

**JUSTIFICATION AND APPROVAL  
OTHER THAN FULL AND OPEN COMPETITION**  
Justification and Approval # NMLC-10050-12

**1. Identification of the agency and the contracting activity.**

This justification is executed by the Naval Medical Logistics Command (NMLC), Fort Detrick, Maryland, on behalf of the Department of Defense (DOD) Drug Testing Program Office requirements.

**2. Nature and/or description of the action.**

This action is for the award of a firm fixed price contract for maintenance services on government owned Roche Hitachi Modular and Cobas High Speed Screening Analyzer equipment. The proposed source is Roche Diagnostics, Incorporated (Roche), 9115 Hague Road, Indianapolis, Indiana 46250.

**3. Description of the supplies/services required.**

The DOD Drug Testing Program Office has a critical requirement for full maintenance service support (i.e., general, preventive, and repair maintenance, telephone support, software and hardware upgrades and updates, repair and upgrade parts) on government-owned Roche Hitachi Modular and Cobas High Speed Screening Analyzer Systems.

The equipment is located at seven DOD military drug testing facilities located in Navy Drug Screening Laboratory (NDSL) Great Lakes, Illinois; NDSL Jacksonville, Florida; NDSL San Diego, California; Army Forensic Toxicology Drug Testing Laboratory (AFTDTL) Fort Meade, Maryland; AFTDTL Tripler Army Medical Center, Hawaii; Headquarters Air Force Drug Testing Laboratory (HQ AFDTL) Lackland Air Force Base, Texas; and Armed Forces Medical Examiner System (AFMES), Dover Air Force Base, Delaware.

Estimated value:

Base Year FY2013 [REDACTED]  
First Option Year FY2014 [REDACTED]  
Second Option Year FY2015 [REDACTED]  
Third Option Year FY2016 [REDACTED]  
Fourth Option Year FY2017 [REDACTED]

Funding will be provided by Navy and Marine Corps Public Health Center through [REDACTED] in fiscal years 2013-2017.

**4. Identification of the statutory exceptions permitting other than full and open competition.**

The statutory authority permitting other than full and open competition for this acquisition is 10 U.S.C. 2304(c)(1), Only One Responsible Source as implemented by paragraph 6.302-1 of the Federal Acquisition Regulation (FAR).

**5. Demonstration that the proposed contractor's unique qualifications or the nature of the acquisition requires use of the authority cited.**

Roche is the only company known to be able to provide continuous support for all Hitachi Modular D/P and Cobas C311 Analyzer Systems used in the DOD laboratories. This equipment is used for initial screening identification drugs of abuse and their metabolites in urine, which is the cornerstone of the DOD Drug Testing Program. Roche is the only known source capable of providing personnel, who have original equipment manufacturers (OEM) training to perform service and upgrades on the analyzer systems, with a minimum of two years experience servicing this equipment in high volume production facilities. Additionally, Roche is the only known source that can provide the required telephonic support, maintenance support with OEM parts, software and hardware updates and upgrades with guaranteed response and repair times that are critical for the DOD drug testing laboratories' continued operation to meet their mission. Since the timely reporting of results is critical, (a positive drug analysis is potentially career ending and almost always result in court martial or administrative separation proceedings), the

quality and integrity of the laboratory results is dependent on maintenance of equipment by highly trained and qualified manufacturer representatives.

The government could solicit services from another source, if the government equipment was from another manufacturer. Replacing all of the equipment covered under this maintenance contract would cost the government over [REDACTED]. That cost does not include the logistics of deinstallation of current equipment, installation of new equipment, software programming to make the new equipment compatible with existing laboratory systems (i.e., laboratory information management system – LIMS), training employees on new equipment, validation of equipment and analyses on new equipment, etc. This option is not feasible or reasonable for the drug testing program.

**6. Description of efforts made to ensure that offers are solicited from as many potential sources as practicable.**

Market research was performed; the result of which is in paragraph 8. This requirement will be posted to Navy Electronic Commerce Online (NECO) and/or Federal Business Opportunities (FedBizOpps) in accordance with FAR 5.202. At the present time there are no other known potential sources.

**7. Determination by the Contracting Officer that the anticipated cost to the Government will be fair and reasonable.**

The Contracting Officer shall determine the anticipated cost to the Government of the supplies/services covered by this Justification and Approval will be fair and reasonable by conducting a price analysis before an award is made. In addition, the Government anticipates that the negotiated contract price will reflect a discount from Roche's commercial price list and will be determined fair and reasonable.

**8. Description of the market survey conducted and the results, or a statement of the reasons a market survey was not conducted.**

A market survey was conducted in March 2012. The market survey involved internet searches and discussions at conferences with representatives in the field of forensic toxicology regarding companies, other than Roche, who could provide Roche Analyzer Systems (hardware and software) updates, upgrades, and maintenance, Roche parts, Roche-trained service personnel, and required service response times. The market survey showed the existence of other vendors who could provide maintenance on limited Roche equipment but, not on the extensive amount of Roche equipment and software systems currently utilized in the DOD laboratories. Roche is the sole proprietor of their software systems and, as such, is the only vendor who can provide updates and upgrades to ensure compatibility with the DOD laboratories' information management system. No other vendors were found who could provide service personnel with Roche original equipment manufacturers training and experience.

**9. Other facts supporting the use of other than full and open competition.**

The DOD Drug Testing Program is mandated by DOD Directive 1010.1 under the Undersecretary of Defense for Personnel and Readiness, and is under the continuous review of the Services Surgeons General. The DOD drug testing program has invested extensive resources in software and hardware systems that are compatible with Roche Analyzer Systems. These systems have gone through rigorous testing and validation in order to be certified for use in forensic laboratories because results must not only be scientifically valid but they must also be legally defensible in a court of law. This equipment must be maintained at the highest standards to ensure forensic integrity and to ensure continued operation so laboratories can provide results in a timely manner so unit commanders can assess unit readiness and take swift action to separate drug users.

Failure to provide this level of support for the government-owned Roche equipment at the military drug testing laboratories would result in the laboratories inability to perform their mission and would impact the safety and readiness of military units.

**10. Listing of Sources, if any, which expressed, in writing, an interest in the acquisition.**

To date, no other sources have written to express an interest. The notices required by FAR 5.201 shall be published, and any bids or proposals received shall be considered.

**11. Statement of actions, if any, the agency may take to remove or overcome any barriers to competition before any subsequent acquisition for the supplies or services required.**

For the reasons set forth in Paragraph 5, NMLC has no plans at this time to compete future contracts for the types of services covered by this document. If another potential source emerges, NMLC will assess whether competition for future requirements is feasible.

**12. Point of Contact.**

The point of contact at the Naval Medical Logistics Command, Fort Detrick, Frederick, MD, regarding the contents of the sole source justification is [REDACTED], who may be reached at [REDACTED].