

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: September 29, 2016

Re: Sole Source Certification Number **SS5051** for **Equipment including COBAS® AmpliPrep, COBAS® TaqMan®, and COBAS® z480 analyzers, AmpliLink Data Station, reagents and related kits rental agreement**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5051** for **Equipment including COBAS® AmpliPrep, COBAS® TaqMan®, and COBAS® z480 analyzers, AmpliLink Data Station, reagents and related kits rental agreement**, please be advised that UMMC intends to award the **Equipment including COBAS® AmpliPrep, COBAS® TaqMan®, and COBAS® z480 analyzers, AmpliLink Data Station, reagents and related kits rental agreement** to **Roche Diagnostics Corporation (Roche)** 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	September 29, 2016
Second Advertisement Date	October 6, 2016
Response Deadline from Objectors	October 13, 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 continue using a fully automated in vitro diagnostic medical device (IVD) platform available on the COBAS® AmpliPrep / COBAS® TaqMan® systems for the diagnosis, prevention, monitoring, treatment, or alleviation of disease. The platform tests for Human immunodeficiency Virus Type 1 (HIV-1), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), Human Papilloma Virus (HPV), Chlamydia/Gonococcus Detection (CT/NG), Cytomegalovirus (CMV), B-Raf protein (BRAF), V-Ki-ras2 Kirsten rat sarcoma viral oncogene homolog (KRAS), and Epidermal growth factor receptor (EGFR).

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

UMMC has been utilizing this instrumentation and methodology since 2002 under a current reagent rental agreement. This new agreement will allow UMMC to add new reagent kit technology, enhance pricing, consolidate agreements, and extend term for a period of three years or 36 months.

The features only offered on the COBAS® AmpliPrep/COBAS® TaqMan® system:

- All four real-time PCR FDA approved assays—HIV-1, HCV, HBV and CMV—can simultaneously run on the COBAS® AmpliPrep and COBAS® TaqMan® platform which also allows for the option of continuous loading of more specimens to maximize laboratory efficiency and decrease result turnaround time.
- The system is FDA approved for operation within the same room, side by side.
- Can process up to 144 samples per shift including unattended overnight operation.
- Batch sizes may range from 9 to 21 samples without reagent waste.
- Each lot of reagent is calibrated within the manufacturing process to ensure traceability to the WHO standard, thereby eliminating on-site, end user lot calibration requirements.
- QS (Quantitation Standard) is included in every reaction to function as an internal control and is co-amplified with the target for the purpose of titer calculations within each reaction.

As of May 2015, Roche offers the most comprehensive companion diagnostic U.S. Food & Drug Administration (FDA) approved portfolio for oncology in the U.S., including tests for B-Raf proto-oncogene, serine/threonine kinase (BRAF), Epidermal growth factor receptor (EGFR), and V-Ki-ras2 Kirsten rat sarcoma viral oncogene homolog (KRAS) mutations. As the only Academic Medical Center and tertiary referral hospital for the citizens of Mississippi, availability of these tests supports the care of patients referred from primary and secondary care providers.

The reliability and test performance of the systems have a proven record with UMMC. HIV positive mothers that give birth with no prior treatment are tested quickly so physicians may make fast and accurate medical decisions for the baby and the mother. Since the need for a rapid turn-around time provided by the random access instrumentation is met, we are requesting approval as a sole source.

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

The Equipment including COBAS® AmpliPrep, COBAS® TaqMan®, and COBAS® z480 analyzers, AmpliLink Data Station, reagents and related kits are solely distributed in the United States by Roche Molecular Diagnostics and unavailable from any other manufacturer. See supporting letter from **Roche Diagnostics Corporation**, Attachment A.

4. Explain why the amount to be expended for the commodity is reasonable:

The estimated amount to be expended for the Equipment including COBAS® AmpliPrep, COBAS® TaqMan®, and COBAS® z480 analyzers, AmpliLink Data Station, reagents and related kits rental agreement over the contract term is \$7,059,105.14. 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 **Equipment including COBAS® AmpliPrep, COBAS® TaqMan®, and COBAS® z480 analyzers, AmpliLink Data Station, reagents and related kits rental agreement** (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 **Roche Diagnostics Corporation**.

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, October 13, 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



Jo Lynn King
University of Mississippi Medical Center
2500 North State Street
Jackson, MS 39216

09/20/2016

Dear Jo Lynn,

Roche Diagnostics would like to provide the following information to support your sole source justification of the COBAS® AmpliPrep / COBAS® TaqMan® system and respective HIV-1 Test, v2.0, HCV Test, v2.0 and HBV Test, v2.0 along with the COBAS® 4800 analyzer system and respective HPV Test, CI/NG Test, BRAF Test, EGFR Test and KRAS (RUO) Test.

The COBAS® AmpliPrep / COBAS® TaqMan® System is a fully automated IVD platform which is distributed in the United States solely by Roche Molecular Diagnostics. Roche is the sole manufacturer and distributor for all IVD assays and general purpose extraction reagents utilized on the system.

The COBAS® 4800 System is a fully automated IVD platform which is distributed in the United States solely by Roche Molecular Diagnostics. Roche is the sole manufacturer and distributor for all IVD assays and general purpose extraction reagents utilized on the system. The Women's Health Assays, HPV & CI/NG are run on the fully automated platform for extraction through Amplification and Detection. The Oncology Markers, BRAF, EGFR and KRAS (RUO), are performed using a Formalin Fixed Paraffin Embedded tumor sample requiring a manual extraction that is then Amplified and Detected on the COBAS® 4800 portion of the COBAS® 4800 portion of the system.

We thank you for your interest in our products. We are glad to provide supporting details regarding our product offering if needed.

Kind Regards,

A handwritten signature in black ink, appearing to read "Keith Obye".

Keith Obye
Marketing Manager Clinical Automation
317-521-4033
keith.obye@roche.com

**Roche Diagnostics
Corporation**

5115 Lagune Road
Indianapolis, IN 46250-0467
USA

Phone: 800-428-5074

Attachment B

**SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS5051
Accepted until October 13, 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