[redacted]

JUSTIFICATION REVIEW DOCUMENT

FAR 13.501 Sole Source Justification and Approval

Simplified Procedures for Certain Commercial Products and Commercial Services

Program/Equipment: Procurement of Multiplex Electrochemiluminescence (ECL) Analyzers, Immunoassay Kits, and Performance Qualification Kits for the Defense Biological Product Assurance Office (DBPAO), Capability Program Executive for Chemical, Biological, Radiological and Nuclear Defense (CPE CBRND), Aberdeen Proving Ground, Maryland.

Authority: Title 41 United States Code (U.S.C.) § 1901(e)(2), as implemented by Federal Acquisition Regulation Overhaul (FAR Overhaul)12.102 (a), sole-source acquisitions under simplified acquisition procedures for certain commercial products and commercial services.

Amount: [redacted]

Type of Funds: Procurement

Justification & Approval Log Number: [redacted]

Prepared and Reviewed By:

Prepared by	[redacted]
Contracting Officer	[redacted]
Technical	[redacted]

Reviews: I have reviewed this justification and find it adequate to support the proposed sole-source action under FAR 13.501.

Program Manager / Program Executive Officer	[redacted]
Legal Counsel	[redacted]

[redacted]

[redacted]

FAR Part 13 Justification and Approval

Simplified Procedures for Certain Commercial Products and Commercial Services

1. Requiring Activity

The requiring activity is the Defense Biological Product Assurance Office (DBPAO), Capability Program Executive for Chemical, Biological, Radiological and Nuclear Defense (CPE CBRND), Aberdeen Proving Ground, Maryland. DBPAO supports Department of Defense (DoD) technical forces and other Government entities requiring an operational biological threat identification capability.

2. Contracting Activity

The contracting activity is Army Contracting Command – Aberdeen Proving Ground (ACC-APG), Edgewood Contracting Division, W911SR, Aberdeen Proving Ground, Maryland.

3. Description of Action

The contracting officer intends to award a new sole-source, Firm-Fixed-Price (FFP), Indefinite Delivery Indefinite Quantity (IDIQ) contract to [redacted], for ECL analyzers, multiplex immunoassay kits, performance qualification kits, reagents, and related consumables. The contract will establish a five-year ordering period from [redacted]. The applicable appropriation type is Procurement. The IDIQ ordering ceiling is [redacted], which equals the five-year IGE total and constitutes the maximum quantity the Government reasonably anticipates ordering over the ordering period.

Period	Period of Performance	IGE Estimated Value
Year 1	[redacted]	[redacted]
Year 2	[redacted]	[redacted]
Year 3	[redacted]	[redacted]
Year 4	[redacted]	[redacted]
Year 5	[redacted]	[redacted]
Five-Year IGCE Total / IDIQ Ordering Ceiling	[redacted]	[redacted]

4. Description of Supplies/Services

The Government requires ECL analyzers and consumables to support field-confirmatory analysis of environmental samples for biological threat identification. The requirement is for an integrated operational system, not for individual laboratory instruments treated as commodities. The system and consumables must operate together as a validated capability in mobile and field laboratory environments, [redacted].

The acquisition includes ECL analyzers, multiplex assay kits (incorporating Government-furnished antibodies and antigens), performance qualification kits, buffer solutions, reagents, related consumables, software support, technical support, and maintenance. Year 1 also includes procurement [redacted].

The minimum material requirements are as follows:

Analytical Function: The analyzer must read ECL immunoassays and permit multiple assays to run simultaneously on a single sample. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Operational Safety: The analyzer must either fit within a standard glovebox (35 in. W × 24 in. D × 28 in. H) or be safely operable outside engineering controls when analyzing biothreat agents by personnel wearing Level D PPE. The analyzer must be designed to prevent aerosol generation during normal operation and must withstand hydrogen peroxide decontamination and remain operable.

Software and Hardware: Computer hardware must be hardened or ruggedized. Software must generate automatic positive/negative result calls following analysis of environmental samples and must be compatible with Army Gold Master configurations. The system must support commercial and customized assay development and must support updates or upgrades to older instrument components.

Commercial Assay and Support Availability: Commercial assays must be available. The vendor must provide installation, fielding, repair, and extended warranty services.

