

**DEPARTMENT OF THE NAVY
NAVAL MEDICAL LOGISTICS COMMAND
LIMITED SOURCE JUSTIFICATION**

1. **IDENTIFICATION OF THE AGENCY AND THE CONTRACTING ACTIVITY:** This is a Limited Source Justification (LSJ). The Naval Medical Logistics Command (NMLC), acting on behalf of Naval Hospital (NH) Oak Harbor, intends to award a delivery order against Federal Supply Schedule (FSS) contract, GS-24F-1184C, pursuant to the authority of the Multiple Award Schedule Program (MASP).

2. **NATURE/DESCRIPTION OF CONTRACT ACTION:** This is a limited source action for an automated laboratory urine analyzer with the capability to do body fluid analysis and chemistry analysis. This unit is manufactured and distributed by Iris International 9158 Eton Ave, Chatsworth, CA 91311. The Government intends on awarding a Firm Fixed Price (FFP) delivery order.

3. **DESCRIPTION OF REQUIRED SUPPLIES/SERVICES:** The proposed acquisition is for an automated laboratory urine analyzer with the capability to do body fluid analysis and chemistry analysis manufactured and distributed by Iris International.

The system shall be able to do the following: chemistry analyzing, microscopic analyzing, body fluid analyzing, and connection to the laboratory information system. The system shall be capable of providing a complete urinalysis with microscopic exam. The microscopic exam shall be able to be performed on the instrument without external processing. The system shall fully automate the complete routine urinalysis profile, including urine test strip chemistry, specific gravity, color, clarity, and microscopic analysis, providing quantitative or qualitative counts of things such as cells, casts, crystals, and microorganisms. The system shall be able to run at least 200 urine chemistry samples or 70 urine microscopy samples per hour. The system shall be able to complete the following chemistry tests: bilirubin, urobilinogen, ketones, ascorbic acid, glucose, protein, blood, pH, nitrite, and leukocyte esterase; specific gravity, color and clarity simultaneously while using digital flow imaging and automatic particle recognition technology to classify and quantify at least 12 urine particles. The system shall operate with at least the following wavelengths: 472nm, 525nm, and 630nm for test strip photometry. The system shall have a sample rack of at least 10 tubes. The test strip capacity shall be from at least 1 to 300 with auto feeding capability. The system shall allow for onboard storage of at least 9,500 patient results. The system shall have automatic barcode identification to prevent sample mistakes. The system shall be able to perform body fluid cell counts with a minimal sample volume of 2mL or less. The linearity of the system shall be able to count cell quantities down to zero cells present. The system shall allow the user to edit a microscopic exam and differentiate specific cellular material in the sample. The system shall fit into a space equal to or less than the following dimensions: 2 ft height, 6 ft width, and 2.5 ft depth, this includes the computer system and printer. The system shall include service/maintenance after the first year as an option. The electrical requirements of the system are 120 V, 60 Hz, less than 20 Amps, and single phase.

Vendor shall be an Original Equipment Manufacturer (OEM) authorized dealer, authorized distributor or authorized reseller for the proposed equipment/system such that OEM warranty and service are provided and maintained by the OEM. All software licensing, warranty and service associated with the system shall be in accordance with the OEM terms and conditions.

Local NH Oak Harbor [REDACTED] estimated in the amount of [REDACTED] will be used for this requirement. Total contract, inclusive of all options is [REDACTED]

4. IDENTIFICATION OF THE JUSTIFICATION RATIONALE AND/OR DEMONSTRATION OF CONTRACTOR'S UNIQUE QUALIFICATIONS: The statutory authority which permits restricting consideration of schedule contractors to fewer than that required in FAR 8.405-1 is 41 U.S.C. 251, as implemented by FAR 8.405-6(a)(1)(i)(B) Only one source is capable of responding.

