

**MISSISSIPPI STATE DEPARTMENT OF HEALTH
 Notice of Proposed Sole Source Purchase #0301-35
 RFX # 3150001225**

The Mississippi State Department of Health (MSDH) 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 State Department of Health (MSDH) is anticipating purchasing the Alere Determine HIV-1/2 Ag/Ab Combo rapid test kit and Controls. This rapid HIV testing kit will replace Alere Clearview Complete which will become obsolete on February 28, 2018.

Alere Determine HIV-1/2 Ag/Ab Combo is an FDA approved *in vitro*, visually read, qualitative immunoassay for the simultaneous detection of Human Immunodeficiency Virus Type 1 (HIV-1), free p24 antigen (Ag) and antibodies (Ab) to HIV Type 1 and Type 2 (HIV-1 and HIV-2) in human serum, plasma, capillary (fingerstick) whole blood or venipuncture (venous) whole blood.

| Item Code | Product Description | Product Price | #Cases (Annually) | Extended Price |
|-----------|---|---------------|-------------------|----------------|
| 7D2648 | Alere HIV-1/2 Determine AG/AB Combo Rapid Test (25 Tests/Kit) | \$200.00 | 1,000 | \$200,000.00 |
| 7D2628 | Alere HIV-1/2 Determine AG/AB Combo Controls Kits(HIV-1/HIV-2/p24Ag/NR) | \$35.00 | 200 | \$7,000.00 |
| | | | | |

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 Alere HIV-1/2 Determine Ag/Ab Combo rapid test Kit and Controls will fulfill the Mississippi State Department of Health’s HIV Prevention Projects CDC grant award requirements. The items will be used to conduct Rapid HIV testing to diagnose new cases of HIV disease in high morbidity areas in Mississippi. The Alere HIV-1/2 Determine Ag/Ab Combo is the only FDA approved rapid HIV test kit to detect both HIV-1 and HIV-2 antibodies (IgM and IgG) and the HIV-2 p24 antigen (a protein of the virus). This enables earlier detection of HIV than any other HIV rapid test kit.

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

Alere Company is the sole manufacturer and supplier of Determine HIV-1/2 Ag/Ab Combo test Kit in the Public Health Market. Alere exclusively sells and distributes the Alere Determine HIV-1/2 Ag/Ab Combo test Kit and Controls in the Public Health Market.

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

The estimated annual cost to supply the Mississippi State Department of Health HIV Program is \$207,000.00 – including all shipping charges. The price per Kit is \$200.00 each, which reflects a 77% discount from the list price of \$598.75. The Controls are \$35.00 each, reflecting a 50% discount off the list price of \$69.95.

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:

MSDH STD/HIV Office have contacted manufacturers of FDA approved rapid HIV tests and examined their products and pricing. The specifications of the Alere Determine HIV-1/2 Ag/Ab Combo cannot be matched by any other product. No other FDA approved rapid test has the following specifications:

- Sensitivity of 99.9% for all sample types – capillary whole blood, venipuncture, serum and plasma;
- Specificity of 99.8% for capillary whole blood;
- Shelf life is 18 months from date of manufacture for the test kits;
- Controls material has 24 month shelf life stability after opening with refrigeration storage;
- All shipping and handling costs are included in the pricing.

Many other State Health Department HIV Prevention Programs have evaluated and made the decision to use the Alere HIV-1/2 Determine Ag/Ab Combo. These include, but not limited to, Louisiana, Alabama, Texas, Arkansas, Kansas, New Mexico, Arizona, Colorado, Nebraska, California, Utah, New York, New Jersey, Philadelphia, Maryland, Delaware, Ohio, Connecticut, Virginia.

MSDH STD/HIV Office believes the Alere HIV-1/2 Determine Ag/Ab Combo is the best selection for the Mississippi State Department of Health HIV Prevention Program, based on the information provided above.

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, December 8, 2017 at 3:00 p.m. (CST)



SALES QUOTATION

Alere North America, Inc.
30 S. Keller Road
Orlando, FL 32810
Customer Service: (877) 441-7440

TO:

Mississippi State Department of Health
570 East Woodrow Wilson Drive
Jackson, MS 39216
Attention: Ms. Ashley Ceaser
Ashley.Ceaser@msdh.ms.gov

Price Firm Until: 12/31/2020

Account Number: 10002516

Thank you for your inquiry. I am pleased to quote you the following:

| PRODUCT NO. | QTY. (KIT) | DESCRIPTION | UNIT PRICE | EXT. PRICE |
|-------------|------------|---|------------|--------------|
| 7D2648 | 1000 | Alere HIV-1/2 Determine Ag/Ab Combo Rapid Test Kit (25 Tests/kit) | \$200.00 | \$200,000.00 |
| 7D2628 | 200 | Alere HIV-1/2 Determine Ag/Ab Combo Controls Kit (HIV-1/HIV-2/p24Ag/NR) | \$35.00 | \$7,000.00 |
| | | | Total: | \$207,000.00 |

The above pricing includes all shipping charges.

Please let me know if I can provide any additional information.

Emma K. Randazzo, Virology Solutions Specialist – (501) 960-4790

November 15, 2017

DATE