MISSISSIPPI STATE DEPARTMENT OF HEALTH

October 26, 2016

MEMORANDUM

TO: Proposed Vendors

FROM: Jennifer Dotson, Director
Facilities, Property and Purchasing

AMENDMENT #1 TO RFx No 3160001250 – Reagent Rental Agreement for FDA approved Nucleic Acid Amplification Tests (NAAT) assay to screen for detection of chlamydia, gonorrhea and trichomoniasis

This correspondence is to make corrections/changes to the Mississippi State Department of Health Invitation for Bids, RFx # 3160001250 due on November 2, 2016.

Corrections/changes have been made to the written description of items to be purchased on Pg. 1 of the IFB.

Additional language has been added to the section concerning F.O.B. Point – F.O.B. Destination on Pg. 3 of the IFB.

Corrections/changes have been made to Item 2. under the section of "The test platform must have the following:" on Pg. 1 of the Minimum Bid Specifications.

A "Revised October 26, 2016" IFB is attached with the areas highlighted concerning the changes to the IFB. Please replace the original IFB dated October 13, 2016 with the revised IFB.

Also, please include a copy of this amendment with your bid submission.

570 East Woodrow Wilson • Post Office Box 1700 • Jackson, Mississippi 39215-1700
601/576-7634 • Fax 601/576-7931 • www.HealthyMS.com

Equal Opportunity In Employment/Service

MISSISSIPPI STATE DEPARTMENT OF HEALTH

INVITATION FOR BID

Issue Date: October 13, 2016
Revised October 26, 2016

RFx NO 3160001250

The Mississippi State Department of Health plans to purchase the following, and invites your bid:

(1) Minimum Bid Specifications for a Reagent Rental Agreement for a FDA approved Nucleic Acid Amplification Tests (NAAT) assay to screen urogenital sites and urine sources on human patients to detect chlamydia and gonorrhea. The test platform must also be FDA approved to test for trichomoniasis assays per the attached specifications. The reagents and kits for chlamydia and gonorrhea assays using a reagent rental agreement must provide the use of the test platform and supporting equipment. Rental pricing of the test platform is built into the pricing of the reagent and kits for chlamydia and gonorrhea.

This bid will be awarded on a total overall review of the specifications listed. The vendor is responsible for providing relevant documentation and demonstration that the instrument quoted in response to the bid meets all of the specifications listed. Pricing for the proposed reagent rental agreement will be for a five (5) year agreement.

BID COORDINATOR
Jennifer Dotson, Purchasing Director
Mississippi State Department of Health
P. O. Box 1700
Jackson, MS 39215-1700
Telephone: 601-576-7627
E-Mail: Jennifer.Dotson@msdh.ms.gov

CLOSING DATE AND TIME
Bids must be received by 10:30 a.m., CST/DST, Wednesday, November 2, 2016

TERMS AND CONDITIONS:

E-Verify Compliance – Contractor/Seller represents and warrants that it will ensure its compliance with the Mississippi Employment Protection Act (Senate Bill 2988 from the 2008 Regular Legislative Session) and will register and participate in the status verification system for all newly hired employees. The term "employee" as used herein means any person that is hired to perform work within the State of Mississippi. As used herein "status verification system" means the Illegal Immigration Reform and Immigrations Responsibility Act of 1996 that is operated by the United States Department of Homeland Security, also known as the E-Verify Program, or any other successor electronic certification system replacing the E-Verify Program. Contractor/Seller agrees to maintain records of such compliance and upon request of the State, provide a copy of each such verification to the State. Contractor/Seller further represents and warrants that any person assigned to perform services hereunder meets the employment eligibility requirements of all immigration laws of the State of Mississippi. Contractor/Seller understands and agrees that any breach of these warranties may subject Contract/Seller to the following: (a)termination of the Agreement and Ineligibility for any state or public contract in Mississippi for up to three (3) years, with notice of such (b) the loss of any license, permit, certification or other document granted to Contractor/Seller by an agency, department or governmental entity for the right to do business in Mississippi for up to one (1) year, or (c) both. In the event of such termination/cancellation, Contractor/Seller would also be liable for any additional costs incurred by the State due to contract cancellation or loss of license or permit.

