United States Department of Agriculture
Class Justification to Restrict Competition
Identification Number: 1164220

In accordance with the Revolutionary Federal Acquisition Regulation (FAR) 12.102(b), the following justification documents the decision to restrict competition for this acquisition.

(1) Mission Area and Contracting Activity.

The contracting activity, USDA, APHIS, Marketing and Regulatory Programs Business Services (MRPBS), Acquisition and Asset Management Division (AAMD), proposes to enter into contracts on the basis of other than full and open competition.

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

This is a Class Justification and Approval (J&A) for the acquisition of specialized diagnostic testing services using other than full and open competition. The Government intends to limit competition to laboratories possessing the unique qualifications, certifications, validated interoperability, and technical capabilities necessary to satisfy the agency's minimum requirements. These diagnostic testing services are commercial in nature and will be procured in accordance with the procedures prescribed in FAR Part 12.

To ensure effective animal disease diagnosis and surveillance, ongoing access to eligible laboratories is essential. These services enhance U.S. animal agriculture by strengthening national veterinary diagnostic networks for early detection, rapid response, and recovery from high-impact diseases. Demand for these services is driven by unpredictable outbreaks, and APHIS expects continued or increased need compared to past efforts.

Authority to act under this class justification expires on 31 May 2036.

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

The laboratories will provide diagnostic testing services for endemic animal diseases of high consequence and foreign animal diseases. The services include conducting a range of approved diagnostic assays for both routine and emergency testing, including during potential bioterrorism events, to ensure the rapid detection, reporting, and confirmation of animal disease occurrences. All samples that test presumptive positive or inconclusive will be submitted to the National Veterinary Services Laboratories (NVSL) for confirmatory testing.

In addition, the laboratories will provide accurate and timely diagnostic data to meet epidemiological and reporting requirements, support responses to foreign animal disease outbreaks and other adverse animal health events, and conduct testing for livestock diseases, including exotic, zoonotic, and emerging diseases, as well as diseases affecting non-livestock species.

These services enable nationwide testing for early detection of outbreaks, allow for rapid processing of large volumes of samples during an event, and support confirmation of disease-free status following eradication efforts. This effort is crucial to maintaining national readiness and operational capacity in response to unpredictable and potentially high consequence animal health events. If these services are not provided, high-consequence animal diseases could spread undetected, causing major livestock

losses, economic disruption, and risks to animals and humans. Reduced capacity to respond to bioterrorist threats, emerging diseases, and foreign animal disease agents would severely impact the mission to protect U.S. agriculture, safeguard the nation's food supply and public health, and support national security.

It is anticipated that approximately fifty-one (51) indefinite delivery, indefinite quantity (IDIQ) contracts, each with five-year order periods, will be awarded, with follow-on contracts expected every five years. The estimated value of this action is $255,000,000 annually, or $2,550,000,000 over the 10-year period covered by this class justification. No individual IDIQ contract will exceed $25,000,000.

(4) Identify the statutory authority permitting other than full and open competition.

The statutory authority permitting other than full and open competition is FAR 6.103-1, Only One Responsible Source. This authority permits limiting competition where only one responsible source or a limited number of responsible sources can satisfy the Government's requirement.

(5) Demonstrate that the proposed contractor's unique qualifications or the nature of the acquisition requires using the authority cited.

The statutory authority permitting other than full and open competition for this procurement applies due to the unique qualifications of the proposed contractors and the nature of the acquisition. Only laboratories approved for membership in the National Animal Health Laboratory Network (NAHLN) are authorized and qualified to perform the required diagnostic assays on approved samples.

The Government's minimum needs require laboratories to maintain a competent and ready network from which APHIS can obtain critical testing services during an animal emergency. Capabilities at time of award must meet stringent membership criteria and standards for participation in the network. To ensure laboratories fully meet all required capabilities at the time of award, NAHLN membership is governed by rigorous, nationally standardized criteria that collectively confirm technical competency, quality assurance, biosafety readiness, and interoperability with federal animal-health systems. Laboratories must satisfy the minimum requirements defined in the NAHLN Program Standards, including maintaining full third-party accreditation (AAVLD or ISO 17025) for assays under NAHLN scope, demonstrating a functional quality management system, and renewing their Agreement for Participation in the NAHLN every 2 years to affirm continued compliance with established standards. They are required to complete government-recognized diagnostic testing using NAHLN-approved, validated methodologies and must hold at least two NAHLN disease approvals requiring molecular assays, supported through proficiency-tested personnel and verifiable assay performance. Laboratories must also demonstrate interoperability with federal electronic reporting requirements by successfully transmitting diagnostic results via LIMS-generated HL7 messaging, a mandatory criterion for NAHLN-approved testing. In addition, participating laboratories must maintain sufficient capacity to meet expected surveillance, and surge testing needs and, for Level 1 laboratories, must possess Biosafety Level 3 (BSL-3) functionality and sustained external funding to ensure high throughput and readiness during animal-health emergencies. Requirements further include validated processes for

chain of custody and data integrity, secure handling of sensitive information, participation in network activities, and adherence to biennial self-assessment and verification processes that review accreditation status, electronic messaging capability, proficiency testing, disease approvals, and overall performance against NAHLN matrices used for level designation decisions. These integrated standards ensure that only laboratories with demonstrated quality, technical capability, regulatory compliance, and operational readiness are awarded NAHLN membership and entrusted with responsibilities essential for national animal-health surveillance and response.

