



DEPARTMENT OF THE NAVY
 NAVSUP FLEET LOGISTICS CENTER SIGONELLA
 PSC 812 BOX 3560
 FPO AE 09627

IN REPLY
 REFER TO:

JUSTIFICATION AND APPROVAL
 FOR OTHER THAN FULL AND OPEN COMPETITION

1. Contracting Activity.

Fleet Logistics Center Sigonella Detachment Naples.

2. Description of the Action Being Approved.

This Justification and Approval (J&A) authorizes the establishment of a Indefinite Delivery Indefinite Quantity (IDIQ) Type Contract with DASIT SPA (the authorized retailer of Sysmex in Italy) Via Merendi 22, Cornaredo 20010, Italy for supplies and services on a sole source basis. This J&A shall be effective from date of approval through the end of the contract term.

3. Description of Supplies/Services.

This contract is for the provision of hematology and coagulation laboratory supplies and services for 2 Sysmex CA560 Coagulation Analyzers, a Sysmex Xt-2000i Hematology Analyzer and a Sysmex Xs-1000i Hematology Analyzer. This shall include full risk maintenance service (i.e., calibration), repair (parts and labor), reagents and all consumables necessary to perform all required testing.

The period of performance consists of a base period of one (1) year, and four option years, for a total of five contract years.

Estimated Dollar Value

Base Year Price	Period of Performance		
	01 Sept 2014 – 31 Aug 2015		
Option Year 1	01 Sept 2015 – 31 Aug 2016		
Option Year 2	01 Sept 2016 – 31 Aug 2017	€	
Option Year 3	01 Sept 2017 – 31 Aug 2018		
Option Year 4		€	
Total Contract Price		€	

- Budget Exchange Rate used is Fiscal Year 2014 (\$1 = Euro 0.7655) foreign currency fluctuation budget rate obtained from the Office of Secretary of Defense (Comptroller);

4. Statutory Authority Permitting other than full and open competition.

10 USC 2304(c)(1), as implemented by FAR 6.302-1, Only one responsible source and no other supplies or services will satisfy the agency requirement

5. Rationale Justifying Use of Cited Statutory Authority.

USNH Sigonella currently utilizes the Sysmex CA560 and XT/XS systems for coagulation and hematology testing. These instruments are fully correlated and validated for the US Naval Hospital Sigonella's use. These instruments are compatible with Laboratory Information System and are capable of transferring automated results to the Composite Healthcare System (CHCS). The U.S. Naval Hospital Sigonella laboratory test methods have been validated (tested and verified) using the Sysmex medical laboratory instruments, reagents, and supplies. As a result, the U.S. Naval Hospital Sigonella Laboratory operating procedures have been written using the Sysmex instruments, reagents, and supplies.

Market research was conducted in the commercial marketplace and by comparing different brands, and for the potential suppliers who could provide the required service and supplies, with special care looking for vendors on the market that represent other firms so that all viable products were considered.

The continuity of laboratory services utilizing the Sysmex CA560 and XT/XS Analyzers is crucial to ensure patient care service.

The following specific characteristic and critical elements were considered:

1. Deviation from the standards and protocols currently in place:

Other brands were considered in our market research, Instrumentation Laboratory and Beckman Coulter, but the Sysmex CA560 and Sysmex XT/XS are the only systems that can fully satisfy the Government's need. By only utilizing the Sysmex CA560 and XT/XS, the USNH Sigonella can continue to use the same laboratory methodology and provide the same service without any interruption or stoppage with the same standard of care to patient testing as well as the established standard of service currently being provided to the ordering providers.

Different instruments and technology would cause a deviation from the standards and protocols currently in place which would require a total re-writing of these procedures, increasing the administrative burden and stopping the Laboratory work for an unknown period of time. A deviation without a change in standards and protocols could result in erroneous test results for patients.

For patient care standards the equipment must be maintained by an authorized manufacturer technician under a timely manner and not by other sources; any modifications done to Sysmex instruments by a third party will void the warranty which is in place and disallow any future coverage.

2. Space/facilities limitations:

Because of our space/facilities limitations, the analyzer must be a table top and fit into the space to where it is currently designated. The analyzers must not exceed the following physical and environmental/specifications:

a. For Coagulation Analyzers:

Width = 22.5 inches
 Height = 19.5 inches
 Depth = 19.5 inches
 Humidity = 10-80%
 Temperature = Operational: 18-32 °C
 Exposure: -30-50 °C

b. For Primary Hematology Analyzer:

Width = 20.9 inches
 Height = 24.8 inches
 Depth = 28.3 inches
 Humidity = 10-80%
 Temperature = Operational: 18-32 °C
 Exposure: -30-50 °C

c. For Secondary Hematology Analyzer:

Width = 12.6 inches
Height = 15.9 inches
Depth = 16.3 inches
Humidity = 10-80%
Temperature = Operational: 18-32 °C
Exposure: -30-50 °C

The Sysmex Analyzers meet all these requirements.

3. Compatibility with the DoD computerized health record, Composite Health Care System (CHCS).

The coagulation and hematology analyzers must be compatible with the DoD computerized health record, CHCS. The Sysmex Analyzers are compatible with CHCS. In keeping the Sysmex Analyzers, the learning curve for the technicians operating the analyzers would be virtually non-existent; reference ranges will remain the same affording a seamless turnover to the ordering providers; and finally the Standard Operating Procedures will not have to be rewritten. Implementation of a different analyzer requires the re-writing/updating of CHCS test methods for new reference ranges, our technicians will require extensive training causing delays in implementation of the new system and thereby potentially causing a delay in patient care.