E-Payments – Payments by The Mississippi State Department of Health shall be made and remittance information provided electronically as directed by The State of Mississippi. These payments shall be deposited into the bank account of the Contractor's Choice. The State may, at its sole discretion, require the Contractor to submit invoices and supporting documentation electronically at any time during the terms of this agreement. Contractor understands and agrees that the State is exempt from the payment of taxes. All payments shall be in United States currency.

Applicable Law – This purchase shall be governed by and construed in accordance with the laws of the State of Mississippi, excluding its conflicts of law provisions, and any litigation with respect thereto shall be brought in the courts of the State of Mississippi. The vendor shall comply with applicable federal, state and local laws and regulations.

Payment Terms – MS Code Section 31-7-305(3) allows a state entity to pay invoices within 45 days without penalty.

Bid terms are welcome, however, they will not be used as criteria for awarding the bid.

Prospective bidders are to contact Jennifer Dotson at (601) 576-7627 or by e-mail at Jennifer.Dotson@msdh.ms.gov with any questions regarding this bid. All questions shall be submitted in writing. Questions shall be submitted in time to be received at least (5) days prior to the IFB closing time and date.

It is incumbent upon each bidder to carefully examine the specifications, terms, conditions, etc. As stated above, all inquiries, requests, etc. concerning interpretation, clarification or additional information shall be made in writing either by E-Mail or by mail to Jennifer Dotson, Purchasing Director, P. O. Box 1700, Jackson, MS 39215-1700 or 570 E Woodrow Wilson, Jackson, MS 39216. The Mississippi State Department of Health (MSDH) will not be responsible for any oral representation(s) given by any employee, representative, or others. The issuance of a written addendum is the ONLY official method by which interpretation, clarification or additional information can be given.

If it becomes necessary to revise or amend any part of this IFB, notice will be given to all prospective bidders who were sent a bid packet. Bidder must acknowledge receipt of amendments in their bid response. Each bidder should ensure that they have received all addenda and amendments to this IFB before submitting their response.

The Mississippi State Department of Health reserves the right to define equals, to reject any or all bids, and waive all informalities. The MSDH also reserves the right to request award of the IFB to the lowest and best overall bid.

F.O.B. Point – F.O.B. Destination – Freight prepaid and allowed. The seller pays and bears the freight charges and owns the goods while they are in transit. Title passes at the buyer's location.

Minimum Specifications – the specifications listed in this IFB are the minimum required for this IFB. They are not intended to limit competition nor specify any particular bidder/respondent, but to ensure that the MSDH receives a quality product.

Contract may be canceled for cause for either party with the giving of 30 days written notice of intent to cancel. Cause for the State Department of Health to cancel shall include, but is not limited to, cost exceeding current market prices for comparable purchases; requests for increase in prices during the period of the contract; or failure to perform to contract conditions. The Contractor will be required to honor all purchase orders that were prepared and dated prior to the date of expiration or cancellation if received by the contractor within a period of 30 days following the date of expiration or cancellation. Cancellation by the State Department of Health does not relieve the Contractor of any liability arising out of a default or nonperformance.

Prior to the time specified for the bid opening, sealed bids along with any other documentation required must be hand delivered or mailed to **Mississippi State Department of Health, PURCHASING DEPARTMENT, ROOM 137A, THE UNDERWOOD BUILDING, 570E. WOODROW WILSON, JACKSON, MISSISSIPPI 39216 OR POST OFFICE BOX 1700, JACKSON, MS 39215-1700.**

Bids must be received, dated and time stamped prior to 10:30 a.m., CST/DST, Wednesday, November 2, 2016 at which time bids will be opened. No bids will be accepted after the established bid opening time. **Bids will be opened and read at 10:30 a.m., CST/DST in Suite 134 Conference Room, Underwood Building, 570 E. Woodrow Wilson, Jackson, Mississippi.**

> In addition, bidders should also submit a bid on-line in the State of Mississippi electronic procurement system, MAGIC. In order to submit bids, bidders must be registered as a vendor in MAGIC system and have an I.D. number and password assigned at the time of registration. Help for registering in MAGIC can be found at www.mmrs.state.ms.us.

No facsimile (FAX) bids will be accepted. This bid must be signed by a person with authority to bind the bidder. Failure to comply with this provision, any other provision of this Invitation for Bid, or any provision of State or Federal Law or regulation regarding the submission of bids will cause the bid to be rejected.

Submitted bids/responses will be available for review at the bid opening.