Conformance Testing: Production lots of ECL multiplex assay kits will be accepted only after successful third-party conformance testing. Failed production lots must be replaced at no additional cost to the Government.

Compatibility: Consumables must be compatible with both the [redacted]

5. Authority Cited

Title 41 U.S.C. § 1901(e)(2), as implemented by FAR Overhaul 12.102authorizes sole-source acquisitions under simplified acquisition procedures for certain commercial products and commercial services when the need to do so is justified in writing and approved at the required level.

6. Reason for Authority Cited

a. Background

This is a recurring field-confirmatory biological toxin identification requirement that has existed for approximately two decades. The requirement supports biological threat identification in environmental samples using electrochemiluminescence (ECL) immunoassay technology, and it is resourced through direct procurement with the manufacturer of the platform and consumables that form the basis of the fielded operational capability.

[redacted] was selected as the only platform that (1) had Government-validated assays for Staphylococcal enterotoxin B (SEB), Botulinum neurotoxin A (BoNT-A), and Ricin, and (2) fit the required safety profile for operational use in mobile laboratory environments. [redacted].

[redacted] have continuously supported Government-validated assays for the three required toxin targets throughout this period. Those assays were part of the down-select history that led to the fielding of [redacted] for this mission area. [redacted] is the DoD source of record for these validated assays through DBPAO, and these assays are used operationally by DoD technical forces and other Government partners with biological toxin identification requirements.

[redacted] is now obsolescing. [redacted] and is providing maintenance support to existing instruments only through [redacted]. The program office has identified the [redacted]. [redacted] is being

[redacted]

[redacted]

fielded to National Guard Bureau (NGB) Civil Support Team (CST) Analytical Laboratory System (ALS) units, and DBPAO will continue to provide assay kits compatible with [redacted] to DoD technical forces and non-DoD partners. This acquisition supports both the transition from the [redacted] and the continued supply of validated consumables across both platforms during the transition period.

A sources sought notice for [redacted] procurement published to SAM.gov in April 2021 received no responses. A Request for Information (RFI) published as W911QY-18-S-0005 did not identify any new systems with Government-validated assays for the required toxin targets. Market research conducted in March 2019, March 2020, CY 2021, and FY 2022 consistently identified [redacted] as the only viable source. Additional sources sought notices W911SR26RECLN and W911SR26ECLB were published in December 2025, and an Intent to Sole Source synopsis was posted to SAM.gov from 25 March through 9 April 2026 with no responses from industry. The acquisition strategy has therefore been sole-source procurement throughout the period of this capability.

(1) Integrated Operational System Requirement

The requirement is not for a laboratory instrument in isolation. The Government requires an integrated operational system consisting of: ECL analyzers; proprietary multiplex immunoassay consumables incorporating Government-furnished antibodies and antigens; performance qualification kits; associated software; technical support; and maintenance support sufficient to sustain biological threat detection capability for distribution to DoD entities and other Government partners. All components must operate together as a validated system in mobile laboratory environments under the operational conditions described in Section 4.

This integrated system character is legally significant because it means the relevant market is not the market for ECL instruments in general, but rather the market for an integrated field-confirmatory biological toxin identification capability meeting the specified operational, safety, software, and ITAR requirements. Evaluated alternatives that meet some but not all of these requirements do not satisfy the minimum need regardless of their commercial availability or cost.

(2) Validated Assay Availability

A core discriminator in this acquisition is not merely instrument availability, but the availability of Government-validated assays for the required toxin targets—SEB, BoNT-A, and Ricin—on a platform suitable for operational use. [redacted] are the only commercially available platform on which those assays currently exist at the manufacturing readiness level required for operational distribution.

Production lots of ECL multiplex assay kits are accepted only after successful third-party conformance testing against [redacted]. Failed lots must be replaced at no additional cost to the Government. This conformance testing requirement means the source must already have the manufacturing controls, quality processes, and technical maturity needed to consistently reproduce acceptable assay lots against established Government test plans. No evaluated alternative source demonstrated the ability to provide validated toxin assays meeting the operational performance thresholds while also integrating with the required field-use platform and the Government-furnished material interface described in subsection (5) below.

