

**MISSISSIPPI STATE DEPARTMENT OF HEALTH**  
**Notice of Proposed Sole Source Purchase #0301-38**  
**RFx # 3150001228**

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 performs the QuantiFERON-TB Gold (QFT) to aid in the detection of *M. tuberculosis* infection. QFT is an interferon  $\gamma$  (IFN $\gamma$ ) release assay (IGRA) which measures the cell-mediated response to specific TB antigens in whole blood. QFT is a modern alternative to the 110 year old tuberculin skin test (or Mantoux test) and is highly accurate and unaffected by Bacillus Calmette-Guérin (BCG) vaccination (2–4). Patients may be tested in a single patient visit, with objective results, eliminating the need for two-step testing that is required by the tuberculin skin test. The MPHL would like to purchase reagents that are FDA approved to perform IGRA testing in its laboratory on human patients using the QuantiFERON-TB Gold test.

Qiagen will discontinue production of the QFT-TB Gold kits in 2018 and will begin to distribute the new FDA approved QFT-TB Gold Plus test kits listed below. The MPHL will continue to use the TB Gold kits until the validation of the new TB Gold Plus kits is completed in accordance with CLIA regulations. Validation of the new TB Gold Plus kits is estimated to be completed by August 2018.

| Product List Number | Product Description                                      | Product Price (Kit) | # Kits (Annual) | Extended Price |
|---------------------|----------------------------------------------------------|---------------------|-----------------|----------------|
| 0594-0201           | QFT 2 Plate kit: ELISA                                   | \$574.20            | 150             | \$86,130       |
| 0594-0501           | QFT Reference Lab Pack                                   | \$5742              | 1               | \$5742.00      |
| 0599-0401           | QFT Multipack (3 Elisa + 600 tubes)                      | \$3142.60           | 1               | \$3142.60      |
| T0590-0301          | QFT tubes (100xniL, 100xTBAG, 100xMit)                   | \$710               | 100             | \$71,000       |
| T0597-0403          | QFT Dispenser Pack (4 X 25 ct)                           | \$710               | 1               | \$710          |
| 622536              | QFT-TB Gold Plus Tubes, 50 each (Nil, TB1, TB2, Mitogen) | \$438               | 300             | \$131,400      |
| 622130              | QFT-TB Gold Plus ELISA, 2-Plate Kit                      | \$438               | 150             | \$65,700       |
| 622832              | QFT-TB Gold Plus ELISA Reference Lab Pack                | \$4,380             | 1               | \$4,380        |
| 622433              | QFT-TB Gold Plus Dispenser Pack, 25 Ct.                  | \$223               | 1               | \$223          |

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 Mississippi Public Health Laboratory (MPHL) currently performs the QuantiFERON-TB Gold to aid in the detection of *M. tuberculosis* infection on human patients using the Qiagen DS2 instrument. All reagents and quality control products must be FDA approved for testing on human patients using the DS2 instrument. The Qiagen QFT is the only FDA approved IGRA test that can be performed in-house.

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

The reagents for the QuantiFERON-TB Gold are manufactured only by Qiagen. Qiagen 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: \$368,427.60 per year (based on the current volume of IGRA tests performed by the MPHL)
- The MPHL receives 5%-25% discount off list price.
- Shipping fees are waived.

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:

- Qiagen is the sole manufacturer and sole vendor of these products and sells directly to laboratories.
- No other test reagents are FDA approved to perform QFT tests on human patients using the Qiagen DS2 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](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: Tuesday, December 12, 2017 at 3:00 p.m. (CST)



### INFORMATION ABOUT THE VENDOR/INDIVIDUAL SUBMITTING OSS FORM

Date Form Submitted: REIN# (OE#)

RFIN#: CRF x #

### INFORMATION ABOUT THE PURCHASING AGENCY

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.

This image shows a single sheet of white paper with horizontal blue or grey ruling lines. The lines are evenly spaced and run across the width of the page. There are approximately 20 lines visible. The paper appears to be a standard notebook page.



October 18, 2017

Joann Young

Laboratory Section Director – Immunology

Mississippi Public Health Laboratory

570 E. Woodrow Wilson Dr.

Jackson, MS 39216

Dear Joann,

Please find your 2018 pricing below, valid through December 31, 2018:

| Item #     | Description*                                             | Current Pricing | New Pricing<br>01/01/2018 | Estimated number | Extended Price |
|------------|----------------------------------------------------------|-----------------|---------------------------|------------------|----------------|
| 0594-0201  | QFT 2 Plate Kit ELISA                                    | \$574.20        | \$596                     |                  |                |
| 0594-0501  | QFT Reference Lab Pack                                   | \$5,742         | \$5,960                   |                  |                |
| 0599-0401  | QFT Multipack (3 x Elisa + 600 tubes)                    | \$3,142.60      | \$3,236                   |                  |                |
| T0590-0301 | QFT Gold Tubes, 100 ea. (Nil, TB Ag, Mitogen)            | \$710           | \$724                     |                  |                |
| T0597-0403 | QFT Dispenser Pack Tubes (4x 25ct)                       | \$710           | \$738                     |                  |                |
| 622536     | QFT-TB Gold Plus Tubes, 50 each (Nil, TB1, TB2, Mitogen) | \$438           | \$438                     |                  |                |
| 622130     | QFT-TB Gold Plus ELISA, 2-Plate Kit                      | \$438           | \$438                     |                  |                |
| 622832     | QFT-TB Gold Plus ELISA Reference Lab Pack                | \$4,380         | \$4,380                   |                  |                |
| 622433     | QFT-TB Gold Plus Dispenser Pack, 25 Ct.                  | \$223           | \$223                     |                  |                |

Shipping is waived

Annual Quote Total [USD]

\$

\*Current QuantiFERON TB Gold products may not be available after June 2018.

Once again, I look forward to working with you to eradicate TB! Let me know if you need any additional information.

Best regards,

*M. E. Doctor*

Michael E. Doctor

[michael.doctor@qiagen.com](mailto:michael.doctor@qiagen.com)

Phone 205-470-8709

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