

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: July 11, 2016

Re: Sole Source Certification Number **SS5040** for **ViroSeq HIV-1 Genotyping System**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5040** for **ViroSeq HIV-1 Genotyping System**, please be advised that UMMC intends to award the purchase of the **ViroSeq HIV-1 Genotyping System** to **Abbott Molecular** as the sole source provider of the **ViroSeq HIV-1 Genotyping System**.

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	July 11, 2016
Second Advertisement Date	July 18, 2016
Response Deadline from Objectors	July 25, 2016, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before November 18, 2016

Project Details

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

The University of Mississippi Medical Center (UMMC) seeks to purchase Viroseq, Abbott's HIV-1 genotyping reagents. UMMC serves to an unusually large HIV patient population in the Jackson metro area. Precise treatment and management of the positive patients depend on HIV genotype-specific information as certain drugs only work on certain HIV genotypes. It became standard of care several years ago. Currently, all HIV genotyping tests from UMMC are sent out to a reference lab.

2. Explain why the commodity is the only one (1) that can meet the needs of the agency:

Abbott Molecular has the only FDA-approved HIV-genotyping IVD test in the market.

3. Explain why the source is the only person or entity that can provide the required commodity:

Abbott Molecular has the only FDA-approved HIV-genotyping IVD test system in the market place and is the sole provider of ViroSeq. Abbott doesn't have any authorized distributors and sells directly to customers. See Vendor letter in 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 **ViroSeq HIV-1 Genotyping System** is \$210,000.00 per year for three years. 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 **ViroSeq HIV-1 Genotyping System** (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 **Abbott Molecular**. 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, July 25, 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



1350 East Touhy Ave.
Dept. V610
Des Plaines, IL 60018

June 16, 2016

University of Mississippi Medical Center
2550 Nesh St.
Jackson, MS 39215

To whom it may concern,

Thank you for your consideration of Abbott Molecular's solutions for Infectious Disease testing to meet your facility needs. Please consider this letter verification that Abbott Laboratories, Inc. is the sole manufacturer, distributor, and service provider of the Abbott m2000 RealTime PCR Platform. It is the only system currently available that is capable of performing FDA approved tests which include HCV and Viroseq on a single molecular platform. Abbott Molecular is the sole provider of Viroseq and is the only FDA approved Viroseq assay on the market.

Please note that this system includes the following unique specifications not found in competitive systems:

- A single molecular platform capable of performing FDA approved tests which include HIV-1, HCV, HBV, HCV Genotype, and CMV; platform should you choose to consolidate testing in the future.
- The m2000g is the only FDA approved system that accepts primary bar coded patient tubes which reduces hands-on time, transcription errors and provides positive sample identification through the entire assay run.
- The m2000p is an open platform that offers flexible protocols for various sample type and volumes, including RNA, DNA and Total Nucleic Acid options.
- The m2000t allows for complete flexibility in defining laboratory-based real-time PCR applications. Abbott, FDA approved assays, ASRs and non-Abbott reagents can be run on the system.
- 2-point external calibration to generate a stored calibration curve which lends to higher precision assay.
- The Abbott Molecular m2000 system is the only PCR based system that uses a non-computing internal control to validate assay performance.
- The m2000t is the only system that uses the maxRatio Data Analysis which incorporates multiple validity checks for improved confidence in patient results. This validates the growth curves and performance of each reaction.
- The m2000 allows for informatics solutions such as mView, AbbottLink, middleware and bi-directional LIS.

Abbott Molecular is committed to molecular diagnostics and we thank you for your interest in our products. We look forward to a long partnership.

Sincerely,

Lauren Plante
Senior Business Manager, East
Abbott Molecular

Attachment B

**SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS5040
Accepted until July 25, 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