Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: May 11, 2017

Re: Sole Source Certification Number **SS5096** for **reagent rental contract for Hologic Limited Partnership ThinPrep® cytopathology testing and imaging equipment**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding Sole Source Certification Number **SS5096** for **reagent rental contract for ThinPrep® cytopathology testing and imaging equipment,** please be advised that University of Mississippi Medical Center (UMMC) intends to award the purchase to **Hologic Limited Partnership** as the sole source provider.

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	May 11, 2017
Second Advertisement Date	May 18, 2017
Response Deadline from Objectors	May 25, 2017, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before July 10, 2017

Project Details

1. **Describe the commodity that the agency is seeking to procure:**

   UMMC Department of Cytopathology is seeking to continue purchasing ThinPrep® Papanicolaou anatomic preparation (PAP) reagents. Additionally, Hologic will provide five (5) instruments for performing the PAP testing. Hologic will also provide the ThinPrep® Imaging System, which uses computer imaging technology to assist in primary cervical cancer screening. Additionally, the ThinPrep Imaging System with Dual Review is the only computer-assisted technology that is FDA approved for use on all patient types, including high-risk patients.

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 and proprietary to the instruments. The Imaging system may also be only used with the ThinPrep® instruments.

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 for the purchase of the **PRODUCT** is $485,590.00. 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** (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 Thursday, May 25, 2017, 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®

February 3, 2017
To Whom It May Concern:

I am writing to inform you that Hologic (MA), LLC, a wholly owned subsidiary of Hologic, Inc., ("Hologic"), is the sole proprietary manufacturer and domestic distributor of the ThinPrep® 2000 Processor; ThinPrep® 3000 Processor; ThinPrep® 5000 Processor; ThinPrep® 5000 Autoloader System; 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, approved for use by the U.S. Food and Drug Administration, contains the following information[1,2]:

> Use for HPV testing using Digene® Hybrid Capture® 2 High-Risk HPV DNA Test.
>
> Use for HPV testing using Hologic Cervista® HPV HR test and Cervista® HPV 16/18 test.
>
> The PreservCyt® Solution component of the ThinPrep Systems is an alternative collection and transport medium for gynecological specimen 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 specimen tests with the Roche Diagnostics cobas® Amplicor Analyzer.

The Aptima® HPV assay and Aptima® HPV 16 18/45 genotype assay package insert labeling, approved for use by the U.S. Food and Drug Administration, contains the following information[3]:

> The PreservCyt Solution component of the ThinPrep Systems is an alternative collection and transport medium for gynecological specimen tests with the Aptima HPV and Aptima HPV 16 18/45 genotype assays.

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.[1]

Additionally, the ThinPrep Imaging System with Dual Review is the only computer-assisted technology that is FDA approved for use on all patient types, including high-risk patients.[4]

If you have any questions or need any additional information, please feel free to call Hologic Customer Service at 1.800.442.9892.

Sincerely,

Thomas West

Division President, Diagnostic Solutions

MISC-01355-001 Rev.002

References: **1.** ThinPrep 2000 [instructions for use] MAN-02624-001 Rev. 003. Marlborough, MA: Hologic, Inc.; 2014. **2.** PreservCyt [package insert] MAN-01328-001 Rev. 003. Marlborough, MA: Hologic, Inc.; 2016. **3.** Aptima HPV assay [package insert] AW -12820 Rev. 001. San Diego, CA: Hologic, Inc.; 2015. **4.** ThinPrep Imaging System [instructions for use] MAN-03938-001 Rev. 002. Marlborough, MA: Hologic, Inc.; 2015.

10210 Genetic Center Drive, San Diego, CA 92121 USA | +1.858.410.8000 | Hologic.com

Attachment B

SUBMITTED IN RESPONSE TO
Sole Source Certification No SS 5096
Accepted until Thursday, May 25, 2017, 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