If an alternate biological toxin identification system lacks existing validated assays for the required biological targets, market research indicates that real-time stability assessments of 12 to 24 months would be required to achieve the shelf-life maturity necessary for logistical distribution to the Services. That development period occurs before conformance testing, safety evaluation, fielding, operator training, and configuration management activities can commence. In practical terms, if an alternative source were identified today, the Government could not expect a fielded, validated replacement capability before calendar year 2028 at the earliest — well after the December 2026 deadline when [redacted] ceases maintenance support for the [redacted]. That sequencing creates a minimum 12-month operational gap that cannot be bridged by the [redacted] installed base alone, because those instruments will be without serviceable maintenance support and will degrade without replacement.

(3) Operational Safety Requirements

Safety is an essential and non-negotiable element of the minimum need because these analyzers are used with unknown environmental samples that may contain hazardous biological material. The fielded operational environment includes NGB CST ALS vehicles with limited engineering controls. The analyzer must either fit

[redacted]

[redacted]

within a standard glovebox (35 inches wide by 24 inches deep by 28 inches high) or be safely operable outside primary engineering controls by personnel wearing Level D personal protective equipment (PPE).

The acceptable platform must be designed to prevent aerosol generation during normal operation. Aerosolization of unknown sample material would create an unacceptable exposure risk to operators in constrained mobile laboratory environments with limited ventilation and containment capability. The analyzer must also withstand hydrogen peroxide decontamination and remain operable so that it can be used and recovered in contaminated operational settings.

These safety constraints materially narrow the field of acceptable products. A platform that depends on internal fluidics or has a housing that does not adequately shield the operator from spills or aerosolized material is not suitable for this requirement, even if it performs analytical functions acceptable in a conventional laboratory setting. The market research record identifies the [redacted]r as an example of a commercially available ECL platform that fails this requirement: its internal fluid handling system and housing do not adequately shield the operator from aerosolized biological hazard material, and NGB mobile laboratories do not have sufficient space in a glovebox or biological safety cabinet to contain the [redacted] approach to meeting this requirement was therefore not viable regardless of the assay chemistry offered.

(4) Compatibility and Interoperability

Compatibility with the existing fielded baseline is a central requirement. The Government has already fielded [redacted] Existing toxin assay kits, plate formats, software workflows, and performance qualification materials are designed around the [redacted]. The required 3-plex toxin assay kits are configured with Government-furnished antibodies and antigens for standard and open-layout assay formats that rely on [redacted], [redacted]

Procuring an alternate analyzer would not be a simple substitution. A different platform would require redevelopment of assay configurations, qualification materials, software workflows, field procedures, and supporting technical documentation before the capability could be used operationally. Commonality across users is also essential for mission support. A single platform family reduces the risk of fragmented training pipelines, incompatible assay inventories, inconsistent maintenance methods, and divergent configuration baselines across the force. Those fragmentation risks are unacceptable in a mission area that depends on standardized and validated field capability.

The requirement also includes Army Gold Master (AGM) compatibility and ruggedization or hardening of computer hardware. Software must generate automatic positive/negative result calls following analysis of environmental samples. These software and hardware constraints further narrow the field of acceptable platforms, because they require not merely that the system generate raw analytical data, but that it generate operationally actionable pass/fail results compatible with Army information system requirements.

(5) Security, ITAR, and Government-Furnished Material Requirements

The requirement includes significant security and access control obligations. The consumables incorporate Government-furnished antibodies and related biological materials that are listed on the United States Munitions List under 22 C.F.R. Part 121 and are therefore subject to International Traffic in Arms Regulations (ITAR) controls. That means performance of this contract requires not only the technical ability to manufacture assay kits, but also the demonstrated organizational capability to securely receive, store, account for, use, and report on sensitive Government-furnished materials throughout production.

The contractor must protect Government-furnished property and information, restrict access to personnel with a need to know, comply with applicable security classification guidance, ensure Operations Security awareness training, and store and protect Controlled Unclassified Information in accordance with NIST SP 800-171 and DFARS 252.204-7012. The performance framework requires monthly and periodic reporting, configuration management controls, quality assurance plans, inspection and test plans, and Government property accountability procedures tailored to this production environment. These requirements presuppose a source that has already demonstrated compliance with the applicable ITAR and GFM handling regime—not merely a source with potential capability to develop such compliance.