All bidders are invited and encouraged to attend the bid opening to review the submitted bids. After the close of the bid opening, the bids will be considered to be in the evaluation process and will not be available for review by bidders.

Any award notice, successful or unsuccessful, will be provided in written form and sent to all participants of the IFB.

PLEASE MARK YOUR ENVELOPE: Bid Due 10:30 a.m. CST/DST, Wednesday, November 2, 2016 .

RFx # 3160001250

(If the agency, MSDH, is closed for any reason, including but not limited to: acts of God, strikes, lockouts, riots, acts of war, epidemics, governmental regulations superimposed after the fact, fire, earthquakes, floods, or other natural disasters (the "Force Majeure Events"), which closure prevents the opening of bids at the advertised date and time, all bids received shall be publicly opened and read aloud on the next business day that the agency shall be open and at the previously advertised time. The new date and time of the bid opening, as determined in accordance with this paragraph, shall not be advertised, and all bidders, upon submission of a bid proposal, shall be deemed to have knowledge of and shall have agreed to the provisions of this paragraph. Bids shall be received by the agency until the new date and time of the bid opening as set forth herein. **The agency shall not be held responsible for the receipt of any bids for which the delivery was attempted and failed due to the closure of the agency as a result of a Force Majeure Event.** Each bidder shall be required to ensure the delivery and receipt of its bid by the agency prior to the new date and time of the bid opening.)

MSDH

BID FORM RFx 3160001250

Estimated Annual Volume 73,000 chlamydia/gonorrhea combination tests:

CT/GC NAAT Test Kit – Number of tests/kit_____ $_____/test kit

$_____/test

$_____/annual total

$_____/five year total

Specimen Collection Kit – Number of kits/box_____ $_____/box

$_____/collection kit

$_____/annual total

$_____/five year total

Company Name: _____

Quoted By: _____

Signature: _____

Telephone: _____

E-Mail Address: _____

RFx 3160001250
Revised October 26, 2016

Minimum Bid Specifications for Nucleic Acid Amplification Test (NAAT) to Detect Chlamydia, Gonorrhea, and Trichomoniasis

The purpose for these reagents will be to simultaneously testing for chlamydia and gonorrhea from a single tube in symptomatic and asymptomatic patients using a NAAT duplex assay. The test platform must also be able to detect trichomoniasis from the same collection tube used for chlamydia and gonorrhea testing.

The Mississippi State Public Health Laboratory (MPHL) proposes to purchase reagents and kits to perform *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis* using a reagent rental agreement that provides the use of the test platform. All costs, including pricing of the test platform, is built into the pricing of the reagents and kits for the specified term. The test platform must be fully automated and be an FDA approved NAAT assay. The test platform must be fully automated and be an FDA approved NAAT assay to screen various human sample matrixes for chlamydia and gonorrhea simultaneously and trichomoniasis from the same sample. The platform included in the quote must be for a new test platform; components and the unit cannot be refurbished, previously owned or used for demonstration. A list of equipment, reagents, controls and consumables must be included as stated in the package insert that is approved by the FDA for proper test performance.

The test platform must have the following:
1. The test platform must be a FDA approved NAAT for testing men and women with and without symptoms from urogenital sites and urine to detect chlamydia and gonorrhea simultaneously using a duplex assay.
2. The test platform must also be FDA approved NAAT for testing endocervical, vaginal or urine sources to detect trichomoniasis in symptomatic and asymptomatic women from the same chlamydia/ gonorrhea the collection tube. We are not currently requesting pricing for the trichomoniasis test kits in this IFB. If and when we have a need for the trichomoniasis testing we would request pricing at that time, separate from this contract.
3. Specimens must be stable at room temperature during transport and testing at least ten days after collection for endocervical swabs, urethral swabs, vaginal swabs and urine in vendor specific collection/transport tubes.
4. Specimen collection tubes must have pierceable caps and require no sample processing or cap removal after transport to the laboratory to decrease hands-on time and potential cross-contamination.
5. The test platform must be a fully automated walk-away random access system.
6. The test platform must have an automatic pipettor with the ability to obtain a sufficient amount of sample directly from collection tube and pipette sample to the testing vessel.
7. The NAAT assay must have equivalent sensitivity and specificity for detection of chlamydia and gonorrhea in urine and specimens collected with swabs.
8. The test platform must have an internal mechanism to automatically decontaminate amplicons in the closed system to prevent cross-contamination.
9. The NAAT assay must not react with nongonococcal commensal Neisseria.
10. The assay must have ability to process at least 400 specimens for chlamydia and gonorrhea in a six-hour period each workday with 800 reportable test results.

