Justification for Other than Full and Open Competition

1. **Identification of the agency and contracting activity.**

   a. **Federal agency and contracting activity.**

   Department of Health and Human Services (HHS)
   National Institutes of Health (NIH)
   Clinical Center (CC)

   b. **Sponsoring organization.**

   Department of Laboratory Medicine (DLM)
   Microbiology Service

   c. **Project Officer information.**

   - [redacted]
   - [redacted]

     [redacted]
   - [redacted]
   - [redacted]

2. **Nature and/or description of the action being approved.**

   a. **Acquisition purpose and objectives.**

   This acquisition is for a reagent rental arrangement supporting an automated molecular diagnostic testing platform for the Department of Laboratory Medicine (DLM), Microbiology Service, NIH Clinical Center.

   The acquisition will support clinical molecular diagnostic testing for Cytomegalovirus (CMV), Epstein-Barr Virus (EBV), BK Virus (BKV), respiratory viruses (SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus), and Adenovirus. The acquisition includes instrumentation, reagents, controls, calibrators, consumables, technical support, training, and warranty coverage necessary to support clinical testing and future expansion of molecular diagnostic capabilities within the Microbiology Service.

   The objective of this acquisition is to consolidate molecular diagnostic testing currently performed across multiple platforms, reduce manual

specimen handling tasks, increase workflow automation, transition selected testing from FDA-modified and laboratory-developed methodologies to FDA-cleared methodologies where available, and improve continuity of testing operations within the NIH Clinical Center.

b. Project background.

The Microbiology Service currently performs molecular diagnostic testing utilizing multiple platforms, including the Hologic Panther Fusion system, bioMérieux EMAG extraction system, and Thermo Fisher QuantStudio amplification platform.

Current workflows require multiple manual processing and documentation steps, including specimen aliquoting, extraction setup, nucleic acid retrieval, PCR reaction preparation, specimen tracking, spreadsheet management, manual result entry, and management of controls and standards associated with laboratory-developed testing. These workflows increase operational complexity, require significant staff effort, and create multiple opportunities for specimen handling and transcription errors.

The Microbiology Service also maintains several laboratory-developed molecular assays that require ongoing validation, quality management, and assay maintenance. These requirements contribute additional operational burden and consume technical resources that could otherwise be directed toward clinical testing operations.

The current testing environment lacks redundant instrumentation for several critical molecular testing workflows. Previous instrument downtime events have resulted in testing disruptions and, in some instances, required referral of patient specimens to external reference laboratories at additional cost to the Government.

The Government seeks to implement a consolidated molecular diagnostics platform capable of supporting current and future testing needs while reducing operational complexity, improving workflow standardization, and supporting continuity of testing operations.

3. Description of the supplies or services required to meet the agency's needs (including the estimated value).

a. Project title.

Reagent Rental Acquisition for Automated Molecular Diagnostic Testing Platform.

b. Project description.

This acquisition is for a reagent rental arrangement supporting an automated molecular diagnostic testing platform for the Department of Laboratory Medicine, Microbiology Service, NIH Clinical Center.

The acquisition includes molecular diagnostic instrumentation, reagents, controls, calibrators, consumables, technical and maintenance support, operator training, warranty coverage, and associated services necessary to support clinical molecular diagnostic testing.

A detailed description of the Government's requirements is provided in the accompanying Statement of Need (SON).

- **Requirement type.**

  ❑ Research & development (R&D)
  ❑ R & D support services
  ❑ Support services (non-R&D)
  ☑ Supplies/equipment
  ❑ Information technology (IT)
  ❑ Construction
  ❑ Architect-engineer (A & E) services
  ❑ Design-build
  ❑ Other (specify): _____

- **Type of action.**

  ☑ New requirement
  ❑ Follow-on
  ❑ Other (specify): _____

- **Proposed contract/order type.**

  ☑ Firm-fixed-price
  ❑ Other fixed-price (specify, e.g., fixed-price award-fee, fixed-price incentive-fee): _____
  ❑ Cost-plus-fixed-fee
  ❑ Other cost reimbursement (specify, e.g., cost-plus-award-fee, cost-plus-incentive-fee): _____
  ❑ Time and materials
  ❑ Indefinite quantity (specify whether indefinite quantity, definite quantity, or requirements): _____
  ❑ Other (specify): _____
  ❑ Completion Form ❑ Term form

- **Acquisition identification number.** To be determined.

c. Total estimated dollar value and performance/delivery period.

Estimated Contract Value:
$350,000

Period of Performance:
Base Year Only

4. **Identification of the statutory authority permitting other than full and open competition.**

   ☑ **This acquisition is conducted under the authority of 41 United States Code (U.S.C.) 253(c)(1) as set forth in Federal Acquisition Regulation (FAR) 6.302-1.**

   ❑ **This acquisition is conducted under the authority of section 4202 of the Clinger-Cohen Act of 1996.**

   ❑ **This acquisition is conducted under the authority of the Services Acquisition Reform Act of 2003 (41 U.S.C. 428a).**

5. **Demonstration that the proposed contractor(s) unique qualifications or the nature of the acquisition requires use of the authority cited.**

   a. **Name and address of the proposed contractor(s).**

      Roche Diagnostics Corporation
      9115 Hague Road
      Indianapolis, Indiana 46250

   b. **Nature of the acquisition and proposed unique qualifications of the contractor(s).**

      The Department of Laboratory Medicine (DLM), Microbiology Service, requires acquisition of an automated molecular diagnostic testing platform through a reagent rental arrangement to support clinical molecular diagnostic testing performed for patients of the NIH Clinical Center.