[redacted]

[redacted]

(6) Market Conditions and Source Capability Summary

Commercial technologies were examined over multiple years, including ECL and related immunoassay platforms, but the practical result was a very limited supplier base once all mission conditions were applied together. The deficiencies identified in evaluated alternatives are summarized in Section 11a. Other products reviewed in the market did not satisfy the full set of minimum requirements: some lacked methods and assays developed for the required biological targets; some were not safely operable by personnel in Level D PPE without primary engineering controls; some could not generate environmental-sample positive/negative calls; and some were not clearly compatible with Army Gold Master configurations.

The absence of an acceptable alternative source is driven by capability, not vendor preference. The problem is not simply that other firms did not submit quotations; rather, other identified technologies failed one or more essential requirements tied to validated assay availability, operational safety, interoperability, software compatibility, or readiness for field deployment. The contracting officer determined that no responsible alternative source currently exists that can satisfy the integrated requirement described in Section 4.

c. Alternatives Considered

The Government considered three principal alternatives to the proposed sole-source award: (1) [redacted] (2) a competed acquisition for alternate commercial systems; and (3) award to a [redacted] identified through market research.

The first alternative—continued reliance on the [redacted]—does not address the obsolescence problem because [redacted] no longer manufactures the instrument and maintenance support for existing units ends in December 2026. Continued procurement [redacted] without a viable replacement analyzer would create operational risk as the installed base of instruments degrades without serviceable replacements.

The second alternative—a competed acquisition without source restriction—would not remove the requirement for validated toxin assays, safe operation in mobile laboratories without primary engineering controls, compatibility with operational software constraints, Army Gold Master compatibility, or production readiness. Competition does not create capability where none exists in the marketplace. If no evaluated alternative source currently meets the minimum requirements, a competition would either receive only [redacted] offer or result in an award to a source that cannot actually perform, either of which fails to achieve the Government's acquisition objectives.

The third alternative—award to a [redacted] identified through market research—is not viable for the reasons set forth in subsection (b). All specifically identified alternative platforms failed at least one material requirement. If an alternate biological toxin identification system lacks existing validated assays for the required biological targets, market research indicates that real-time stability assessments of 12 to 24 months would be required to achieve the shelf-life maturity necessary for logistical distribution. That development window precedes conformance testing, safety evaluation, fielding, training, and configuration management, meaning the earliest a validated replacement could be fielded from a new source identified today is calendar year 2028 — a minimum of 12 months after the December 2026 [redacted] maintenance cutoff. If a candidate system also requires a primary engineering control due to aerosolization or spill risk, additional time would be required to design containment infrastructure and integrate the technology into NGB mobile laboratory vehicles before safe operational use could commence. These concrete schedule drivers disqualify alternative platforms as viable solutions within the timeframe this acquisition must address.

d. Impact if Not Approved

Disapproval of this justification would create an imminent and unacceptable gap in the supply of ECL analyzers and validated consumables essential to operational biological toxin identification. The [redacted] are obsolescing; [redacted] has confirmed that manufacturing of the [redacted] has ceased and that maintenance support for existing instruments will terminate in December 2026. The absence of a follow-on contract would directly interrupt DBPAO's ability to distribute assay kits and performance qualification kits to DoD technical forces and other Government partners that rely on DBPAO as the validated assay source.

Substitution of a non-compatible or unvalidated platform during any resulting gap period is not operationally viable. New assay validation and real-time stability assessment would require a minimum of 12 to 24 months, which must occur before conformance testing, fielding, operator training, and configuration management

[redacted]

[redacted]

activities can commence. For the duration of that developmental period, NGB CST units and other end users would be without a fielded ECL capability meeting the minimum requirements for toxin target coverage, mobile laboratory operational safety, and automatic positive/negative result calls. Disapproval would therefore materially degrade the Department's biological threat identification capability at precisely the moment when the program is executing the transition from the [redacted] replacement platform.

7. Efforts to Obtain Competition

The acquisition record documents multiple market research and industry engagement events spanning more than a decade. The chronology below reflects all known efforts and has been updated through the date of this document.