Iris International (Iris Diagnostics) is the only vendor that can provide a fully automated laboratory urine analyzer capable of body fluid and chemistry analysis that meets all the minimum requirements of the Government. Iris International is the only vendor that provides a system capable of doing body fluid testing, microscopy, and chemistry all with one system, all in-house, which is available on FSS. Body fluid testing has been cited as a deficiency during regulatory audits. The facility has small space available (2ft H by 6ft W by 2ft D) for these testing capabilities and therefore requires these capabilities to all be available in one system with a single sample. No other system can provide all fully automated testing with a less than 2mL sample. Without a fully automated in-house system, testing results for patient will be delayed which would affect diagnosis and treatment of the patient. If multiple devices were to be purchases instead of a fully automated system, the system would not meet the space requirements put in place by the facility and the whole laboratory area would have to be redesigned to meet that new requirement, costing the Government millions of dollars in facilities modifications as well as forcing patient testing and treatment to be sent out to the economy. No other vendor available on the FSS can provide a system that meets these size requirements along with all other minimum requirements of the Government.

5. DETERMINATION OF BEST VALUE: In accordance with FAR 8.404(d), GSA has already determined the prices of equipment and fixed price services of the schedule contracts to be fair and reasonable. Therefore, ordering activities are not required to make a separate determination of fair and reasonable pricing. The Contracting Officer will determine, using the procedures in FAR 8.405, that the order represents the best value and results in the lowest overall cost alternative (considering price, special features, administrative costs, etc.) to meet the Government's needs. The Contracting Officer may also seek additional discounts before placing the order.

6. DESCRIPTION OF MARKET RESEARCH: Market research was conducted by technical experts in the March/April 2012 timeframe. This research included a thorough search of open market contractors and FSS contractors. Search engines utilized include Google, VA, FSS, and GSA Advantage. Also, a search was conducted through the ECRI 2012 sourcebook catalog.

Siemens Clinitek and Sysmex provide a fully automated laboratory urine analyzer capable of completing chemistry and microscopic analysis but none are able to accommodate the body fluid testing and complete all testing necessary from a single less than 2mL sample. The Siemens Clinitek Atlas system and the Sysmex UF-1000i system does not meet the throughput requirement nor does it have the capability to do body fluid analysis or both chemistry and microscopic analysis. The Siemens Clinitek AUWi system does not allow for the throughput necessary to meet the minimum requirement and does not have the capability for body fluid testing. Also, Sysmex offers a standalone body fluids analyzer. Sysmex does not offer a system with all capabilities necessary to meet the requirement. If individual system components were to be bought from a different vendor, the systems would exceed the space requirements addressed above. There are a number of other sole body fluid analyzers that are not available via the FSS. These manufacturers do not meet the minimum requirements of the Government as they cannot provide complete automated urinalysis. Iris International (Diagnostics) is available on a FSS and is the only vendor that can provide a system that meets all the minimum requirements of the Government.

7. ANY OTHER SUPPORTING FACTS: This procurement uses a FSS Schedule and will be solicited and awarded in accordance with FAR Subpart 8.4.

8. ACTIONS TAKEN TO REMOVE BARRIERS TO COMPETITION: All future requirements will be handled on a case-by-case basis. As the barriers that preclude the agency from the requirements of section 8.405-1 (SUPPLIES) are due to limited vendors on schedule, no actions can be taken by this agency to remove those barriers. If additional vendors are added to the FSS for this equipment, they will be considered as applicable.

9. CONTRACTING POINT OF CONTACT: The point of contact at NMLC, Fort Detrick, Maryland is [REDACTED], commercial [REDACTED] or by e-mail at [REDACTED]

10. TECHNICAL AND REQUIREMENTS CERTIFICATION REQUIRED BY FAR 8.405-6(e)(x)

I certify that the facts and representations under my cognizance which are included in this justification, which form a basis for this justification, are complete and accurate.

[Redacted] Phone Date
Technical Reviewer

[Redacted] Phone Date
Requirements Cognizance

CONTRACTING OFFICER CERTIFICATION

I certify that this justification is accurate and complete to the best of my knowledge.

[Redacted] Phone Date
Contracting Officer