

**MISSISSIPPI STATE DEPARTMENT OF HEALTH**  
**Notice of Proposed Sole Source Purchase #0301-19**  
**RFx # 3150000822**

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 uses the Inbios Detect IgM ELISA test to perform arboviral testing for West Nile and Dengue Fever. These kits are FDA cleared for use on human patients. The Inbios Zika Virus Detect IgM ELISA is FDA approved as an Emergency Use Authorization (EUA) for testing and is included in the CDC issued test algorithm. The MPHL would like to purchase sufficient test kits to meet the current demand for testing and respond to future demands for active mosquito transmission of the Zika virus. Inbios is the sole manufacturer and distributor of these test kits.

Product List Number	Product Description	Product Price (Kit)	# Kits (Annual)	Extended Price
ZIKV-E	ZIKV Detect IgM Capture ELISA	547.00	50	27,350.00
WNMS-1	West Nile Detect IgM Capture ELISA	318.15	60	19,089.00
DDMS-1	DENV Detect IgM Capture ELISA	475.00	20	9,500.00
	Insulated Shipping Carton (1 per shipment)	39.00	12	468.00

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 MPHL has used the Inbios West Nile Detect IgM Capture ELISA for several years and has recently validated the IgM ELISA test for Zika and Dengue virus as required by the Clinical Laboratory Improvement Amendments (CLIA). The enzyme-linked immunosorbent assay (ELISA) is a test that uses antibodies and color change to identify a substance. The ELISA test is an analytic biochemistry assay that uses a solid-phase enzyme immunoassay (EIA) to detect the presence of a substance, usually an antigen, in a liquid sample or wet sample.

In recent months an international health crisis has emerged related to the spread of the Zika, Dengue Fever and Chikungunya virus by mosquitoes. The recent public health crisis related to the spread of Zika and other arboviruses has increased the need for public health laboratories to validate serological tests to perform testing for Zika, Dengue and Chikungunya in addition to West Nile in accordance to the CDC issued test algorithm for suspected arboviral disease. In order to maintain adequate test kits to perform tests on human patients suspected of having West Nile, Zika and Dengue viruses, the MPHL requests an authority to purchase sufficient kits to avoid testing delays. The MPHL must be able to respond to testing large quantities of specimens if active transmission of the Zika virus from mosquitoes to people occurs in Mississippi. Mississippi already has active transmission of the West Nile Virus from mosquitoes to people. An adequate number of validated test kits must be on-hand to support current testing and future surge testing for arboviruses.

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 Zika, West Nile and Dengue Detect IgM Capture ELISA are manufactured only by Inbios. Inbios 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: \$56,407.00 per year (based on the current volume of the arboviral testing performed by the MPHL and surge testing if mosquito transmission of the Zika virus occurs).
- The MPHL receives public health pricing with a 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:

- Inbios is the sole manufacturer and sole vendor of these products and sells directly to laboratories.
- Inbios has agreed to hold pricing firm for these items through December 31, 2017.
- 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](mailto: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)