Date / Period	Event	Result
2012–2014	CALS down-select process; prior replacement for BioVeris M1M	[redacted] selected in 2014 as the only platform with Government-validated assays for SEB, BoNT-A, and Ricin meeting the required safety profile. CALS Program of Record validated by Army Test and Evaluation Center.
2018	RFI / Sources Sought W911QY-18-S-0005	No new systems identified with Government-validated assays for the required toxin targets.
March 2019; March 2020	Market research and RFI W911SR20RBIOL (SAM.gov)	No new items identified meeting or exceeding CALS FC ACS requirements.
Sep 2018	Solicitation W911SR18S0002, "Sensitive and Specific Detection and Identification of Various Bacteria, Viruses, and Biological Toxins in Environmental Samples"	Only [redacted] responded with a commercially available system ([redacted]).
CY 2021	JPdM CDMA market research for [redacted] obsolescence; multiple candidate systems assessed	[redacted] none met combined operational requirements.
April 2021	DBPAO sources sought notice for [redacted] procurement (SAM.gov)	No responses received.
FY 2022	JPdM CDMA RFI for alternative technologies	[redacted] identified as the best candidate to safely operate in mobile laboratories with available validated assays for the required toxins.
December 2025	DBPAO sources sought notices W911SR26RECLN and W911SR26ECLB (SAM.gov)	Two responses: ([redacted]—response did not address requirements and did not describe ECL technology; [redacted]—described assays for the [redacted] which does not meet the operational safety requirement in [redacted] glovebox space constraints).
25 March – 9 April 2026 (15 days)	Intent to Sole Source synopsis published on SAM.gov (W911SR-26-R-ECLB or applicable notice	No responses received from industry during the 15-day notice period. The absence of responses further corroborates the market research record showing no

[redacted]

[redacted]

	number) for 15-day public notification period per FAR 5.201	responsible alternative source capable of meeting the combined minimum requirements.
Pre-award (required)	Synopsis / pre-award notice under FAR Overhaul 5.201	Notice has been published as described above. Any timely capability statements or proposals received in response to this or subsequent notices will be evaluated against the minimum requirements before award.

8. Effective Competition and Subcontracting Competition

Effective competition is not anticipated based on the current market research record. The sources sought notices published in December 2025, the Intent to Sole Source synopsis posted from 25 March through 9 April 2026, and all prior market research and RFI activity stretching back to 2018 produced no responsible source other than [redacted] capable of providing the integrated ECL analyzer and validated consumables meeting the operational assay, safety, software compatibility, and production readiness requirements.

Subcontracting competition for the core analyzer and proprietary assay consumables is limited by the need for [redacted] compatible products and validated assay lots produced with Government-furnished antibodies and antigens. For non-proprietary supplies, logistics, packaging, shipping, and support items, the contractor should be required to obtain competition to the maximum practicable extent consistent with the FFP commercial product acquisition. The contracting officer should verify [redacted]s current business size in SAM.gov and determine whether a small business subcontracting plan is required under FAR Overhaul 19.302.

9. Actions to Increase Competition

The Government will take the following actions to increase future competition:

(a) Publish the notice required by FAR Overhaul 5.201 and evaluate all timely responses against the stated minimum requirements before award.

(b) Document all source evaluations against the stated minimum requirements. Each evaluated vendor's capability must be assessed against each material requirement (validated assay availability, operational safety, positive/negative call algorithm, Army Gold Master compatibility, and production readiness) with specific findings recorded in the market research file.

(c) Continue periodic market research and technology readiness evaluations for ECL and other field-confirmatory biological toxin identification technologies, specifically tracking whether non-[redacted] vendors can demonstrate: [redacted]

(d) Identify and document the Government's existing data rights and technical data holdings relevant to this requirement. The Government owns the validated assay performance specifications, conformance testing plans, and [redacted]; however, the Government does not currently hold a technical data package or intellectual property rights sufficient to competitively reprocure the proprietary [redacted] assay plates, barcoding system, or Discovery Workbench software interface. The contracting officer shall assess, in consultation with the program office and legal counsel, whether the Government should pursue acquisition of additional data rights — including interface control data or Government Purpose Rights in assay specifications — under the contemplated contract as a mechanism to enable a future competitive acquisition. The outcome of that assessment shall be documented in the contract file before award.