The Sysmex Analyzers are currently compatible with the DoD CHCS. The use of a new system would require the CHCS administrator to develop computer codes to be compatible with the new system based on their specific software language, and then re-writing the test methods in CHCS then mapping them over to the Armed Forces Health Longitudinal Technology Application (AHLTA). Additionally, there is no guarantee once CHCS maps with AHLTA that the analyzer codes will work jointly and this could cause potential delays and erroneous test results in patient care.

4. The Sysmex analyzers are FDA approved.

Source Selection Information – See FAR 2.101 and 3.104

If a different brand is procured, the following changes will have to take place:

- Re-training of all technical staff on a new system. This training usually involves securing 3-5 key operator slots wherein operating technicians and supervisors attend specialized training at the manufacturer's location for extensive training on troubleshooting problems that may arise during testing.
- Re-establishment of reference ranges. All methodologies, and likewise, all manufacturers, have their own reference ranges for the test performed on the analyzers. These reference ranges must be correlated with the old systems currently in place, validated and clinical reportable ranges established. These ranges are then presented to ECOMS (Executive Committee of the Medical Staff).
- Once accepted by the medical staff, new test methods in the DOD's Composite Health Care System (CHCS) must be built and validated in USNH Sigonella's Information Systems through guidance and support from Military Health Systems (MHS). Further, the drivers for the new analyzer need to be installed, and communication between the analyzer and CHCS must be established. Once this takes place, validations of all the tests confirming results must cross over from CHCS to AHLTA (Armed Forces Health Longitudinal Technology Application) and the Essentris Medical Records system. This process, depending on the driver installation and test method file builds, can potentially take up to 6 months.

The above changes could result in a cost of approximately \$500,000.00 to the government.

USNH Sigonella is requesting cost per test contract for 2 Sysmex CA560 Coagulation Analyzers, 1 Sysmex XT2000 Hematology Analyzer and 1 Sysmex Hematology Analyzer XS1000. The instruments are all currently on board and are only 2 years old. Previous Cost per Tests contracts did not meet laboratory requirements. Procuring the services included with the Sysmex analyzers will not require training and writing of procedures. Also re-establishment of reference ranges will not be necessary.

Furthermore, Sysmex Corporation when contacted on 16 April 2013, regarding solicitation bidding, responded that DASIT SPA is the sole and exclusive distributor of Sysmex supplies and services in Italy, as dated by their exclusivity letter of 18 April 2013.

Based on the information above, and considering that the USNH has space facility limitations, continuing to utilize the current hematology and coagulation technology is the only acceptable manner of proceeding with the current requirement. Therefore, the Government requires a sole source to DASIT SPA since they are the only authorized dealer for the Sysmex analyzers in the commercial market place in Italy.

6. Description of Efforts Made to Solicit Offers from as Many Offerors as Practicable.

Sysmex Corporation was contacted in regards to providing a source list for Sysmex products in Italy. However, based on the "exclusivity letter" received by the company on 18 April 2013, DASIT SPA is the only company that can provide the US Naval Hospital Sigonella with the Sysmex equipment, consumables, tests and maintenance services in Italy.

7. Determination of Fair and Reasonable Cost.

The Contracting Officer has determined the anticipated cost to the Government of the supplies/services covered by this J&A will be fair and reasonable.

8. Actions to Remove Barriers to Future Competition.

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

9. Contracting Point of Contact

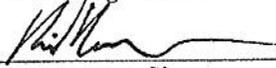
Sebastiano Paciello
Contracting Officer
NAVSUP FLCSI-NAPLES
DSN: 626-3848
Email: Sebastiano.Paciello.IT@eu.navy.mil

CERTIFICATIONS AND APPROVAL

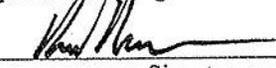
TECHNICAL/REQUIREMENTS CERTIFICATION

I certify that the facts and representations under my cognizance which are included in this Justification and its supporting acquisition planning documents, except as noted herein, are complete and accurate to the best of my knowledge and belief.

Technical Cognizance:

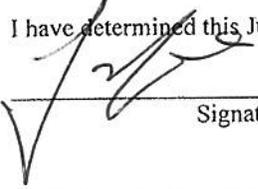
	David J Rogers	624-4731	4 Sep 2014
Signature	Name (Printed)	Phone No.	Date

Requirements Cognizance:

	David J Rogers	624-4731	4 Sep 2014
Signature	Name (Printed)	Phone No.	Date

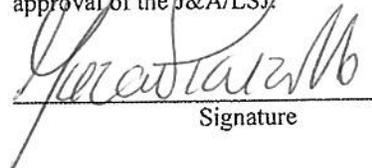
LEGAL SUFFICIENCY REVIEW

I have determined this Justification is legally sufficient.

	Josephine M Dezin		26 sept 14
Signature	Name (Printed)	Phone No.	Date

CONTRACTING OFFICER CERTIFICATION

I certify that this Justification is accurate and complete to the best of my knowledge and belief. To the extent that the J&A/LSJ value is between \$150K and \$650K, the Contracting Officer's signature below also represents approval of the J&A/LSJ.

	MARCO PICCIRILLO	626-3938	09/05/14
Signature	Name (Printed)	Phone No.	Date

CONTRACTING ACTIVITY COMPETITION ADVOCATE REVIEW

To the extent that the J&A/LSJ value is between \$650K and \$12.5M, the Competition Advocate's signature below also represents approval of the J&A/LSJ.

N/A			
Signature	Name (Printed)	Phone No.	Date