

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: October 17, 2016

Re: Sole Source Certification Number **SS5054** for **One Lambda transplant diagnostic reagents**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5054** for **One Lambda transplant diagnostic reagents**, please be advised that UMMC intends to award the purchase of the **One Lambda transplant diagnostic reagents to One Lambda Inc. (One Lambda)** as the sole source provider of the **One Lambda transplant diagnostic reagents**.

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	October 17, 2016
Second Advertisement Date	October 24, 2016
Response Deadline from Objectors	October 31, 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 reagents from One Lambda to use together with One Lambda's Human leukocyte antigen (HLA) Fusion analysis software. As the only HLA laboratory in the state of Mississippi, the UMMC HLA laboratory provides all of the tissue typing and antibody screening services for the UMMC Transplant Center and the Mississippi Organ Recovery Agency. The HLA laboratory also performs HLA typing for the Bone Marrow Transplant Program and for various disease associations, including ankylosing spondylitis, celiac disease, and abacavir hypersensitivity (for HIV treatment).

The HLA laboratory uses the HLA Fusion software to perform the complex data analysis required for molecular HLA typing. In order to use HLA Fusion, the typing must be performed using one of One Lambda's deoxyribonucleic acid (DNA) typing kits. The HLA laboratory currently performs HLA typing using the LABType sequence specific oligonucleotide (SSO) DNA typing kits and Micro SSP DNA typing kits. LABType is a reverse SSO DNA typing system that consists of SSO probes bound to color-coded microspheres using Luminex's xMAP technology. This robust assay can be run in a 96-well format, allowing higher throughput, and provides an intermediate to high resolution HLA type. The LABType SSO DNA typing kits are the primary method used by the UMMC HLA laboratory to determine the HLA phenotype of all solid organ transplant and bone marrow transplant patients. Micro SSP is a sequence specific priming (SSP) DNA typing system that consists of a 96-well tray containing pre-aliquoted and dispensed primers and an internal control in each well. This method allows for relatively rapid identification of a low to intermediate resolution HLA phenotype, and is the primary method used by the UMMC HLA laboratory for STAT deceased donor HLA typing.

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

One Lambda produces the HLA Fusion analysis software, which can only be used with One Lambda reagents. HLA Fusion is a powerful tool that is able to import raw data directly from the Luminex analyzer, improving efficiency and reducing transcription errors. Importantly, the HLA laboratory already owns the interface between HLA Fusion and HistoTrac, which is the laboratory's primary database for storing all patient results and demographics. This allows results from HLA Fusion to automatically populate the correct fields in HistoTrac, again improving quality and patient safety by reducing transcription errors.

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

One Lambda Inc. is the sole manufacturer of One Lambda transplant diagnostic reagents. The products are not available from other distributors or resellers. See Supporting Letter from **One Lambda Inc.**, Attachments A,B, and C.

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

The estimated amount to be expended for One Lambda transplant diagnostic reagents is approximately \$10,465,778.00 over the five year contract term. 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 **One Lambda transplant diagnostic reagents** (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 **One Lambda 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, October 31, 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.

Attachments A, B, and C: Vendor Correspondence
Attachment D: Objection Certification

Attachment A



One Lambda, Inc.
A Thermo Fisher Scientific Brand
21001 Kittling Street
Canoga Park, CA 91303
Tel: (800) 822-8824
Fax: (818) 702-8824
www.onelambda.com

May 5, 2016

University of Mississippi Medical Center
2500 No. State Street
Jackson, MS 39216

Dear Mr. Brian R. McCarty:

This letter is to confirm that the products listed below are solely manufactured and exclusively provided by One Lambda, Inc. in the United States.

FL12-60	FlowPRA™ HLA Class I & II Screening Test
FLCNTBD	FlowPRA™ Control Beads
FL1-30	FlowPRA™ HLA Class I Screening Test
FL2-30	FlowPRA™ HLA Class II Screening Test
FL-RP	FlowPRA™ Reagent Pack
LS1A04	LABScreen™ Single Antigen HLA Class I –Combi
LS2A01	LABScreen™ Single Antigen HLA Class II - Group I
LS1PRA	LABScreen™ PRA Class I
LS2PRA	LABScreen™ PRA Class II
LS-NC	LABScreen Negative Control
LS-AB2 PE	Conjugated Goat Anti-Human IgG
RSSOH1A	LABType™ HD Class I A Locus Typing Test
RSSOH1B	LABType™ HD Class I B Locus Typing Test
RSSOH1C	LABType™ HD Class I C Locus Typing Test
RSSO1E47	LABType™ SSO Class I Exon 4-7 Supplement Typing Test
RSSOH2B1	LABType™ HD Class II DRB1 Typing Test
RSSO2345	LABType™ SSO Class II DRB3,4,5 Typing Test
RSSO2Q	LABType™ SSO Class II DQA1/DQB1 Typing Test
RSSO2P	LABType™ SSO Class II DPA1/DPB1 Typing Test
LT-SAPE	PE - Conjugated Streptavidin
SSP1A	Micro SSP™ HLA Class I A Locus Specific DNA Typing Tray
SSP1B	Micro SSP™ HLA Class I B Locus Specific DNA Typing Tray
SSP1C	Micro SSP™ HLA Class I C Locus Specific DNA Typing Tray
SSP1L	Micro SSP™ Generic HLA Class I DNA Typing Tray
SSP2L	Micro SSP™ Generic HLA Class II DNA Typing Tray
SSP2HQA1	Micro SSP™ High Resolution HLA Class II DNA Typing Tray - DQA1
SSP2HDP	Micro SSP™ High Resolution HLA Class II DNA Typing Tray - DPA1/DPB1
SSPDRQPI	Micro SSP™ Generic HLA Class II DRB, DQB, DPB DNA Typing Tray