(e) When an alternate source appears capable of meeting the minimum requirements, consider a technology demonstration, validation strategy, or phased acquisition approach—such as a prototype Other Transaction under 10 U.S.C. § 4022 for non-traditional or innovative approaches—that could establish manufacturing readiness and enable a future competitive acquisition.

[redacted]

[redacted]

(f) Ensure DBPAO conducts and documents technology readiness evaluations not less than annually and that results are incorporated into subsequent market research reports and J&A updates for follow-on actions.

10. Market Research

Market research was conducted from 2019 through 2026 by program managers, project officers, and subject matter experts at DBPAO and JPdM Chemical Detection and Mobile Analytics. Research techniques included RFIs, sources sought notices, commercial web searches, scientific literature searches, vendor website reviews, technology information submitted through the JPEO-CBRND Joint Enterprise Technology Tool, and direct engagement with vendors. There are no known Federal Supply Schedule contracts, General Services Administration contracts, or Defense Logistics Agency contracts for these technologies. Searches of the AbilityOne procurement list on 3 March 2025 and 2 February 2026 did not identify the required product or commercial system.

Commercial systems that appeared to have potential to satisfy portions of the requirement were reviewed, but further analysis identified gaps in safety, assay readiness, result interpretation, software compatibility, or production readiness for each alternative. The market research report dated January 2026 ([redacted]) supports a commercial product determination. In accordance with DFARS PGI 212.102(a)(iii)(A)(1), the DoD Commercial Item Database was searched on 10 February 2026. A prior commercial item determination made in connection with contract W911QY-21-D-0019 was identified in the database. In accordance with DFARS 212.102(a)(ii)(A), that prior determination serves as the commerciality determination for this procurement. A copy of the prior determination from contract W911QY-21-D-0019 shall be included in the contract file. The contracting officer shall upload the updated determination to the DoD Commercial Item Database within 30 days of contract award as required by DFARS PGI 212.102(a)(iii)(C).

11. Interested Sources and Other Facts

a. Interested Sources

Source	Information Reviewed	Assessment
[redacted]	[redacted]	[redacted]
[redacted]	Response to December 2025 sources sought notices W911SR26RECLN and W911SR26ECLB	Response did not address any of the requirements listed in the notices and did not describe ECL technology or available products. Response does not establish that [redacted] an meet the requirement.
[redacted]	ECL assays and [redacted] response to December 2025 sources sought	[redacted]
[redacted]	Commercial systems identified during multi-year market research	Each system was found to have one or more of the following deficiencies: (1) no developed methods/assays meeting CALS FC ACS sensitivity and specificity thresholds for the required toxin targets; (2) not safely operable with personnel using Level D PPE

[redacted]

[redacted]

[redacted]		outside primary engineering controls; (3) no algorithm to enable positive/negative calls following analysis of environmental samples; (4) unknown or confirmed incompatibility with Army Gold Master.

b. Procurement History

Contract No. / Contractor	Type	Method	Offerors	Amount	Period of Performance
GS01T13BKD0004 / Veteran Corps of America	FFP	Full and Open Competition after exclusion of sources / Small Business Set-Aside	3	[redacted]	SEP 2017 – JAN 2018
W911QY-18-D-0108 / [redacted]	FFP	Sole Source	1	[redacted]	12 MAY 2020 – 11 MAY 2021
W911QY-21-D-0019 / [redacted]	FFP IDIQ	Sole Source	1	[redacted]	23 MAR 2021 – 22 MAR 2026

Contract GS01T13BKD0004 was awarded to Veteran Corps of America for 19 CALS FC ACS Systems that included the [redacted] analytical instrument as a component. Procurement was through full and open competition after exclusion of sources/small business set-aside, with three offerors. The total awarded amount was [redacted] with a period of performance of one year. Fair and reasonable price was established through price analysis on a lowest-price basis.

Contract W911QY-18-D-0108 was awarded sole source to [redacted], accessories, and training ([redacted], FFP, one year). Fair and reasonable price was established through cost realism and cost analysis.

