

**MISSISSIPPI STATE DEPARTMENT OF HEALTH**  
**Notice of Proposed Sole Source Purchase #0301-18**  
**RFx # 3150000821**

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 Mississippi Public Health Laboratory (MPHL) currently possesses a Cepheid GeneXpert System and performs the *M. tuberculosis*/Rifampin Nucleic Acid Amplification Test (MTB/RIF NAAT) on this platform. The MPHL would like to purchase test kits that are FDA approved to perform MTB-RIF NAAT testing on human patients using the Cepheid GeneXpert System.

Product List Number	Product Description	Product Price (Kit)	# Kits (Annual)	Extended Price
GXMTB/RIF-US-10	GeneXpert MTB/RIF Kit	595	96	57,120

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 MTB/RIF NAAT is used to test respiratory specimens for tuberculosis and rifampin drug resistance directly from a clinical specimen. The test is used by clinicians to help determine treatment options for patients exposed to tuberculosis. The kit for the GeneXpert MTB/RIF NAAT is the only kit for use on the Cepheid GeneXpert System. In accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88) FDA approved assays must be performed as indicated on the manufacturer's test package insert without deviations.

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

The test kits for the MTB/RIF NAAT are manufactured only by Cepheid. Cepheid does not use distributors in the clinical market and sales directly to laboratories.

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

- Estimated Cost: \$57,120 per year (based on the current volume of the MTB/RIF NAAT tests performed by the MPHL) plus S/H approx. \$6348.00 The estimated number of tests is 960/year for patient specimens and controls.
- The MPHL receives public health pricing at a 15% discount off list price.

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:

- Cepheid is the sole manufacturer and sole vendor of these products and sells directly to laboratories.
- No other test kits are FDA approved to perform MTB/RIF NAAT tests on human patients using the GeneXpert instrument.
- 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: \_December 22\_, 2016 at 3:00 p.m. (CST)