      The Government's requirement extends beyond assay availability and analytical performance alone. Market research identified multiple commercially available molecular diagnostic platforms capable of supporting portions of the Government's testing requirements. Platforms evaluated included the Roche cobas 5800 and Abbott Alinity m systems. While evaluated platforms demonstrated comparable capabilities for CMV, EBV, BKV, and respiratory virus testing, the Government identified additional operational requirements that are critical to supporting patient care and continuity of laboratory operations.

      The Microbiology Service currently performs molecular diagnostic testing across multiple platforms, including the Hologic Panther Fusion, bioMérieux EMAG, and Thermo Fisher QuantStudio systems. Existing workflows require multiple manual processing tasks, including specimen aliquoting, extraction setup, PCR preparation, manual specimen tracking, manual result management, management of laboratory-developed testing controls and standards, and ongoing assay maintenance and validation workflows.

      The Roche cobas 5800 platform supports consolidation of these workflows into a single molecular diagnostics environment while reducing

manual specimen handling, supporting transition to FDA-cleared methodologies where available, reducing validation and quality management burdens associated with laboratory-developed testing, and providing a pathway for future migration of additional molecular testing, including Adenovirus testing.

Continuity of clinical testing operations is a critical Government requirement. Interruptions in molecular diagnostic testing can negatively impact result turnaround times, delay clinical decision-making, and adversely affect patient care. The Government therefore requires a solution that supports operational resiliency and continuity of testing services.

The Department of Transfusion Medicine currently operates two Roche cobas 5800 systems and one Roche cobas 6800 system within the NIH Clinical Center. These instruments are located on the same floor as the Microbiology Service and are readily accessible for contingency operations.

Implementation of a Roche cobas 5800 platform within the Department of Laboratory Medicine would establish a common molecular diagnostics platform environment and provide immediate instrumentation redundancy. In the event of instrument downtime, maintenance requirements, or other operational disruptions, testing could be transitioned to existing Roche instrumentation within the Clinical Center, minimizing interruption of testing services and reducing the risk of delays in reporting patient results.

The Microbiology Service does not currently have comparable redundancy for the existing Panther Fusion platform. Previous instrument downtime events have resulted in testing disruptions and, in some instances, required referral of patient specimens to external reference laboratories at additional cost to the Government. Referral testing may increase turnaround times and delay availability of results required for patient management.

The Government also evaluated laboratory space utilization and installation considerations. The Roche cobas 5800 footprint is compatible with the existing laboratory space currently occupied by the Panther Fusion system and is substantially smaller than competing high-throughput platforms evaluated during market research. The Roche cobas 5800 is also comparable in weight to the currently installed Panther Fusion system, whereas competing platforms are substantially heavier and may require additional evaluation of installation and facility considerations.

Based upon market research, operational analysis, continuity-of-operations requirements, workflow consolidation objectives, laboratory space considerations, future testing expansion needs, and the Government's requirement for instrument redundancy to support uninterrupted clinical testing operations, Roche Diagnostics was identified

as the only source capable of satisfying the Government's complete operational requirement.

6. **Description of the efforts made to ensure that offers are solicited from as many potential sources as practicable. Indicate whether a SAM.gov notice was or will be publicized as required by FAR Subpart 5.2 and, if not, which exception under FAR 5.202 applies.**

7. **Determination by the Contracting Officer that the anticipated cost/price to the Government will be fair and reasonable.**

8. **Description of the market research conducted (see FAR Part 10) and the results, or a statement of the reasons market research was not conducted.**

   Market research was conducted in accordance with FAR Part 10 to identify commercially available molecular diagnostic platforms capable of supporting the Department of Laboratory Medicine's current and future molecular testing requirements.

   The Government evaluated commercially available molecular diagnostic systems capable of supporting Cytomegalovirus (CMV), Epstein-Barr Virus (EBV), BK Virus (BKV), respiratory virus testing (SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus), and future molecular diagnostic expansion opportunities. Platforms evaluated included the Roche cobas 5800 and Abbott Alinity m systems.

   The Government reviewed assay availability, analytical performance characteristics, workflow automation capabilities, laboratory space requirements, continuity-of-operations considerations, instrument redundancy, future testing expansion opportunities, and reagent rental acquisition models.

   Market research determined that Roche and Abbott provide comparable FDA-cleared assay availability and analytical performance for the Government's primary testing menu. However, Roche was identified as providing additional operational advantages related to workflow consolidation, reduction of manual processing requirements, future Adenovirus testing opportunities, laboratory space utilization, continuity of testing operations, and instrument redundancy within the NIH Clinical Center.

A detailed Market Research Report documenting the Government's evaluation methodology, findings, and conclusions is included as part of the acquisition package and is incorporated herein by reference.

9. Any other facts supporting the use of other than full and open competition.

The Government's evaluation considered operational continuity, instrument redundancy, workflow consolidation, laboratory space utilization, and future molecular diagnostic testing requirements. These considerations are discussed in greater detail within the accompanying Statement of Need and Market Research Report and are incorporated herein by reference.

10. Listing of sources, if any, that expressed, in writing, an interest in the acquisition.

11. Statement of the actions, if any, the agency may take to remove or overcome any barriers to competition before any subsequent acquisition for the required supplies or services.

For future acquisitions, the Government will continue to assess commercially available molecular diagnostic platforms and evaluate opportunities to increase competition while meeting the operational, clinical, and continuity-of-operations requirements of the Department of Laboratory Medicine.

12. Program office certification.

This is to certify that the portions of this justification that have been developed by the undersigned program office personnel, including supporting information and/or data verifying the Government's minimum needs, schedule requirements and other rationale for other than full and open competition, are accurate and complete.

Official	Name & Title	Signature	Date
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