Control Number: FY26-0648

Nucleic Acid Analyzer (Grifols) Justification and Approval (J&A) Federal Acquisition Regulation (FAR) 6.103-1 Only one responsible source and no other supplies or services will satisfy agency requirements & FAR 12.201-1 Simplified Procedures

1. Identification of the Agency and Contracting Activity: Defense Health Agency (DHA), DHA Contracting Activity (DHACA), Healthcare Contracting Division (HCD) - South

Requiring Activity: 59th Medical Wing (MDW), Blood Donor Center JBSA Lackland, Texas

2. Nature and/or Description of Action being Approved: This is a new requirement for a lease only contract to use 3 (three) Nucleic Acid Testing (NAT) analyzers (molecular diagnostic instrument) designed to screen blood and plasma donations for infectious diseases. The proposed action is to award a single-award, Firm-Fixed Price (FFP) contract to Grifols Diagnostic Solutions Inc. (CAGE: 7AJ96) for one period of 12-months. This contract will include the use of the analyzer, ongoing maintenance, service, and technical support required to perform mission-critical nucleic acid testing for the 59th MDW in accordance with FAR 6.103-1.

3. Description of Supplies/Services: The Armed Services Blood Bank Center-San Antonio (ASBBC-SA) has a critical need for the simultaneous testing of blood units for the West Nile Virus (WNV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Human Immunodeficient Virus (HIV), and Babesia. The analyzers will support the medical processing of approximately 30,000 Basic Military Trainees annually and the collection of 10,000 blood units at the Blood Donor Center. Other key requirements include a throughput of 275 results in 8 hours, 24/7 live telephone hotline with a 24 hour technical service response time, and ability for the systems to fit within the existing physical footprint of 238 sq. ft. of available laboratory space.

Period	Period of Performance	Estimated Value	Type of Funding
Base Period	29 May 2026 – 28 May 2027	[redacted]	O&M
	Total	[redacted]	

4. Statutory Authority Permitting the Sole Source Acquisition: 10 United States Code 3204(a)(1) as implemented by FAR 6.103-1: Only one responsible source and no other supplies or services will satisfy agency requirements & FAR 12.201-1 Simplified Procedures.

Controlled by: Defense Health Agency (DHA)
Controlled by: HCD-S
CUI Category(ies): SP-PROCURE
Limited Dissemination Control: FEDCON
POC: Corey Black

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5. Rationale Justifying Use of Authority Cited:

The Grifols Procleix Panther is the only system that combines continuous sample loading with all the other non-negotiables of our requirement. The continuous loading sample is mission essential as it enables a flexible workflow and rapid turnaround time required to meet quotas and daily needs of the customer. Alternative systems such as the Roche cobas 201 rely on batch testing which do not provide the necessary speed flexibility. Unlike continuous loading systems, batch testing methodologies necessitate that samples are aggregated and loaded in a single, complete run. This inherently rigid process prevents the introduction of urgent samples, creating unacceptable delays that conflict with mission-critical timelines. For instance, with implementation of batch testing, an additional eight hours of next day testing would occur, leading to detrimental delays in reporting and blood product distribution. While the Roche Cobas 6800 offers continuous loading, its physical footprint is too large due to lab size limitations. The Hologic Panthers does not offer the required type of assays and therefore does not meet our requirement.

The analyzer must be capable of performing the full panel of tests currently utilized, including West Nile Virus (WNV), Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Babesia screening. The Roche Cobas 6800/8800 can perform these tests however; a new collection tube would need to be added to the sets used when collecting donors for blood donation. The Roche Whole Blood Collection Tube contains Guanidine HCl and is required to test for Babesia. The six (6) CONUS donor centers that Armed Services Blood Bank Center-San Antonio (ASBBC-SA) performs Babesia testing for would need to source the required tube and ensure it is incorporated into their process prior to shipment. In addition, testing performed for Walking Blood Bank pre-screen deployment members would be drastically impacted as the clinics performing these collections do not have regular access to these tubes needed. This can significantly delay the required testing needed in a short amount of time prior to the member's deployment date. In some cases, the clinic has less than 48 hours notification that the members will need this testing. Getting these tubes to participating clinics across the Department of War is unfeasible.

