

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: February 16, 2017

Re: Sole Source Certification Number **SS5076** for **TLAB Transjugular Liver Biopsy Kits and accessories**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5076** for **TLAB Transjugular Liver Biopsy Kits and accessories**, please be advised that UMMC intends to award the purchase of the **TLAB Transjugular Liver Biopsy Kits and accessories** to **Argon Medical Devices** as the sole source provider of the **TLAB Transjugular Liver Biopsy Kits and accessories**.

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	February 16, 2017
Second Advertisement Date	February 23, 2017

Response Deadline from Objectors	March 2, 2017, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before March 3, 2017

Project Details

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

The University of Mississippi Medical Center (UMMC) seeks to purchase TLAB Transjugular Liver Biopsy Kits and accessories. The kits consist of transjugular biopsy needles, introducer sheaths, and catheters.

The TLAB Transjugular Liver Biopsy items are utilized under fluoroscopic guidance in obtaining histological samples from patients with acute or chronic liver disease who have severe coagulation abnormalities or ascites. The use of ultrasonographic guidance for percutaneous puncture of the right internal jugular vein is recommended to decrease the incidence of local cervical minor complications. For patients with severe coagulation abnormalities or ascites, standard percutaneous liver biopsy is associated with a high risk of hemoperitoneum, which can be life threatening. Transjugular biopsy is the alternative option that is better tolerated by patients.

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

Transjugular liver biopsies are checked regularly by moderate use of fluoroscopy. Ultrasonographic guidance avoids accidental puncture of the ipsilateral carotid artery and pneumothorax, and allows the most suitable puncture point to be chosen. Argon is the only product for transjugular liver biopsies with radiopaque catheter tips.

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

Argon is the sole manufacturer and distributor of the TLAB Transjugular Liver Biopsy Kits and accessories. See supporting letter from **Argon Medical Devices**, 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 **TLAB Transjugular Liver Biopsy Kits and accessories** is \$75,000. 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 **TLAB Transjugular Liver Biopsy Kits and accessories** (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 **Argon Medical Devices**. 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, March 2, 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



January 17, 2017

University of Mississippi Medical Center
2500 North State Street
Jackson, Mississippi 3921

Dear Sir or Ma'am,

Transjugular liver biopsies require specialized systems that enable clinicians to obtain a sample of the liver via a patient's natural vascular pathways under fluoroscopic guidance. Currently, only the TLAB® transjugular liver biopsy kits include a needle, a sheath, and catheters that are visible under fluoroscopic guidance. Argon Medical Devices is the manufacturer and sole distributor of the TLAB transjugular liver biopsy kits.

The complete TLAB Transjugular Liver Biopsy Kits from Argon Medical Devices include:

- 1 18-gauge (TL-18C) or 19-gauge (TL-19) transjugular liver biopsy needle
- 1 7F introducer sheath with a metal stiffening cannula
- 1 5F MPA catheter
- 1 5F straight catheter
- 4 sample retrieval swabs

Should you have any additional questions about Argon Medical Devices' TLAB Transjugular Liver Biopsy kits, please feel free to contact me at 972-272-3888.

Sincerely,

A handwritten signature in black ink that reads 'Thomas B. Younker'.

Tom Younker
Senior Product Director

5151 Headquarters Drive # 210
Plano, Texas 75024 USA
www.argonmedical.com

Attachment B

**SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS5076
Accepted until March 2, 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