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS5009
Accepted until May 5, 2016, at 3:00 p.m.**

I certify that the information contained in this objection is true and accurate to the best of my knowledge. I understand that UMMC will investigate all statements made in this objection and that any false or misleading information provided may result in adverse action.

Objector Name
Objector's title

Date