ASBBC-SA's primary testing mission is to provide accurate results for labeling blood products for transfusion. MTFs across the Department of War require blood products from the clients that ASBBC-SA provides infectious disease testing results for. Without these products, significant impact to patient care and surgical demand are severely diminished. In addition to MTF needs, ASBBC-SA provides testing for products that are sent down range. Each day these products are delayed due to testing prevents them from being stored in potential areas of conflict where blood is scarce. The secondary type of testing performed at ASBBC-SA relates to deployment testing. This allows members to be screened for infectious diseases prior to deployment, so if needed, they can donate a unit of blood in an emergent or traumatic situations. Deployments can happen rapidly, so it is important these results are received as soon as possible prior to the member reaching his or her deployment location.

Additionally, the ASBBC-SA currently owns three Grifols Xpress Pipettors, a proprietary automated laboratory instrument, designed to work exclusively with the Grifols Procleix Panther system that was purchased in 2020 for $495,000. The pipettors allow for lysing and pooling of

samples to be tested on the Grifols Panther analyzer. It will aliquot a small amount of plasma from eight (8) different samples and pool into one sample for testing. This drastically cuts down on turnaround time, as the analyzer can release five (5) results every five (5) minutes after the initial run time. By pooling it is releasing 40 results every five (5) minutes. The use of this Government-owned equipment for sample pooling also generates substantial cost savings. Based on an annual volume of 60,000 samples, continued use of this integrated system results in an estimated annual cost savings of over $651,000. These savings are realized from the reduced cost per test for Babesia ($2.58), Ultrio Elite ($5.51), and West Nile Virus ($2.76). Awarding to another vendor would render this Government-owned equipment obsolete and forfeit these significant savings, resulting in an unjustifiable duplicate cost to the Government.

Lastly, the Armed Services Blood Bank Center has a fixed, available workspace of only 238 square footage for these analyzers. The Grifols Panther system's small footprint (48 in W, 32 in D, 69 in H) allows the facility to house the required number of analyzers for redundancy and throughput. No other analyzers with the required type of assays can fit with this workspace.

6. Description of Efforts Made to Ensure that Offers are Solicited from as Many Potential Sources as is Practicable:

In accordance with Federal Acquisition Regulation (FAR) 5.201, a notice of intent to award a sole source action for the associated use of three (3) Nucleic Acid Testing Analyzers was published on the System for Award Management (SAM.gov) on 19 March 2026. The notice provided a 15-day response period, and closed on 03 April 2026, for any responsible sources to submit a capability statement. The Government's notice of intent to sole-source yielded zero interested parties.

7. Actions to Increase Competition/Remove or Overcome any Barriers to Competition:

The contracting activity will take concrete steps to overcome the barriers to competition for this requirement in the future. The most critical action will be to align the ordering periods of this analyzer equipment contract with the separate vehicle for the procurement of reagents currently under FA301625A0018. By synchronizing the expiration of these two efforts, the Government will be positioned to compete the requirement as a total package solution (analyzers and reagents), thereby eliminating the barrier of a pre-existing, proprietary consumables contract. In preparation for this future competition, the Government will conduct market research through a Request for Information (RFI) or an Industry Day to engage with potential vendors and better understand the full scope of emerging capabilities becoming available in the marketplace. It is noted that new technologies must be overwhelmingly beneficial to the Government to substantiate deviating from Government-owned Pipettors where significant cost savings can be realized.

Furthermore, the program office will plan and budget for the necessary one-time costs associated with validation, training, and transition to a new vendor's system, ensuring that these expenses are anticipated and do not constitute an unacceptable cost in a future competitive scenario. These combined actions are designed to foster a competitive environment for the follow-on contract, ensuring the Government receives the best possible value.

The Government will continue to conduct market surveillance to identify new technologies and vendors in the NAT marketplace. We will actively monitor competitors such as Roche & Hologic for advancements in their platforms that may meet the Government's technical and physical requirements in the future.

8. Market Research:

Market research confirmed that Grifols Diagnostic Solutions is the only source capable of meeting the Government's need. No other manufacturer (e.g., Roche & Hologic) can provide a system compatible with existing reagent contract as well as the Government-owned Pipettor system. The research included a review of commercially available systems and an evaluation of their capabilities against the mission-critical needs of the ASBBC-SA. A "Notice of Intent to Sole Source" was also prepared for public posting to invite any responsible sources to submit a capability statement.

The salient requirements for this acquisition are:

- Fully automated system with continuous sample and reagent loading to allow for flexible workflow and rapid turnaround times.
- Compact physical footprint to fit within the existing 238 sq. ft. of available laboratory space.
- Simultaneous testing for West Nile Virus (WNV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV), and Babesia.
- Minimum throughput of 275 results in an 8-hour shift.
- Compatibility with existing laboratory utilities and ancillary equipment (Pipettor).