Contract W911QY-21-D-0019 was awarded sole source to [redacted] for multiplex assays, kits, and components ([redacted], FFP IDIQ, five years with one base and four option periods). Fair and reasonable price was established through cost realism and cost analysis. The current action is the follow-on to W911QY-21-D-0019 and is driven by the continued operational need for validated ECL consumables, fielding of the [redacted] replacement, and the absence of an evaluated alternate meeting the combined minimum requirements. The Actions to Increase Competition section of the justification supporting W911QY-21-D-0019 identified continued market research and technology readiness evaluations as the principal mechanisms for future competition. Those actions were carried out through market research events in CY 2021, FY 2022, and December 2025, including sources sought notices W911SR26RECLN and W911SR26ECLB and an Intent to Sole Source synopsis posted from 25 March through 9 April 2026. The results of those efforts are detailed in Section 7 and Section 10 of this justification. No alternative source meeting the combined minimum requirements has been identified. The barriers to competition identified in the prior justification — the absence of validated assays for required toxin targets on a platform meeting the operational safety and software requirements — remain unchanged. In accordance with DFARS PGI 206.304(a)(S-70)(ii), the contracting officer shall confirm the applicable approval authority level for this follow-on action based on whether the prior J&A's planned competition actions were fully accomplished, and shall document that determination in the contract file before routing for approval.

[redacted]

[redacted]

c. Other Facts

Pricing information for [redacted] was generally not publicly available through vendor websites. The IGCE was developed using unit prices from option year four of W911QY-21-D-0019 with an applied inflation factor, historical order data from DBPAO's Ordering System for Critical Assays and Reagents (OSCAR), and supplier tiered pricing information received in response to the 2026 sources sought. Economies-of-scale discounts are available from [redacted] according to their 2026 RFI response. Technical data packages, specifications, and engineering descriptions suitable for full and open competition have not been developed and are not currently available. [redacted] holds all intellectual property and proprietary rights required to manufacture the ECL assay plates, barcode system, and associated reader firmware. The Government does not possess, and has not acquired, the manufacturing data or proprietary formulations needed to independently describe the supplies in a manner that would permit competition among alternative manufacturers. No remedial action to develop such a package was taken under W911QY-21-D-0019. As noted in Section 9(d), the contracting officer will assess whether targeted data rights provisions in the contemplated contract can begin to address this gap for future procurements.

End items are subject to ITAR controls because Government-furnished antibodies incorporated into the consumables are listed on the United States Munitions List under 22 C.F.R. Part 121. This ITAR status supports the need to document and enforce configuration control, conformance testing, Government-furnished property accountability, and ITAR compliance requirements in the contract, consistent with DFARS 252.225-7048 and applicable security classification guidance.

12. Technical Certification

I certify 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]

13. Requirements Certification

I certify 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]

14. Fair and Reasonable Cost Determination

I hereby determine that the anticipated price/cost to the Government for this contract action will be fair and reasonable. This determination is based on price analysis conducted under FAR Overhaul 15.404-1(b), using the following techniques:

(a) Comparison of proposed prices to the IGCE developed using option year four pricing from W911QY-21-D-0019 with an applied inflation factor.

(b) Comparison of proposed prices to historical prices paid under W911QY-21-D-0019 and W911QY-18-D-0108 for the same or similar items.

[redacted]

[redacted]

(c) Market research information regarding commercial availability, quantity discounts, and tiered pricing received through the 2026 sources sought notice.

(d) Data other than certified cost or pricing data under FAR Overhaul 15.403-3, as needed.

Certified cost or pricing data will not be required if the contracting officer determines that the supplies and services meet the commercial product or commercial service exception at FAR Overhaul 15.403-1(b), consistent with the commerciality determination documented in Section 10. The contracting officer shall document the price analysis and fair-and-reasonable determination in the contract file before award.

[redacted]

15. Contracting Officer Certification

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

[redacted]

[redacted]

[redacted]

APPROVAL

Based on the foregoing justification, I hereby approve the procurement of Multiplex Electrochemiluminescence (ECL) Analyzers, Immunoassay Kits, Performance Qualification Kits, reagents, and related consumables on a sole-source basis under simplified acquisition procedures for certain commercial products and commercial services pursuant to the authority of Title 41 U.S.C. § 1901(e)(2), as implemented by FAR Overhaul 12.102.

[redacted]

[redacted]