

# Notice of Intent to Certify Sole Source

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**To:** Interested Parties

**From:** Stacy Baldwin  
Agency Procurement Officer

**Date:** February 4, 2016

**Re:** Sole Source Certification Number **SS5011** for **FibroScan® 502 Touch, powered by Vibration Controlled Transient Elastography (VCTE)**

**Contact Email Address:** [solesource@umc.edu](mailto:solesource@umc.edu)

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## Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5011** for **FibroScan® 502 Touch, powered by Vibration Controlled Transient Elastography (VCTE)**, please be advised that UMMC intends to award the purchase of the **FibroScan® 502 Touch** to **Echosens** as the sole source provider of the **FibroScan® 502 Touch**.

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

<b>Task</b>	<b>Date</b>
First Advertisement Date	February 4, 2016
Second Advertisement Date	February 11, 2016

Response Deadline from Objectors	February 18, 2016, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before March 31, 2016

## Project Details

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

The University of Mississippi Medical Center Department of Medicine/Infectious Diseases is requesting the purchase of the FibroScan ® 502 Touch, powered by Vibration Controlled Transient Elastography (VCTE). Because the U.S. Prevention Task Force made a one-time screening for Hepatitis C a Category 1 recommendation for all baby boomers (birth years 1945 – 1965), we anticipate that there will be an influx of people needing treatment for Hepatitis C, and we would like UMMC to be on the forefront. We would like to be able to provide FibroScan services for patients inside and outside of UMMC to be able to get accurate, inexpensive, and noninvasive liver testing, to allow them to avoid liver biopsy.

FibroScan uses a patented, and unique technique called Vibration Controlled Transient Elastography (VCTE). The use of this equipment makes it possible for individuals to have their liver disease measured without liver biopsy, and the results are highly reliable and correspond more closely than any other non-invasive measure to actual liver disease. No other device offers VCTE, and measurements by simple transient elastography are less reliable. Liver biopsy is much more expensive and invasive, and there can be error based on where the sample of liver tissue is collected. FibroScan can diagnose cirrhosis, which is very important for providing information to guide hepatocellular carcinoma (HCC) screening for the lifetime of the individual, screening for esophageal varices, and to determine the urgency of treatment. The FibroScan is used widely in Europe as the first-line tool for liver fibrosis evaluation.

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

This purchase is needed for research and clinical care reasons at UMMC and throughout Mississippi, as at this point there are no other FibroScans in Mississippi. In research, NIH has agreed to pay half of the cost of the FibroScan because they are highly interested in gathering FibroScan data from the Women’s Interagency HIV Study (WIHS) cohort at UMMC, which are being collected in all the other cohort sites, via FibroScan with VCTE. This is the only equipment that will meet the needs with the technology provided via VCTE, as no other device offers this capability. In order to participate with this particular NIH study, the FibroScan with VCTE is needed. In addition, the Department of Medicine/Digestive Diseases is interested in using FibroScan for clinical trials. FibroScan is very important for clinical care reasons, as a non-invasive, rapid, and clinic-based approach to measuring liver fibrosis, without the invasiveness of liver biopsy. Being the only facility in the state with this capability will allow for surrounding practices to send certain patients to UMMC for the FibroScan versus making the patient endure an invasive procedure.

The FibroScan powered by VCTE is now the gold standard noninvasive test. The machine fits on a small cart and can be moved from room to room. FibroScan provides information to guide the operator in the choice of the correct probe, when the probe is positioned correctly, and lets the operator know the quality of the signal and the best pressure to use. It also provides a printed report that can be given to the patient or transmitted electronically. When used for research purposes, those studies specifically ask for FibroScan results, and cannot be substituted with other alternatives such as transient elastography and/or serological markers.

Transient elastography, and serological markers are the other noninvasive alternatives to liver biopsy. Transient elastography is expensive and must be referred out, and serological markers have limitations in accuracy, especially in mid-levels of fibrosis. VCTE through FibroScan offers increased accuracy, decreased cost, the ability to conduct the test quickly in clinical practice settings, and correlation with serological markers greatly limit the number of individuals who need progress to a liver biopsy to determine accurate fibrosis. Although high body mass index in obesity makes measurements more difficult, there is a probe that is specifically used for obese patients to increase the reliability.

