MISSISSIPPI STATE DEPARTMENT OF HEALTH

Notice of Proposed Sole Source Purchase # 0301-08

RFX # 3150000472

The Mississippi State Department of Health anticipates purchasing the item(s) listed below as a sole source purchase. Anyone objecting to this purchase shall follow the procedures outlined below.

Commodity or commodities to be purchased (make, model, description):

The Biofire FilmArray®system 2.0 is a CE-marked and US Food and Drug Administration (FDA)-cleared multiplex PCR molecular biology system that is easy to use, accurate and rapid. It makes it possible to identify, in a single reagent or panel, the most common disease-causing organisms responsible for a syndrome, whether they are viruses, bacteria, fungi or parasite. The filmarray system integrates sample preparation, amplification, detection, and analysis into one system. The system requires less than five minutes for set-up and produces a test result within one hour. The initial purchase will include the Filmarray system, the computer and printer required to utilize the system. The sole source purchase will also include various clinical test kits that are FDA cleared for use with the system over a one-year period.

Product	Product Code	Estimated Annual Quantity
• FilmArray 2.0	FLM2-ASY-0001	1 (one-time purchase)
• Computer Kit	FLM2-ASY-0003	1(one-time purchase)
• Printer Kit	FLM2-ASY-0008	1(one-time purchase)
• GI Panel kit	RFIT-ASY-0116	5 kits/year
• Respiratory Panel kit	RFIT-ASY-0105	5 kits/year
• Meningitis/Encephalitis Panel Kit	RFIT-ASY-0118	5 kits/year
• Verification Package-FA 2.0 GI	FLM1-ASY-0130	1 kit
• Verification Package-FA 2.0 ME	FLM1-ASY-0145	1 kit
• Verification Package-FA 2.0 RP	FLM1-ASY-0122	1 kit

Explanation of the need to be fulfilled by this item(s) and why it is the only one that can meet the specific needs of the department:

The Biofire respiratory panel kit will fulfill the grant related testing activities to decrease turn-around-time for detection, response and epidemiological investigation of large complex respiratory disease outbreaks. Grant related activities for timely testing, identification and reporting of Vaccine Preventable Diseases (VPD) from spinal fluid can only be accomplished by a FDA approved system. The Biofire FilmArray System is the only system that is FDA cleared to simultaneously test for fourteen of the most common causes of community-acquired Central Nervous System infections from cerebrospinal fluid and is FDA cleared to test for twenty upper respiratory pathogens in a multi-agent respiratory panel from a single nasopharyngeal swab.

Name of company/individual selling the item and why that source is the only possible source that can provide the required item(s):

The Biofire Filmarray system and all reagents approved for this system are available only through BioFire Diagnostics, LLC.

Estimated cost of item(s) and an explanation why the amount to be expended is considered reasonable:

- Estimated Cost for the system and components- one-time purchase: $38,125.00
- Estimated Annual Cost for test kits: $85,200
- Total Estimated Cost for system, components and test kits: $123,325.00
- The MPHL receives a 5% discount off list price on selected items.

Explanation of the efforts taken by the department to determine this is the only source and the efforts used to obtain the best possible price:

- BioFire Diagnostics is the sole manufacturer and sole vendor of these products and sells directly to laboratories.
- No other test reagents are FDA cleared to detect the causative agents of Meningitis/Encephalitis tests from spinal fluid.
- All applicable discounts were explored and applied.

Any person or entity that objects and proposes that the commodity listed is not sole source and can be provided by another person or entity shall submit a written notice to: Jennifer Dotson, Mississippi State Department of Health Purchasing Department, 570 E. Woodrow Wilson, Room 134 Underwood Building, Jackson, MS 39216 or P. O. Box 1700, Jackson, MS 39215-1700.

Responses may be hand delivered, via regular mail, overnight delivery or by e-mail: jennifer.dotson@msdh.ms.gov The envelope or e-mail should reference the sole source number.

The notice shall contain a detailed explanation of why the commodity is not a sole source procurement. Appropriate documentation shall also be submitted if applicable. The enclosed form (OSS) may be used if you so desire.

If after a review of the submitted notice and documents, Mississippi State Department of Health determines that the commodity in the proposed sole source request can be provided by another person or entity, then Mississippi State Department of Health will withdraw the sole source request publication from the procurement portal website and submit the procurement of the commodity to an advertised competitive bid or selection process.

If Mississippi State Department of Health determines after review that there is only one (1) source for the required commodity, the Mississippi State Department of Health will appeal to the Public Procurement Review Board. Mississippi State Department of Health will have the burden of proving that the commodity is only provided by one (1) source.

Notices/objections, etc. will be accepted at any time prior to: __Friday, May 13_, 2016 at 3:00 p.m. (CST) (DST)

OFFICE OF PURCHASING, TRAVEL AND FLEET MANAGEMENT
OBJECTION TO SOLE SOURCE DETERMINATION (0SS)

VENDOR FORM

INFORMATION ABOUT THE VENDOR/INDIVIDUAL SUBMITTING OSS FORM

Vendor/Representative Name: _____

Responsible Contact: _____

Phone/Email/Fax Contact: _____

Date Form Submitted: _____ RFIN#: (RFx#) _____

INFORMATION ABOUT THE PURCHASING AGENCY

Agency: _____

Proposed Commodity Provider Name: _____

Type of Commodity: _____

Provide a detailed explanation of why the commodity is not a sole source commodity; including why you believe that you, your company, or another entity can provide the commodity required by the Agency.

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