The Government determined these requirements are essential to mission accomplishment and are not administrative preferences. The emergent and unpredictable nature of foreign animal disease outbreaks requires immediate access to laboratories already authorized, trained, and validated under the NAHLN framework. Based on market research, only laboratories currently operating within the existing National Animal Health Laboratory Network are known to satisfy all requirements without substantial duplication of cost, unacceptable delays or unacceptable performance risk to ensure their continued availability and capability in the event of a national animal health emergency, as set forth in 7 U.S.C. § 8308a(a), "Animal Disease Prevention and Management," National Animal Health Laboratory Network. Because non-NAHLN laboratories cannot legally or operationally begin testing without federal authorization, only NAHLN labs can meet the agency's minimum response timeline.

(6) Provide a description of efforts made to ensure that offers are solicited from as many potential sources as possible, including whether a notice was or will be publicized as required by Part 5 and, if not, which exception under Part 5 applies.

In accordance with RFO FAR 12.202(b), a combined pre-solicitation notice and solicitation will be posted to the SAM website.

The Government will continue to assess the marketplace to identify additional laboratories capable of meeting the minimum requirements. Laboratories that have already completed NAHLN's comprehensive vetting and approval process, establishes their technical capability, performance qualifications, and authorization to conduct diagnostic testing on approved samples will also be eligible. The Government may consider onboarding additional laboratories if those laboratories successfully complete all the required qualifications, interoperability, accreditation and validation processes.

(7) A determination by the Contracting Officer that the anticipated cost to the Government will be fair and reasonable.

The Contracting Officer will determine the anticipated cost to the Government of the services covered by this J&A will be fair and reasonable based on a thorough comparison of historical pricing data from prior contracts, the development of an Independent Government Cost Estimate (IGCE) using current market rates, and a review of available catalog pricing.

(8) A description of the market research conducted, and the results or a statement of the reason Market Research was not conducted.

Market research, including a review of universities and state laboratories capable of providing the required diagnostic testing services, indicates that numerous laboratories within the United States meet the technical qualifications and minimum requirements established for NAHLN-eligible facilities. These laboratories possess the necessary infrastructure, validated assays, quality management systems, and biosafety capabilities to perform the required diagnostic testing. It is anticipated that a sufficient number of laboratories will continue to pursue and maintain eligibility under the established NAHLN standards, ensuring a capable national network remains available to respond to threats arising from animal disease or bioterrorism.

(9) Any other facts supporting use of other than full and open competition, such as:

The purpose of the NAHLN is to coordinate and integrate USDA's NVSL with the capacity, facilities, professional expertise, and support of state and university laboratories. The network provides an extensive, geographically distributed infrastructure of facilities, equipment, and trained personnel that can be accessed rapidly in the event of an animal health emergency. APHIS uses the NAHLN to enhance early detection of foreign animal disease agents and newly emerging diseases, to improve the national response to animal health emergencies, including bioterrorism events that threaten the nation's food supply and public health, and to assist in assessing the nation's animal health status through surveillance and shared diagnostic data.

(10) A listing of the sources, if any, that expressed an interest in the acquisition in writing.

None

(11) A statement of the actions, if any, the agency may take to remove or overcome any barriers to competition before any subsequent acquisition of the supplies or services required.

To support future competition to the maximum extent practicable, laboratories that are not currently authorized to perform the required diagnostic testing may pursue eligibility by following the established NAHLN standards and approval process. Laboratories may initiate this process by submitting a Letter of Intent and completing the program's published technical and quality requirements. Expressions of interest may be submitted in writing to NAHLN@usda.gov.

The criteria, procedures, and evaluation standards governing eligibility for participation in the National Animal Health Laboratory Network are publicly available at the following link: https://www.aphis.usda.gov/sites/default/files/genprocnahlnapproval.pdf.

Technical / Requirements Personnel Certification
I certify this requirement meets the Government's minimum need and that the supporting data, which forms a basis for this justification, is complete and accurate.

CHRISTINA LOIACONO
Digitally signed by CHRISTINA LOIACONO
Date: 2026.05.30 06:37:15 -04'00'

Christina Loiacono — Date
National Animal Health Laboratory Network Coordinator

Contracting Officer's Certification
I certify that the data supporting the recommended use of other than full and open competition accurate and complete to the best of my knowledge and belief.

ROBERT ZEGLIN
Digitally signed by ROBERT ZEGLIN
Date: 2026.06.02 16:04:02 -05'00'

Robert Zeglin — Date
Contracting Officer

Competition Advocate (greater than $900,000 but not exceeding $20M).
I have reviewed this justification and find it to be accurate and complete to the best of my knowledge and belief. Therefore, unless additional approvals are required as prescribed below, as advocate for competition for the procuring activity, I hereby approve this justification. If required, my approval constitutes clearance for submission to the Head of the Contracting Activity (HCA).

HOWARD PRICE
Digitally signed by HOWARD PRICE
Date: 2026.06.04 16:32:03 -04'00'

Howard Price — Date
Competition Advocate

HCA (greater than $20M but not exceeding $90M).
I have reviewed this justification and find it to be accurate and complete to the best of my knowledge and belief. Therefore, unless additional approvals are required as prescribed below, as Head of the Procuring Activity, I hereby approve this justification. If required, my approval constitutes clearance for submission to the Senior Procurement Executive (SPE).

CRAIG HARPER
Digitally signed by CRAIG HARPER
Date: 2026.06.11 09:08:17 -05'00'

Craig Harper — Date
Head of Contracting Activity (HCA)
United States Department of Agriculture

SPE of the Agency ($90M and over).
I have reviewed this justification and find it to be accurate and complete to the best of my knowledge and belief. Therefore, as the Senior Procurement Executive, I hereby approve this justification.

HILARY ERICKSON

Digitally signed by HILARY ERICKSON
Date: 2026.06.12 07:39:53 -05'00'

Hilary Erickson
Senior Procurement Executive (SPE)
United States Department of Agriculture

Date