

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: November 24, 2016

Re: Sole Source Certification Number **SS5040** for **ViroSeq HIV-1 Genotyping System reagents and related consumables**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5040** for **ViroSeq HIV-1 Genotyping System reagents and related consumables**, please be advised that UMMC intends to award the purchase of the **ViroSeq HIV-1 Genotyping System reagents and related consumables** to **Abbott Molecular Inc. (Abbott)** 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	November 28, 2016
Second Advertisement Date	December 5, 2016
Response Deadline from Objectors	December 12, 2016, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before January 20, 2017

Project Details

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

The University of Mississippi Medical Center (UMMC) seeks to purchase ViroSeq HIV-1 Genotyping System reagents and related consumables for use in the Molecular department of the Clinical Laboratory. UMMC serves an unusually large human immunodeficiency virus (HIV) patient population in the Jackson metro area. Precise treatment and management of positive patients is dependent on HIV genotype-specific information which is used to determine susceptibility to various HIV drugs. The utilization of this information became the standard of care several years ago. Currently, all HIV genotyping tests from UMMC are sent to a reference laboratory.

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

Abbott Molecular Inc. has the only FDA-approved HIV-genotyping in vitro diagnostic (IVD) test in the market. Abbott Molecular Inc. is also the sole provider of a commercially available research use only (RUO) Integrase test that can be run on a sequencer, which is a related consumable for the Viroseq HIV-1 Genotype System.

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

Abbott Molecular Inc. is the sole manufacturer and exclusive distributor. Abbott Molecular Inc. 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 for the purchase of the **ViroSeq HIV-1 Genotyping System reagents and related consumables** over the contract term is \$1,538,622.01. 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 reagents and related consumables** (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 Inc.** 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, December 12, 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

November 14, 2016

University of Mississippi Medical Center
2500 North State Street
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 for HIV, HBV, HCV viral loads, CTNG, and HCV Genotyping on a single molecular platform. Abbott Molecular is the sole provider of Viroseq, the only FDA approved test for HIV Genotyping on the market. Abbott Molecular is also the sole provider of a commercially available RUO Integrase test that can be run on a sequencer.

Viroseq

04194-093 ViroSeq HIV-1 Genotyping System
04194-093 Seq Consumables Pack

Integrase

04194-071 ViroSeq HIV-1 Integrase RUO
04194-072 ViroSeq HIV-1 Integrase Sample Prep Kit
04194-073 PCR Cleanup Kit

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 CTNG platform should you choose to consolidate testing in the future.
- The m2000sp 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 m2000sp is an open platform that offers flexible protocols for various sample type and volumes, including RNA, DNA and Total Nucleic Acid options.
- The m2000rt allows for complete flexibility in defining laboratory-based real-time PCR applications. Abbott FDA approved assays, ASRTs and non-Abbott reagents can be run on the system.
- 2-point external calibration to generate a stored calibration curve which leads to higher precision assay.
- The Abbott Molecular m2000 system is the only PCR based system that uses a non-competing internal control to validate assay performance.
- The m2000rt is the only system that uses the mastatic Data Analysis which incorporates multiple validity checks for improved confidence in patient results. This validates the growth curves and performance of each reaction.



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• The m2000 allows for informatics solutions such as nView, 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,

A handwritten signature in black ink that reads 'Melissa Christoffel-Capocella'.

Melissa Christoffel-Capocella
Senior Business Manager, East
Abbott Molecular

Attachment B

**SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS5040
Accepted until December 12, 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