

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: May 1, 2017

Re: Sole Source Certification Number **SS5093** for **LinkS_{eq} assay designs, reagents, SureTyper software, and all related accessories**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5093** for **LinkS_{eq} assay designs, reagents, SureTyper software, and all related accessories**, please be advised that UMMC intends to award a contract to **Linkage Bioscience**, 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 1, 2017
Second Advertisement Date	May 8, 2017
Response Deadline from Objectors	May 15, 2017, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before May 22, 2017

Project Details

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

The University of Mississippi Medical Center (UMMC) seeks to purchase Human Leukocyte Antigen (HLA) typing kits, LinkSēq assay designs, reagents, SureTyper software, and all related accessories, from Linkage Bioscience to be able to perform by real time polymerase chain reaction (PCR). As the only HLA laboratory in the state of Mississippi, UMMC performs all tissue typing on organ donors for the Mississippi Organ Recovery Agency. HLA typing is required to be performed on all organ donors before allocation.

The current methodology used by the UMMC HLA laboratory for typing deceased donor's sequence specific priming (SSP) takes approximately 4-6 hours. The laboratory seeks to procure a real time PCR HLA typing kit that will reduce the amount of time required per typing. The product must use SYBR® green so that multiple trays can be amplified at once on a thermal cycler, and then subsequently analyzed on the real time PCR instrument. This is important as it allows multiple donors to be typed concurrently. The product also must be able to type all of the loci required by the United Network of Organ Sharing (UNOS) for deceased donors, and additionally should be able to resolve the specific alleles that correspond to those on the currently available single antigen bead antibody screening products. This will enable the lab to determine whether or not an allele-specific antibody is donor-specific, and will improve organ allocation.

LinkSēq assay designs, reagents, SureTyper software, and all related accessories reduces the total time to type an organ donor to approximately 2 hours. The improved turnaround time for HLA typing results would lead to a reduction in organ cold ischemia time, which in turn results in improved patient outcomes and fewer discarded organs. The current technique requires running PCRs in multiple 96-well trays, then running out the amplification products on multiple gels and manually reading the positive wells from the gel. The Linkage Bioscience HLA typing kit is a single 384-well tray that uses SYBR® green, allowing the amplification products to be detected without the need to run gels. The results are automatically analyzed using Linkage Bioscience's SureTyper software, reducing the likelihood of errors in data interpretation or transcription.

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

Linkage Bioscience is the only manufacturer that produces a PCR HLA typing kit with a method of typing 11 loci in one plate and molecular genotyping results in approximately 90 minutes on three trays simultaneously allowing typing up to three donors. Linkage Bioscience also offers a specialized typing tray that allows the lab to correlate the typing results with the currently available single antigen bead antibody screening tests. This allows the lab to determine at a higher degree of resolution whether or not the donor and recipient are compatible, and would be expected to improve organ allocation and patient outcomes.

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

Linkage Bioscience is the sole manufacturer and distributor of LinkSēq assay designs, reagents, SureTyper software, and all related accessories. Linkage Bioscience 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 expected amount to be expended for Linkage Bioscience for one year is approximately \$178,335.00. 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 **Linkage Bioscience products** (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 **Linkage Bioscience**. 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 May 15, 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:



890 Dubuque Avenue, South San Francisco, CA 94080 USA Phone: +1.415.346.5262 Fax +1.415.346.5360

March 29, 2017

To Whom It May Concern:

Linkage Biosciences, Inc. has developed and sells a proprietary product for typing Human Leukocyte Antigen (HLA) alleles. With less than 10 minutes of set-up time and no further operator intervention, LinkS_{eq}™ uses state of the art real-time PCR detection to provide complete molecular genotyping results in approximately 90 minutes. By contrast, legacy methods of molecular HLA typing require significant hands on time and can take 3 to 7 hours to obtain results. These other methods require manipulating and analyzing DNA gels or performing hybridization and washing of fluorescent beads, which are labor intensive processes completely eliminated using LinkS_{eq}. In addition to more streamlined laboratory processes, LinkS_{eq}'s data analysis is also automated, requiring no manual data entry, transferring of gel images and subsequent band analysis, or manual settings of probe thresholds. LinkS_{eq} technology provides digital positive or negative results analyzed directly from a Real-Time PCR instrument.

Linkage Biosciences is the sole manufacturer and distributor of these products.

Linkage's patented LinkS_{eq} technology provides distinct advantages to laboratories requiring molecular HLA genotyping. LinkS_{eq} is:

- The only molecular HLA typing method that uses melt curve analysis to determine allele identity (HLA type) based on DNA melting temperatures, a patented process in countries around the world.
- The only method able to amplify on a standard thermocycler for high throughput analysis.
- The only method that can be used on multiple Real-Time PCR instruments including both the Roche Light Cycler 480 and the Applied Biosystems Quant Studio 6.
- The only molecular HLA typing method that uses SureTyper™, a proprietary HLA analysis software, with features such as allele frequency tagging, HaploCheck for additional assignment confidence, virtual cross matching tool for DPA1 and DPB1, and more. Results are ready in a few seconds.

These points, combined with LinkS_{eq}'s robust chemistry and user friendly analysis create a unique product offering not available from any other vendor.

We hope this information is helpful. Please do not hesitate to call with additional questions.

Thank you,


Linkage Biosciences

Attachment B

**SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS5093
Accepted until May 15, 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