11. The vendor must provide sufficient reagents, consumables and testing supplies for the lab to verify the performance specifications of each test prior to reporting patient results.
12. The vendor must provide information pertaining to specimen transport requirements, including the following: specimen collection processes; specimen storage condition and storage time between collection and test performance; specimen storage condition and storage time after test completion; number of time specimen can undergo freeze-thaw conditions and specimen processing requirements prior to testing, including centrifugation or swab removal.
13. Documentation must be provided to support FDA approval for all specimen collection, handling, storage and transport statements.
14. The package insert or technical specifications must be included with the quotation.
15. The test platform must have on-board reagent storage.
16. The test platform must have auto detection of adequate reagent or specimen.
17. The vendor must define the calibration requirements and frequency associated with all requested tests on the platform.
18. The test platform must have an autocalibration alert.
19. The vendor must define all instrument maintenance requirements, including all daily, weekly or monthly maintenance, the staff hands-on time to complete, and must provide an estimate of the annual maintenance supply costs associated with the instrument.
20 The vendor must define the quality control features and requirements of the test platform.
21. The vendor must provide the data on accuracy, precision, reportable range and linearity of all requested tests.
22. The test platform must have a bar code reader for specimen tracking. The specifications for labels must be included.
23. Stored results and QC data must be retrievable from the test platform for up to one month.
24. The vendor must state whether the instrument has the capability to send QC data to a LIMS via an interface.
25. A UPS battery back-up/surge protector must be included.
26. If instrument monitoring is required by the vendor, the method, specifications and requirements for monitoring must be clearly stated.
27. An itemized list for reagents, controls and consumables, including quantity per unit of measure and individual prices must be provided.
28. The vendor will include the facility service specifications required for instrument installation (water, drain, venting, room size, requirements for waste disposal, etc.).
29. The vendor must provide information regarding features of the instrument that are not specified herein and any upgrades or additional tests available on the test platform that may expand its capacity.
30. Must provide technical assistance for initial setup for workflow, airflow, and environmental controls for contamination.
31. The vendor must provide a list of at least 5 current clients that use their instrument. Client estimated testing volume and test list must be included.
32. At the end of the contract period of five (5) years, the vendor will be responsible for the removal of the instrument with no expense to the MPHL. The instrument must be coordinated with the laboratory.
33. Price for reagents included in the proposed reagent rental agreement should be based on an annual volume of 73,000 chlamydia/gonorrhea combination tests. The term for the proposed reagent rental agreement is a five (5) year period. Pricing should be listed for the first year and for five years.
34. The vendor must provide a written response as to how each listed item included in the bid specifications will be met by the proposal that is submitted.

Software Specifications

1. The systems software must be 100% compatible and bi-directionally interfaceable with the current MPHL Laboratory Information Management Systems (LIMS), Common Cents ApolloLIMS used to support clinical testing.
2. Instrument software updates must be provided as part of the agreement and with no cost to the MPHL.

Training requirements

1. The company must provide on-site instrument and software training and certification for all lab testing personnel and off-site training as required by the manufacturer.
2. All expenses for off-site vendor sponsored instrument and software training, if required, must be included as part of the quotation. The expenses for the training that are covered by the vendor must be itemized in the bid response.
4. 5. The company must provide training modules for specimen collection, handling and interpretation for clinicians.

Installation requirements

1. The vendor must provide technical assistance and on-site installation for the initial setup as part of the agreement.
2. Instrument must be received and installed and ready for use by the customer within four (4) weeks of the bid award.
3. The vendor must specify the electrical requirements for the instrument.

Service requirements

1. Must provide a toll free telephone number for technical assistance that is accessible Monday through Friday from 8:00 a.m. - 5:00 p.m. CST/CDT.
2. The company must be able to provide expedited service when there is an instrument malfunction. Vendor must provide response time in documents that are submitted.
3. Must provide the base location of the nearest service representative.
4. Must provide on-site service calls to perform preventive maintenance as required by the manufacturer.
5. The cost of the service agreement must be included as part of the reagent rental agreement.

_____Initial - All minimum bid specifications for RFx 3160001250, pages one through three, have been met.