

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

PR 689-14-3-7821-0190

1. **Contracting Activity:** Department of Veterans Affairs, VISN 1, VACT Medical Center, PR# 689-14-3-7821-0190.
2. **Nature and/or Description of the Action Being Processed** . The VA Connecticut Healthcare System (VACHS) proposes to negotiate a noncompetitive award (sole source) with Sandhill Scientific, Inc. 8955 South Ridgeline Blvd., Suite 500, Highland Ranch, CO 80129, for a FibroScan ultrasound-based liver elastography system, including M and XL probes, all set up, on-site training and a comprehensive extended service agreement for one (1) year plus four (4) option years. The intent is to award a firm fixed priced new contract to procure the FibroScan.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The FibroScan 502 touch w/m+ probe is highly specialized equipment that will be used in the liver suite. It is used in the evaluation of patients with chronic Liver disease (Hepatitis C, Cirrhosis- a growing problem among Veterans). The FibroScan determines the degree of fibrosis. Total estimated cost to purchase one (1) FibroScan 502 Touch w/Probe to include a base plus four (4) option years extended service agreement is . Estimated delivery is four (4) weeks after receipt of award.
4. **Statutory Authority Permitting Other than Full and Open Competition:**
 - (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
 - () (2) Unusual and Compelling Urgency per FAR 6.302-2;
 - () (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
 - () (4) International Agreement per FAR 6.302-4
 - () (5) Authorized or Required by Statute FAR 6.302-5;
 - () (6) National Security per FAR 6.302-6;
 - () (7) Public Interest per FAR 6.302-7;
5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**

Sandhill Scientific, Inc., 8955 South Ridgeline Blvd., Suite 500, Highlands Ranch, CO 80126 is the only known distributor that sells this specific equipment in the US. This equipment will benefit our veterans, and will reduce cost to the VACT Healthcare. Without this purchase, VACT will continue to incur added expense due to Non-VA Care. It was approved by the US-FDA earlier this year and is now commercially available. Using this device will not only result in minimizing risk and discomfort to our Veterans, but will also lead to cost and time savings.

The FibroScan is used in the clinical management of patients with liver disease to determine the degree of fibrosis. Fibrosis is stiffening and scarring of the liver caused by different liver diseases and conditions such as fat liver disease, liver damage due to alcohol abuse and chronic viral hepatic. Fibrosis is the most important correlate of the risk of progression into cirrhosis in chronic liver disease. Detecting fibrosis early provides an opportunity to change a patient's lifestyle to prevent

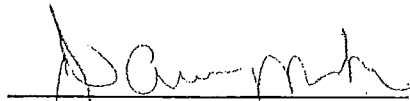
the fibrosis becoming more widespread and leading to an even more severe chronic liver disease. Based on a technology called transient elastography, FibroScan assesses liver shear wave speed and equivalent stiffness at 50Hz in a rapid, simple, non-invasive and totally painless way. It is a non-invasive, quick and simple test that works using ultrasound. All patients get their FibroScan results immediately. These results, displayed as readings rather than an image, will show whether there are any regions of scarring and also how stiff the liver is. Liver disease is increasingly seen among individuals with obesity and the metabolic syndrome. The FibroScan XL probe provides enhanced capability of obtaining precise readings in obese patients where the thickness of abdominal wall would otherwise impair detection sensitivity. FibroScan has been used for many years in most parts of the world and there is a large scientific literature to evidence its utility in the noninvasive assessment of chronic liver disease. The FDA approved the use of FibroScan in the United States in April 2013. Based on its ease of use and proven lack of any significant adverse effects, there is currently no comparable test for quick, non-expensive, multiple, and reproducible fibrosis assessment in the liver.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Sandhill Scientific, Inc. is the only known US-FDA vendor that has the state of the art FibroScan equipment requested. A Sources Sought Notice has been published. No responses are anticipated because Sandhill Scientific, Inc. is the only US distributor for this highly specialized piece of equipment which is manufactured in France by Echosens. While there are additional imaging modalities for the diagnosis of fibrosis, including MR and b-mode ultrasound devices, which may at times become necessary for more detailed investigation of fibrosis and other pathological changes in the liver, none of these methods can compare to the ease of use, quick and immediate evaluation, user-friendliness, and relatively low price of FibroScan. There is simply no comparable technology on the market that would fulfill all the requirements needed for a complete, accurate, non-invasive, low cost testing.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The cost to the government will be determined fair and reasonable by comparing the cost to the same FibroScan equipment from other VA locations, specifically most recently, the VA Boston Healthcare System.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** An online market research was conducted to find that Sandhill Scientific, Inc. has the distribution rights for the United States market. They were FDA approved in April 2013.

Any Other Facts Supporting the Use of Other than Full and Open Competition: VACTHS GI/Liver section has a substantial professional expertise in the diagnosis of chronic liver disease. Our faculty members regularly visit major national conferences and instrumental exhibits, read and publish in major journals of the field, provide CME-accredited courses in hepatology, and are well aware of the currently available opportunities and the equipment for the noninvasive testing of chronic liver disease. FibroScan is a non-invasive study that uses a modified ultrasound probe to measure the velocity of a shear wave created by a vibratory source. Estimates of stiffness of the liver by ultrasound correlate with fibrosis stage. It can be performed in approximately 95% of patients. This study will decrease the need for biopsies, which in turn decreases anxiety and discomfort to the patient.
9. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** No responses are anticipated to the Sources Sought Notice.
10. **A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before making subsequent acquisitions for the supplies or services required:** Ongoing

market research will be conducted if and when further FibroScan equipment is needed to determine if any additional manufacturers have entered the market.

11. **Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.



Name: Jo-Ann Machle
Title: Administrative Officer
Facility: VACT

5/9/14
Date

12. **Approvals in accordance with FAR 6.304**

- a. Contracting Officer's Certification (required): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.


james.corbett2@va.gov

Digitally signed by james.corbett2@va.gov
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Date: 2014.05.11 08:54:54 -04'00'

JAMES CORBETT
CONTRACTING OFFICER
VAMC CT West Haven

Date

- b. NCM/PCM/DESIGNEE: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



CAROL H. DOMINGUE
SUPERVISORY CONTRACT OFFICER
For Deborah Mattingly, Director
Network Contracts Office 1 (NCO 1)

5/13/2014
Date