

J&A Number: YOK 15-0064

**Justification and Approval for Sole Source Procurement
Under Simplified Acquisition Test Program at FAR 13.5**

1. Name of Requiring and Contracting Activity

Requiring Activity: Armed Services Blood Bank Center, U.S. Naval Hospital Okinawa (USNH Okinawa), Japan

Contracting Activity: NAVSUP Fleet Logistics Center (FLC), Yokosuka, Japan

2. Nature and/or Description of the Action Being Approved: Preventive maintenance and repair services for the Grifols (Formerly Chiron Novartis) Procleix TIGRIS Instrument analyzer system (Serial number 1952), an automated system for state-of-the-art nucleic acid testing (NAT) for blood screening. This instrument was procured on August 22nd 2014 as a collateral piece of equipment to the USNH Okinawa when it was built in 2014. The purchase price of the TIGRIS instrument was . The TIGRIS analyzer allows testing via DNA amplification technology for the newly mandated screening for the Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), and West Nile Virus (WNV). The system contains all materials to implement this requirement minus testing personnel and reagent costs. Additionally, it will allow for minimal modification of spaces and provides a unique walk-away technology where samples are loaded and run with minimal technical supervision of the process required.

3. Description of the Supplies and Services Being Procured: Semi-annual preventive and corrective maintenance services of the Grifols Procleix TIGRIS Instrument, base year plus three option years. The preventive maintenance includes the replacement of consumable parts such as valves, cables, vacuum switches, timing belts, o-rings, filters, tubing assemblies, syringes, wash aspirators, fittings, and etc. The corrective maintenance will include phone support, with an expectation that issues will be resolved within 48 hours. If needed Grifols will fly a technician to troubleshoot and repair the issue.

4. Statutory Authority to Procure Requirement under Sole Source Procedures:

Section 4202 of the Clinger-Cohen Act of 1996 – a sole source acquisition under the authority of the test program for certain commercial items, as implemented by FAR 13.501(a).

5. Description of the Unique Capabilities or Qualifications, which Requires Acquisition under Sole Source Procedures: Grifols is the sole manufacturer of the Procleix TIGRIS System. Grifols is the only source who has the capability to service this analyzer and provide Original Equipment Manufacturer (OEM) specification and parts. Unapproved, unauthorized, and/or non-certified companies may potentially cause malfunction and damage to the analyzer. Grifols demands their maintenance and services and no other supplier to avoid damage or potential harm. Engineer and technical support specialists that work on Tigris Systems must be certified and trained at Grifols Emery Ville Training Center. The training is only available to Grifols employees or authorized persons. As Grifols is the sole proprietor of this analyzer, there are no other sources that can provide the reagents for use with neither the system, nor the maintenance and repair.

6. Description of Efforts Made to Ensure that Offers Are Solicited from as Many Potential Sources as Is Practicable (i.e., FACNET, CBD Synopsis or Documentation Explaining Exception to Synopsis Requirement): Requirements for reagents from Grifols were publicized on Federal Business Opportunities and were awarded to Grifols, since they were the only company to responded to the solicitation. There are no other known source that can supply the parts, support, and technical expertise to upkeep this highly specialized medical testing instrument.

7. Determination that the Anticipated Cost to the Government Will Be "Fair and Reasonable": From historical comparison, around will be determined "Fair and Reasonable." Grifols provided a quote with the annual estimate of with option three option years. The contracting officer will compare the

consumable parts to similar parts for similar applications on different types of medical equipment. Labor hours and labor categories for the semi-annual visits will also be evaluated for reasonless. They will be compared to the labor rates of similar labor categories in the field.

8. Description of the "Market Research" Conducted and the Results or a Statement Explaining the Reason Market Research Was Not Conducted: An internet search was conducted and there are no authorized companies that can provide maintenance and repair services. There were other systems before the TIGRIS, but not on a massive scale for the testing of blood donors and Grifols owns proprietary rights to this technology. In accordance with DFARS PGI 206.302-1, Sources Sought Notice N62649-15-Q-1801 was posted on Asia NECO for two weeks. No responses were received.
9. Any Other Documentation that Would Lend Support to the Sole Source Justification: Material Management Department at USNH Okinawa conducted a market research. We contacted the Technical Support Division at Hologic Inc. San Diego, CA on 21 Apr 2015 to ask who would be authorized to perform preventative maintenance on Proclx TIGRIS instrument. They stated only Grifols' Technical Service Division could perform maintenance on their equipment.
10. Listing of Interested Source:
Grifols (HK) limited
Address: Units 1505-07 Berkshire House, 25 Westlands Road Quarry Bay Hong Kong
Phone 852-2161-3100, FAX 852-2337-8100
POC: Sue Young, Commercial Head Asia Pacific Grifols Diagnostic Solutions
e-mail: sue.young@grifols.com
11. Statement of Actions, if any, to Remove Barriers to Competition: Four years from issuance of this contract USNH Okinawa will reassess the blood testing analyzer instrument market, to seek other sources that offer equivalent instruments. If another manufacturer is identified in the future, a competitive solicitation will be issued and award will be made to the Lowest Price Technically Acceptable (LTPA) quoter. In addition, during the next 4 years, USNH Okinawa will continue to perform market research on a regular basis to seek other blood analyzers instrument options that may meet USNH Okinawa's needs. If another option is identified during the next 4 years.
12. Contracting Officer Certification that the Justification Is Accurate and Complete to the Best of the Contracting Officer's Knowledge and Belief with Supporting Data: The Contracting Officer has reviewed the market research findings and historical data provided. Based on USNH Okinawa's market research, the Contracting Officer certifies the justification is accurate and complete to the best of the Contracting Officer's knowledge and belief.
13. Total Estimated Dollar Value of the Acquisition Covered by this J&A:

Base Price:	22 Aug 2015 till 21 August 2016
Option Year I:	22 Aug 2016 till 21 August 2017
Option Year II:	22 Aug 2017 till 21 August 2018
Option Year III:	22 Aug 2018 till 21 August 2019
	Total
14. Contracting Activity Point of Contact: The Contract Specialist for the proposed contract action is:

Ikuhiro Yamada
DSN: 315-243-8398
E-mail: Ikuhiro.Yamada.JA@fe.navy.mil