Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: February 22, 2016

Re: Sole Source Certification Number **SS5015** for reagent rental contract for Hologic Limited Partnership ThinPrep® cytopathology testing and imaging equipment, as well as service and supplies

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5015** for **reagent rental contract for ThinPrep® cytopathology testing and imaging equipment, as well as service and supplies**, please be advised that UMMC intends to award the purchase of the **reagent rental contract for ThinPrep® cytopathology testing and imaging equipment, as well as service and supplies** to **Hologic Limited Partnership** as the sole source provider of the **reagent rental contract for ThinPrep® cytopathology testing and imaging equipment, as well as service and supplies**.

UMMC issues this notice in accordance with Mississippi state law, policy, and procedures for sole source procurements.

Sole Source Criteria

1. Where the compatibility of equipment, accessories, or replacement parts is the paramount consideration (and manufacturer is the sole supplier).
2. Where a sole supplier's item is needed for trial use or testing.
3. Where a sole supplier's item is to be required when no other item will service the needs of UMMC.

Schedule

Task	**Date**
First Advertisement Date	February 22, 2016
Second Advertisement Date	February 29, 2016
Response Deadline from Objectors	March 7, 2016, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before May 20, 2016

Project Details

1. **Describe the commodity that the agency is seeking to procure:**
   The University of Mississippi Medical Center (UMMC) requests approval for a reagent rental agreement with Hologic Limited Partnership (Hologic). The agreement allows the Cytopathology Department of UMMC to purchase ThinPrep Papanicolaou anatomic preparation (pap) reagents. Hologic will provide five (5) instruments for performing the pap testing and the needed services for these five (5) instruments. Hologic will also provide the ThinPrep Imaging System, which uses computer imaging technology to assist in primary cervical cancer screening. Additionally, Hologic will provide service for one instrument utilized for pap testing, which UMMC owns.

2. **Explain why the commodity is the only one (1) that can meet the needs of the agency:**
   The three components of the requested purchase are irretrievably tied together - the ThinPrep reagents are unique for the tests to be performed, no other reagents may be used with the ThinPrep processors, and the Imaging system is designed to work only with the ThinPrep processors

   Other companies make a similar system; however, the ThinPrep pap test is the only test approved by the FDA for HPV, Chlamydia, and Gonorrhea "out of the vial" testing, meaning that it provides a platform for testing samples for the presence of all three diseases at one time instead of performing multiple tests. Other companies' systems are not FDA approved for all three tests; specifically, no other company has received FDA approval for HPV testing. When FDA approved products are available on the market, whether reagents, tests, or drugs, it is crucial to use and purchase those products rather than non-FDA approved products. FDA approval means that the manufacturer and its product have undergone rigorous research and testing under the FDA's supervision, and the product receives continued surveillance and tracking throughout its market use. If a laboratory were to use a product for HPV testing that is not FDA approved, it would be required to self-validate the alternative test. However, the self-validation process takes in excess of three months. UMMC does not have the manpower or technical capabilities to perform the self-validation that would be required for the volume of HPV testing it performs.

3. **Explain why the source is the only person or entity that can provide the required commodity:**
   Hologic Limited Partnership is the sole proprietary manufacturer and domestic distributor for the ThinPrep® 2000 Processor, ThinPrep® 3000 Processor, and ThinPrep® Imaging System with Dual Review, the ThinPrep® Pap Test TM Package, and all of the ThinPrep System disposables. There are no other vendors for the ThinPrep System. See supporting letter from Hologic Limited Partnership, Attachment A.

4. **Explain why the amount to be expended for the commodity is reasonable:**
   The estimated amount to be expended is for the purchase of the **PRODUCT** is $422,631.00. This amount is within the expected price range for these products.

5. **Describe the efforts that the agency went through to obtain the best possible price for the commodity:**
   Through market intelligence, UMMC was able to negotiate best pricing for these products. All applicable discounts were explored and applied.

Submission Instructions and Format of Response from Objecting Parties

Interested parties who have reason to believe that the **reagent rental contract for ThinPrep® cytopathology testing and imaging equipment, as well as service and supplies** (hereafter, "Products") should not be certified as a sole source should provide information in the Vendor Form for the State to use in determining whether or not to proceed with awarding the sole source to **Hologic Limited Partnership**.

The Vendor Form may be found at
http://www.dfa.state.ms.us/Purchasing/documents/ObjectiontoSoleSourceDetermination.pdf.

Objections must include the certification in Attachment B.

Comments will be accepted at any time prior to Monday, March 7, 2016, at 3:00 p.m. (Central Time) to solesource@umc.edu. Responses may be delivered via email to solesource@umc.edu. UMMC WILL NOT BE RESPONSIBLE FOR DELAYS IN THE DELIVERY OF RESPONSES. It is solely the responsibility of the Interested Parties that responses reach UMMC on time. Responses received after the deadline and responses that lack all required information will be rejected. UMMC reserves the right to inspect Interested Party's commodity for comparison purposes.

If you have any questions concerning the information above or if we can be of further assistance, please contact solesource@umc.edu.

Attachment A: Vendor Correspondence
Attachment B: Objection Certification

Attachment A

HOLOGIC®

January 15, 2016

The University of Mississippi
ATTN: Rhonda Alexander
2500 N State Street
Jackson, MS 39216

Dear Ms. Alexander:

I am writing to inform you that Hologic Limited Partnership is the sole proprietary manufacturer and domestic distributor of the ThinPrep® 2000 Processor, ThinPrep® 3000 Processor, ThinPrep® Imaging System with Dual Review™, the ThinPrep® Pap Test™ Package, and all of the ThinPrep system disposables. There are no other vendors for the ThinPrep system.

The ThinPrep® Pap Test™ package insert labeling, cleared for use by the U.S. Food and Drug Administration, contains the following information:

> Use for HPV testing using Digene Hybrid Capture System HPV DNA Assay.
>
> Use for HPV testing using Hologic Cervista™ HPV HR and Cervista HPV 16/18 genotyping.
>
> The PreservCyt® Solution component of the ThinPrep Systems is an alternative collection and transport medium for gynecological specimens tests with the Aptima Combo 2® CT/NG Assays.
>
> The PreservCyt® Solution component of the ThinPrep Systems is an alternative collection and transport medium for gynecological specimens tests with the Roche Diagnostics COBAS Amplicor.

The Aptima HPV Assay and Aptima HPV 16 18/45 Genotype Assay package insert labeling, cleared for use by the U.S. Food and Drug Administration, contain the following information:

> The PreservCyt® Solution component of the ThinPrep Systems is an alternative collection and transport medium for gynecological specimens tests with the Aptima HPV and Aptima HPV 16 18/45 Genotype Assays.

The ThinPrep® Pap Test™ is the only product currently available that has this approval in its product labeling.

In addition, the package insert labeling has increased HSIL+ detection by 59.7% in a multi-site, historically controlled study of routine screening and referral patient populations at ten leading academic institutions.

Additionally, the ThinPrep® Imaging System with Dual Review™ is the only computer assisted technology that is FDA approved for use on all patient types to include high risk patients.

If you have any questions or need any additional information, please feel free to call me at 800-442-9892.

Sincerely,

Thomas West
Division President, Diagnostic Solutions

Attachment B

SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS5015
Accepted until March 7, 2016, at 3:00 p.m.

I certify that the information contained in this objection is true and accurate to the best of my knowledge. I understand that UMMC will investigate all statements made in this objection and that any false or misleading information provided may result in adverse action.

_____
Objector Name
Objector's title

_____
Date