DEPARTMENT OF VETERANS AFFAIRS

SOLE SOURCE JUSTIFICATION UNDER SIMPLIFIED PROCEDURES IN ACCORDANCE WITH REVOLUTIONARY FAR OVERHAUL (RFO) 12.102(b)

Acquisition Plan Action ID: 36C248-27-AP-0122

1. **Contracting Activity:** Department of Veterans Affairs (VA), Veterans Health Administration (VHA), Regional Procurement Office East, Network Contracting Office 08 (NCO 08) located at 8875 Hidden River Parkway, Suite 160, Tampa, Florida 33637, in support of VISN 08 Bay Pines VA Health Care System (BPVAHCS), C.W. Bill Young (CWBY) Department of Veterans Affairs Medical Center (VAMC) at 10,000 Bay Pines Blvd. Bay Pines, FL 33744 and Lee County VA Clinic at 2489 Diplomat Parkway East, Cape Coral, FL 33909-5422.

2. **Nature and/or Description of the Action Being Processed:** This acquisition is for a sole source, single-award Indefinite Delivery, Indefinite Quantity (IDIQ) Cost Per Test (CPT) contract for a fully integrated, automated Microbiology Identification (ID) and Antimicrobial Susceptibility Testing (AST) system for the Bay Pines VA Healthcare System, Department of Pathology and Laboratory Medicine Service. The IDIQ contract will provide contractor-owned instrumentation, software, reagents, consumables, maintenance, repairs, technical support, upgrades, training, and all other supplies and services necessary to perform microbiology identification and antimicrobial susceptibility testing in accordance with the Statement of Work. Individual task orders will be issued for the Government's actual requirements during the ordering period. The estimated value of this procurement is [redacted], with an estimated contract ceiling of [redacted].

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The Bay Pines VA Healthcare System, Department of Pathology and Laboratory Medicine Service, requires a fully integrated, automated Microbiology Identification (ID) and Antimicrobial Susceptibility Testing (AST) system under a single-award Indefinite Delivery, Indefinite Quantity (IDIQ) Cost Per Test (CPT) contract to support timely and accurate diagnostic testing for Veteran patient care. The contract shall provide contractor-owned instrumentation, software, reagents, consumables, maintenance, repairs, preventive maintenance, technical support, upgrades, training, installation, and all other supplies and services necessary to perform microbiology identification and antimicrobial susceptibility testing in accordance with the Statement of Work.

   Microbial cultures are used to determine the type of organism present in patient specimens and represent the primary diagnostic method used in clinical microbiology to identify the causative agents of infectious diseases. Antimicrobial susceptibility testing confirms an organism's susceptibility to antimicrobial agents, detects resistance mechanisms, and provides critical information to guide clinicians in selecting the most appropriate antimicrobial therapy. Rapid and accurate organism identification and susceptibility results are essential to supporting infection control, antimicrobial stewardship, and positive patient outcomes.

   The primary instrument supporting these services is the bioMérieux VITEK® 2 XL, an automated microbial identification and antimicrobial susceptibility testing platform. The system provides the capability to identify more than 2,000 phenotypes and generate approximately 20,000 Minimum Inhibitory Concentration (MIC) results, delivering rapid, accurate, and clinically actionable diagnostic information. These capabilities are essential to maintaining timely, reliable, and high-quality

microbiology testing and directly support the delivery of safe and effective patient care for Veterans at the Bay Pines VA Healthcare System.

The anticipated annual workload includes approximately 1,000 bacterial identification tests, 200 yeast identification tests, and 10,000 Gram-positive and Gram-negative antimicrobial susceptibility tests. The CPT contract shall include all equipment, reagents, consumables, software, maintenance, technical support, and related services necessary to ensure continuous operation of the microbiology laboratory throughout the five-year ordering period.

PERIOD OF PERFORMANCE: October 01, 2026 – September 30, 2031

4. **Statutory Authority Permitting Restricted Competition:**
The statutory authority for applying the Simplified Procedures for Commercial Items of RFO Part 12 is 41 U.S.C. 1901 and 1903 and is implemented by RFO 12.102(b) for restricting competition on this procurement. **Competition is restricted on this procurement for the reason below**:

(X) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements
( ) Unusual and Compelling Urgency
( ) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services
( ) International Agreement
( ) Authorized or Required by Statute
( ) National Security
( ) Public Interest

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** The required Microbiology Identification (ID) and Antimicrobial Susceptibility Testing (AST) system must be fully compatible with the Government-owned bioMérieux BACT/ALERT® VIRTUO® blood culture incubation system currently deployed at the Bay Pines VA Healthcare System. The BACT/ALERT VIRTUO and the bioMérieux VITEK® 2 XL operate on the MYLA® middleware platform, which provides a single integrated environment for specimen workflow, quality control, instrument management, result reporting, and data management. This integrated platform supports standardized laboratory processes, improves workflow efficiency, reduces manual intervention, and ensures continuity of microbiology operations.

