Control Number: FY26-0684

Justification and Approval (J&A) for Other than Full and Open Competition
Revolutionary Federal Acquisition Regulation (FAR) Overhaul Part 8.4

1. **Identification of the Agency and Contracting Activity**: The 96th Medical Group (MDG)/Eglin Air Force Base; Defense Health Agency Contracting Activity (DHACA), Healthcare Contracting Division-South (HCD-S).

2. **Nature and/or Description of Action being Approved**: HCD-S intends to award a sole-source task order to the sole manufacturer of BenchMark ULTRA PLUS systems and reagents: Roche Diagnostics Corporation. A review of General Services Administration (GSA) Advantage revealed that Roche Diagnostics Corporation holds a Federal Supply Schedule (FSS) that includes the BenchMark ULTRA PLUS system and reagents; contract number GS-07F-0446V. The place of performance for this system will be at the Eglin Air Force Base 96th Medical Group. This new award shall be Firm Fixed Price (FFP) with an estimated total contract value of [redacted]. The requested period of performance (PoP), to include option periods, is 1 July 2026 through 30 June 2031.

3. **Description of Supplies or Services and Estimated Value**: The 96th Medical Group MDSS/Laboratory, Flight Section, at Eglin Air Force Base, Florida has a new requirement for an Immunohistochemistry (IHC) Stainer reagent rental agreement [redacted] with capabilities of a fully automatic machine that uses antibodies to specifically stain tissue sections, which aids in patient diagnosis in the pathology department. The IHC machine must be fully automated, performing all staining steps on the machine, including target retrieval, without manual intervention. Must have the capacity to process a minimum of thirty (30) slides simultaneously. The system must include features for continuous loading and the ability to run multiple protocols at once to maximize space and improve time efficiency. The daily labor required for maintenance must be minimal.

[redacted]

Controlled by: Defense Health Agency (DHA)
Controlled by: Healthcare Contracting Division – South (HCD-S)
CUI Category(ies): Source Selection
Limited Dissemination Control: FED Only
POC: Karen E. Bradley

4. **Authority Cited**: The acquisition is conducted under the authority of 41 U.S.C. 3304(a)(1) as implemented by Revolutionary FAR Overhaul Part 8.4 and General Services Administration Regulation (GSAR) 538.7104-3(b)(ii): Only One Responsible Source. Only one source is capable of providing the supplies or services required at the level of quality required because the supplies or services are unique or highly specialized.

5. **Rationale Justifying Use of Authority Cited**: Only one source is capable of providing the supplies or services required at the level of quality required because the supplies or services are unique or highly specialized. The 96th Medical Group's Laboratory Flight currently lacks in-house IHC capabilities, necessitating the outsourcing of this critical testing to external facilities, including LabCorp and other DoD reference laboratories. This operational gap creates significant financial and logistical challenges.

Financial and Operational Impacts:

The Government requires the Fully Automated IHC Staining System with the following critical characteristics:

a) Automation: The machine must be fully automated, performing all staining steps, including target retrieval, without manual intervention.
b) Capacity: Must have the capacity to process a minimum of thirty (30) slides simultaneously.
c) Efficiency: The system must include features for continuous loading and the ability to run multiple protocols at once to maximize space and improve time efficiency.
d) Maintenance: The daily labor required for maintenance must be minimal.

The Roche Diagnostics BenchMark Ultra Plus system is engineered to meet and exceed the requirements of a modern, efficient IHC laboratory, capable of testing all required assays. It is designed to provide a fully automated, high-throughput, and efficient staining solution with minimal user intervention. The system offers complete “walk-away” automation. It handles all critical steps of the staining process on board, from baking and deparaffinization to the final staining of the tissue samples. This comprehensive automation eliminates manual steps, ensuring consistency and reducing the chances of human error. The BenchMark Ultra Plus has a capacity for thirty (30) individual slides. Each slide is housed in its own independent drawer, allowing for simultaneous processing. The system can process up to 90 slides in a standard 8-hour shift, with the ability to run an additional 30 slides overnight. The system’s design is centered around maximizing laboratory workflow and efficiency. This is achieved through: Continuous Loading, slides can be added or removed at any time without interrupting the staining runs in progress. This