Schedule B



One Lambda, Inc.
 A Thermo Fisher Scientific Brand
 21001 Kittinger Street
 Canoga Park, CA 91303
 Tel: (805) 822-8624
 Fax: (818) 702-8604
 www.onelambda.com

SSPR1-03	Micro SSP™ Allele Specific HLA Class I DNA Typing Tray - A*03
SSPR1-07	Micro SSP™ Allele Specific HLA Class I DNA Typing Tray - B*07
SSPR1-15	Micro SSP™ Allele Specific HLA Class I DNA Typing Tray - B*15
SSPR1-23	Micro SSP™ Allele Specific HLA Class I DNA Typing Tray - A*23
SSPR1-27	Micro SSP™ Allele Specific HLA Class I DNA Typing Tray - B*27
SSPR1-35	Micro SSP™ Allele Specific HLA Class I DNA Typing Tray - B*35
SSPR1-44	Micro SSP™ Allele Specific HLA Class I DNA Typing Tray - B*44
SSPR1-68	Micro SSP™ Allele Specific HLA Class I DNA Typing Tray - A*68
SSPR1-C02	Micro SSP™ Allele Specific HLA Class I DNA Typing Tray - C*02
SSPR1-C04	Micro SSP™ Allele Specific HLA Class I DNA Typing Tray - C*04
SSPR1-C07	Micro SSP™ Allele Specific HLA Class I DNA Typing Tray - C*07
SSPR1-C12	Micro SSP™ Allele Specific HLA Class I DNA Typing Tray - C*12
SSPR1-C15	Micro SSP™ Allele Specific HLA Class I DNA Typing Tray - C*15
SSPR1-C16	Micro SSP™ Allele Specific HLA Class I DNA Typing Tray - C*16/17/18
SSPR2-104	Micro SSP™ Allele Specific HLA Class II DNA Typing Tray - DRB1*04
SSPR2-4	Micro SSP™ Allele Specific HLA Class II DNA Typing Tray - DRB4
SSPR2-Q1	Micro SSP™ Allele Specific HLA Class II DNA Typing Tray - DQB1
SSPWT12	SSP Class I & Class II Wipe Test (100 tests)
SXTBF100	SXTB Buffer with Ethidium Bromide
5300025	SeCore™ A Locus Sequencing Kit
5311025D	SeCore™ B Locus Sequencing Kit, Single Amplification System
5320025	SeCore™ C Locus Sequencing Kit
5341025D	SeCore™ DQB1 Locus ZAMP
5351025	SeCore™ DPB1 Locus Sequencing Kit
74601250	PCR MARKERS 50-2000 BP 250UL
A15571	SeCore™ DRB1 Locus Exon 2 & 3 Sequencing Kit
54010D	AllSet™ Gold SSP A Locus High Resolution Kit
54020D	AllSet™ Gold SSP B Locus High Resolution Kit
54030D	AllSet™ Gold SSP Cw Locus High Resolution Kit
54040D	AllSet™ Gold SSP DRB1 Locus High Resolution Kit
54050D	AllSet™ Gold SSP DQB1 Locus High Resolution Kit
54070D	AllSet™ Gold SSP DPB1 Locus High Resolution Kit
54080D	AllSet™ Gold SSP DRB345 Locus High Resolution Kit
789991	DNA Wipe Test

The products listed above require HLA Fusion™ Software, which is One Lambda, Inc.'s proprietary software.

Attachment C



One Lambda, Inc.
A Thermo Fisher Scientific Brand
21001 Kirtcove Street
Cancoga Park, CA 91303
Tel: (800) 822-5824
Fax: (818) 702-5004
www.onelambda.com

If you have any further questions, please contact your sales consultant Jason Crumpton at jason.crumpton@thermofisher.com.

Sincerely,

A handwritten signature in black ink that reads "Sebastian J. Rider". The signature is written in a cursive style.

Sebastian Rider
Manager, Domestic Sales

Attachment D

**SUBMITTED IN RESPONSE TO
Sole Source Certification No. XXXXX
Accepted until October 31, 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