The Government-owned BACT/ALERT VIRTUO system has an estimated remaining service life of approximately five years. Replacing the existing bioMérieux ID/AST platform with a system from another manufacturer would require replacement or extensive reconfiguration of the MYLA middleware environment, development and validation of new instrument interfaces, modification of laboratory workflows, revision of standard operating procedures, comprehensive method verification and validation studies, retraining of laboratory personnel, and potential replacement or modification of existing Government-owned equipment. These efforts would require significant expenditures of Government resources and would result in a substantial duplication of costs that are not expected to be recovered through competition.

In addition to the financial impact, transitioning to a different manufacturer's platform would increase operational risk by disrupting established laboratory workflows, delaying implementation,

and potentially affecting the timely reporting of microbiology results that are essential for diagnosis, antimicrobial stewardship, infection prevention, and patient treatment decisions. Maintaining compatibility with the existing blood culture incubation system and middleware is critical to ensuring uninterrupted laboratory operations and continuity of patient care.

Accordingly, bioMérieux is the only firm capable of providing the supplies and services described in Section III above without the Veteran's Health Administration experiencing substantial duplication of cost that could not be expected to be recovered through competition and and unacceptable disruption to agency operations.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** The Government conducted market research to identify potential sources capable of meeting the requirement. Although several manufacturers offer microbiology identification and antimicrobial susceptibility testing systems, the research confirmed that only bioMérieux can provide a solution that is fully compatible with the Government-owned BACT/ALERT® VIRTUO® blood culture incubation system and existing MYLA® middleware platform.

7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** The Contracting Officer will determine that the anticipated price is fair and reasonable by evaluating the contractor's pricing against historical prices paid for similar requirements, pricing previously available under the contractor's GSA Federal Supply Schedule contract, and any other relevant market data. Award will not be made until the Contracting Officer determines that the final price is fair and reasonable.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** The applicable NAICS code for this requirement is 334516, Analytical Laboratory Instrument Manufacturing, with a corresponding size standard of 1,000 employees. The applicable PSC is 6640, Laboratory Equipment and Supplies.

   Market research included a review of the SBA Small Business Search, SBA Nonmanufacturer Rule Class Waiver List, recent federal procurement history, and the GSA eLibrary for contractors offering microbiology cost-per-test laboratory systems. The SBA class waiver identified for certain mass spectrometry systems is not applicable to this requirement. Federal procurement history and GSA Schedule research identified several large business manufacturers capable of providing microbiology identification and antimicrobial susceptibility testing systems, including Beckman Coulter, Becton, Dickinson and Company, Siemens Healthcare Diagnostics, and bioMérieux.

   Although multiple manufacturers offer similar systems, only bioMérieux can provide a solution that is fully compatible with the Government-owned BACT/ALERT® VIRTUO® blood culture incubation system and the existing MYLA® middleware platform. Procuring another manufacturer's system would require replacement or reconfiguration of the existing middleware environment, additional validation, retraining of laboratory personnel, and potential replacement or modification of Government-owned equipment. This would result in substantial duplication of cost that could not reasonably be expected to be recovered through competition and would cause unacceptable delays in meeting the Veterans Health Administration's requirements.

   Because market research confirmed that only one responsible source could satisfy the Government's minimum needs, a Sources Sought Notice was not issued.

The Government initially attempted to procure this requirement through the GSA Federal Supply Schedule under RFQ No. 36C24826Q0558. During the solicitation, bioMérieux advised that the estimated annual quantity did not meet the minimum order threshold for its GSA Schedule contract; therefore, the requirement could only be fulfilled on an open-market basis. As a result, the RFQ was cancelled and the acquisition was converted to an open-market sole-source procurement.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** The Statement of Work was developed to reflect the Government's minimum needs and is written in performance-based terms to the maximum extent practicable. However, due to the requirement for compatibility with the existing Government-owned bioMérieux BACT/ALERT® VIRTUO® blood culture incubation system and MYLA® middleware platform, the Government's minimum requirements can only be met by bioMérieux. Developing specifications that would permit full and open competition would require eliminating the compatibility requirement, resulting in substantial duplication of cost, unnecessary disruption to laboratory operations, and unacceptable delays in providing critical microbiology testing services. Therefore, a competitively neutral specification is neither practical nor in the Government's best interest.

10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** bioMérieux

11. **A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required**: The Government will continue to conduct market research to ascertain if there are changes in the marketplace and Government's needs that would enable future actions to be competed.

12. **Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

[redacted]

Laboratory Manager
Pathology & Laboratory Medicine Service
Bay Pines VA Healthcare System

13. **Approvals in accordance with the VHAPM Part 806.3 OFOC SOP:**

    a. **Contracting Officer or Designee's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

[redacted]

Contracting Officer
Network Contracting Office 08

b. **<u>One Level Above the Contracting Officer (Required over $350K but not exceeding $900K):</u>** I certify the justification meets requirements for other than full and open competition.

[redacted] _____

Acting Branch Chief, Bay Pines Services/Commodities
Network Contracting Office 08