"single-piece flow" eliminates the need for batching and allows for urgent (STAT) samples to be prioritized. Independent Protocols, each of the 30 slides positions, can be programmed with a different staining protocol and has independent temperature control. This allows for running multiple different assays simultaneously. Several features contribute to a reduced daily maintenance workload: Automated Waste Management, the system features a proprietary solution that automatically degrades hazardous DAB waste to non-hazardous levels, simplifying disposal. Bulk Reagent and Waste Handling: Large capacity, color-coded bulk reagent containers and waste carboys can be refilled and emptied at any time without interrupting the instrument's operation. User-Friendly Design: Features like an integrated touchscreen for on-instrument management and remote monitoring capabilities streamline daily operations and reduce the need for constant hands-on attention. The Roche Diagnostics BenchMark Ultra Plus system is a comprehensive solution that directly addresses the need for a fully automated, high-capacity, efficient, and low-maintenance IHC staining platform. Furthermore, Roche Diagnostics research concluded that their BenchMark Ultra Plus system, along with its reagents and required service, is proprietary. Roche Diagnostics is the sole manufacturer and distributor, and no other vendors, resellers, or third-party developers offer a compatible system that meets the Government's mandatory technical needs (30-slide capacity, continuous loading, and multi-protocol capability). Given that Roche Diagnostics is the only reasonably available source to fulfill this mission-critical patient care requirement, a sole-source justification is warranted.

6. **Market Research**: Searches were performed on GSA Advantage, SAM.gov, and the open market for Immunohistochemistry Stainer/Analyzer and similar terms between 18 March 2026 and 2 April 2026. A thorough analysis was conducted through market research for mandatory and non-mandatory sources. In addition, the 96th MDG identified other manufacturers/Instruments that were determined to be most similar to the Roche BenchMark Ultra Plus system: [redacted] Additional instruments and/or testing methods would be required to fulfill the 96th MDG entire testing menu. The results from the market research confirm Roche Diagnostic is the original equipment manufacturer and sole provider of the proprietary BenchMark Ultra Plus system and reagents. Additionally, in response to the sources sought posted on GSA eBuy Roche Diagnostic provided a sole source letter dated 13 April 2026 corroborating that they are the sole source for the BenchMark Ultra Plus system and reagents.

7. **Other Facts**:

a. Procurement history.

(1) Is this a new requirement? Yes

(2) If 7.a.(1) is No, was the action just prior to this one competed? *Not Applicable.*

(3) If 7.a.(2) is Yes, what has changed where this action cannot be competed? *Not applicable*.

b. **Additional Information**: A Request For Information (RFI) – Sources Sought special notice was posted on the General Services Administration (GSA) eBuy website on 02 April 2026 to query the marketplace for Immunohistochemistry Stainer/Analyzer. The RFI – Sources Sought closed

on 13 April 2026, [redacted] However, [redacted] only one vendor, Roche Diagnostics Corporation, demonstrated the ability to meet all the Government's mandatory technical requirements. [redacted]

[redacted]

8. **Anticipated cost to the Government will be fair and reasonable**: Contracting Officers are responsible for evaluating and documenting the reasonableness of the awarded price in accordance with Revolutionary FAR Overhaul Part 8.4. Agencies must purchase supplies and services from responsible sources at fair and reasonable prices. The Contracting Officer will analyze various price elements that are presented in the quote/proposal, as well as review actual costs from comparable procurements from other Governmental Agencies as well as open market prices to form a fair and reasonable price determination for the supplies/services covered by this justification.

9. **Actions to Remove or Overcome any Barrier to Competition**: The 96th MDG located at Eglin AFB, Florida will continue to evaluate other products' capabilities from other distributors through continuing market research. Additionally, if the Government's requirement changes in the future, the intent of the Government would be to issue a full and open competitive solicitation in order to provide the greatest amount of competition as practicable. Continued efforts in this regard will ensure that the Government is receiving the best value at a fair and reasonable price by ensuring the Government utilizes the most efficient and economical means possible. The Government will issue a notice of intent (NOI) to sole source this action on the SAM.gov website, Contract Opportunities, to encourage small business participation and foster competition. Any responses to the NOI will be reviewed by the Government.

[redacted]

[redacted]

[redacted]