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

This equipment is FDA-approved for non-invasive measurement of Hepatitis B and C liver fibrosis, which measures liver stiffness through ultrasound shear wave measurement through the liver. Its accuracy is higher than any other noninvasive tests, and is most accurate when combined with serological biomarkers of fibrosis. VCTE is the only product which meets the criteria of CPT code 91200 and it is the only device listed on the Clinical guidelines from American Association for the Study of Liver Diseases (AASLD), European Association for the Study of the Liver (EASL), the World Health Organization (WHO), and the National Institute for Health and Care Excellence (NICE). There are also over 850 white papers on VCTE currently.

At this point, the Women's Interagency HIV Study has been engaged in Hepatitis research in all of the sites around the country using FibroScan. Studies that have been funded by NIH include two studies: R56AI52065, HIV and HCV Disease Progression in Women on HAART, with Andrea Kovacs as PI, and R01AI087176, Visceral Adiposity, HIV and HCV: Biologic Mediators of Hepatic Steatosis, with Phyllis Tien as PI. Dr. Tien has also proposed a WIHS-wide study as a follow up of her existing R01. There are also two small NIH-funded substudies in WIHS that use the FibroScan: The Effects of HIV/HCV and menopausal transition on steatosis and fibrosis, with Phyllis Tien as PI, and Immunologic and Clinical Consequences of Hepatitis C Cure with Audrey French as PI.

Echosens is the only United States distributor of FibroScan. It is not available from any other distributor. See supporting letter from **Echosens**, 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 **FibroScan® 502 Touch** is \$162,350. The company provides on-site training and certification of 3-6 operators, each of whom must perform 3 studies under supervision of a certified trainer. The service

agreement includes annual probe calibration for the two probes, and Echosens has offered discounted prices for parts needed. On-site training will be provided once a year, as well as any on-site repairs. 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 **FibroScan® 502 Touch** (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 **Echosens**. 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, February 18, 2016, at 3:00 p.m. (Central Time) to [solesource@umc.edu](mailto:solesource@umc.edu). Responses may be delivered via email to [solesource@umc.edu](mailto: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](mailto:solesource@umc.edu).

Attachment A: Vendor Correspondence  
Attachment B: Objection Certification

## Attachment A



### Echosens North America, Inc. Sole Source Justification

Echosens North America, Inc. is the sole source provider of the goods and services outlined in quotation (please see the attached quotation). Following is the list of proprietary items, services, and features contained in Echosens North America, Inc.'s quotation. For clarity, the list is divided into the areas of "Liver Stiffness Testing" and "Training and Education."

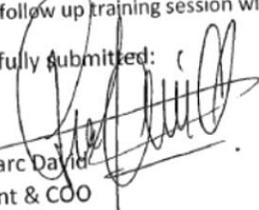
#### Liver Stiffness Testing:

- Vibration Controlled Transient Elastography (VCTE™) System validated in more than 900+ peer-reviewed clinical publications (see VCTE bibliography)
- Exclusive VCTE System used in multiple clinical studies to establish normative data
- 3 cubic-centimeter Explored Volume Shear Wave Propagation Map
- M+ probe for delivery of shear wave and measurement of shear wave speed through liver for Skin-to-Liver- Capsule distance is 25-35 mm (25 MHz)
- Controlled force 50 Hz Shear Wave Attenuator
- Automatic probe-specific selector guide only on M+ and XL+
- Manual probe specific program(s) selection on optional S probe
- Liver Examination Depth (S1: 15-40mm, S2: 20-50mm, M+: 25-65mm, XL+: 35-75mm)
- Quality Controlled measurement tools, including:
  - TM-mode and A-mode ultrasound signals to localize liver parenchyma
  - Liver Targeting Tool to affirm proper location of probe tip
  - Automatic "invalid Measurement" feature
- Shear Wave Speed (m/sec) and Liver Stiffness (kPa) calculations per measurement
- Optional CAP™ Ultrasound Attenuation Rate (quantitative parameter for steatosis measured in dB/m)
- Integrated IQR and IQR/Median real-time update per measurement
- Integrated Windows 7 operating system (2.0.5 version) and data acquisition software, reducing study complexity, optimizing data consistency and patient data protection through encryption
- Application specific system console provides a touch-screen monitor, integrated power isolation transformer and an 128 GB hard drive
- Ergonomic design allows operation from a seated position for data acquisition and data review
- Report output in PDF, XLS, FIBX formats and optional DICOM connectivity
- Logo on reports

#### Echosens North America, Inc.'s Training Package includes:

- Initial training session at time of installation
- One follow up training session within 12 months (up to 6 operators total)

Respectfully submitted:

  
Jean-Marc David  
President & COO  
Echosens North America, Inc.

Attachment B

**SUBMITTED IN RESPONSE TO  
Sole Source Certification No. SS5011  
Accepted until February 18, 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