Competitors identified through market research are listed below followed by the reason for not meeting the Government's requirement.

1. Cobas 6800/8800 Roche Molecular System

    - Reason for Rejection: Although the Cobas 6800 met the requirements throughput and list of required assays, a single Cobas 6800 analyzer requires approximately 240 sq. ft., which exceeds the total available space in the laboratory. Building modifications or relocation are not feasible due to the prohibitive cost, extended timeline, and the significant risk of sample contamination during any potential construction. Furthermore, the Roche systems have different utility requirements that are not compatible with the existing laboratory infrastructure without modification. This analyzer would also require an additional costly reagent supply solution and is not compatible with the existing Government-owned Pipettors.

2. Hologic Panther System

- Reason for Rejection: The Hologic Panther system, while also a fully automated and compact NAT platform, is primarily designed for clinical diagnostics rather than blood screening. Its approved test menu is focused on infectious diseases like COVID-19, sexually transmitted infections, and cervical cancer screening. The contract specialist verified Hologic does not have FDA approval for the full panel of blood screening assays required by the SOW (WNV, HBV, HCV, HIV, and Babesia) in a single, integrated system. The Hologic Panther did meet the required throughput. Further, this analyzer is not compatible with the existing Government-owned Pipettors. As such, it does not meet the Government's testing requirements.

Market research concludes that Grifols Diagnostic Solutions is the only source capable of meeting the Government’s requirements without incurring substantial duplication of cost and unacceptable mission delays. This is due to several logistical and financial barriers, beginning with the laboratory's restrictive physical footprint of just 238 square feet, a constraint that only the compact Procleix Panther system can accommodate. Furthermore, the Government-owned, automated pipettor would be rendered obsolete when using another system, forfeiting significant cost savings. Given these combined constraints, only Grifols can fulfill the agency's needs.

9. Other Facts:

a. Procurement History:

(1) Is this a new requirement? Yes, this is a new DHA requirement.

(2) If 9.a.(1) is No, was the action just prior to this one competed? Not applicable.

(3) If 9.a.(2) is Yes, what has changed where this action cannot be competed? Not Applicable

b. Additional Information: N/A

10. Interested Sources: No other sources have expressed written interest in this acquisition.

J&A prepared by HCD-S Contract Specialist Matthew Brinkmann.

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11. Technical Certification:

I certify the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

PHELPS.MEGAN.LYNN.1126699766 Digitally signed by PHELPS.MEGAN.LYNN.1126699766 Date: 2026.04.23 12:09:18 -05'00'

Megan Lynn Phelps
SBB Director, Armed Services Blood Bank Center - SA

12. Requirements Certification:

I certify the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

ARMBRUST.BAILEY.MAREN.1548208358 Digitally signed by ARMBRUST.BAILEY.MAREN.1548208358 Date: 2026.04.23 12:22:42 -05'00'

Bailey Armbrust, SSgt, USAF
NCOIC, Acquisitions and Customer Service
Lackland Medical Logistics & Readiness Squadron
Wilford Hall Ambulatory Surgical Center

13. Legal Review:

I have reviewed this justification and have found it to be legally sufficient.

VOLSEY.JESSICA.F.1464689326 Digitally signed by VOLSEY.JESSICA.F.1464689326 Date: 2026.04.30 10:25:47 -05'00'

Jessica Volsey
Office of General Counsel

14. Contracting Officer Certification:

Fair and Reasonable Cost Determination: I have determined that the anticipated cost to the Government for this action will be fair and reasonable, in accordance with FAR Overhaul 15.402.

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

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Corey Black
HCD-S Contracting Officer

Control Number: FY26-0648

Approval

Based on the foregoing justification and the authority under 41 U.S.C. 1901 as implemented in FAR 12.201-1, I hereby approve a Firm-Fixed-Price (FFP) contract with Grifols Diagnostic Solutions for the lease of three (3) NAT systems. This acquisition has a total estimated ceiling of [redacted] and will be awarded on a sole source basis pursuant authority 10 U.S.C 3204 as implemented by FAR 6.103-1 (Only one responsible source and no other supplies or services will satisfy agency requirements), subject to availability of funds, and provided that the services herein described have otherwise been authorized for acquisition.

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Corey Black
HCD-S Contracting Officer