Biomedical Advanced Research and Development Authority (BARDA)

Administration for Strategic Preparedness & Response (ASPR)
U.S. Department of Health and Human Services (HHS)

Request for Information (RFI) for

"High Performance Antigen Diagnostics"

Issued: 16 June 2026

Responses Due: 1pm EDT, 17 July 2026

Biomedical Advanced Research and Development Authority (BARDA)
Contracts Management & Acquisition (CMA)
400 7th Street, SW, Washington, DC 20024

MedicalCountermeasures.gov

“High Performance Antigen Diagnostics”

Request for Information (RFI)

Purpose

The Rapid Response Partnership Vehicle (RRPV) is issuing this Request for Information (RFI) to better understand the research, development, and product landscape of current and next-generation high-performance immunoassay technologies suitable for antigen testing in near-patient settings. While conventional antigen-based immunoassays offer speed, ease of use, and low cost, they remain limited by lower analytical sensitivity and limited multiplexing capability compared to nucleic acid amplification tests (NAATs), limiting their clinical utility, particularly for early infections and syndromic panels.

BARDA is interested in identifying technologies capable of achieving NAAT levels of clinical performance, particularly ~1-10 pg/mL limits of detection (or better), and understanding how such capabilities can be translated into point-of-care (ideally CLIA-waived) or at-home testing formats. Existing high-performance laboratory platforms (e.g., those used for the detection of cardiac biomarkers such as high-sensitivity troponin assays) demonstrate that this level of performance is achievable; however, significant challenges remain in reducing system complexity, size, cost, and operational requirements for point-of-care, at-home, and/or remote/field use. This RFI seeks to understand both currently available systems and emerging technologies, including integrated platforms and enabling components, that can bring ultra-sensitive performance into smaller, faster, more deployable, and ideally multiplexed platforms or formats. Submissions focused primarily on antibody/binder/molecular recognition element generation are outside the scope of this RFI. However, novel assay formats or enabling chemistries (e.g., amplification or detection strategies) that substantially increase sensitivity are of interest.

Potential areas of interest (non-exhaustive list):

- High-sensitivity immunoassay platforms being developed or adapted for point-of-care, CLIA-waived use, or at-home use. Include information on current or planned multiplexing capabilities.
- Next-generation detection technologies or assay formats that enable ultra-low limits of detection and/or high multiplexing (e.g., GFETs, arrays, emulsions, single-molecule detection or signal amplification approaches)
- Miniaturization and system integration strategies to translate lab-based sensitivity and multiplexing into portable or fieldable devices
- Continuous or near-continuous monitoring approaches, including wearable or minimally invasive systems
- Sample processing and concentration methods (on- or off-device) that enable improved recovery of low-abundance antigens.

Request for Information

The objective of this RFI is to solicit feedback from industry, academia, and other stakeholders to assist BARDA in identifying technologies, capabilities, and potential partnerships that can substantially

improve the sensitivity of antigen-based diagnostics for use in near-patient settings (e.g. point-of-care and at-home).

Respondents do not have to be a member of the RRPV consortium to submit a response for this RFI; however, they must be a member of the consortium to respond to any future request for project proposals (RPP) for this requirement.

Please submit responses by email to rrpv@ati.org no later than

1pm EDT July 17, 2026

Late responses will not be considered.

This RFI is for information gathering purposes only. It does not constitute a Request for Project Proposal (RPP) nor does it imply any obligation to issue a future solicitation, make any award, or pay any costs associated with responding to this RFI. Submission is voluntary and does not commit the responder to respond to any subsequent opportunities (if any) related to this topic. The RRPV will not return or provide feedback on any submissions; however, BARDA reserves the right to further engage with respondents in a Market Research Call to clarify understanding of submitted information. All responses to this RFI will be treated as sensitive information and confidentiality will be protected accordingly.

Requested Information:

Respondents are invited to provide a concise response addressing the following topics:

1. **Organizational Overview**
   - Brief description of your organization/team, core expertise, and primary focus areas
   - Summary of prior experience with diagnostics

2. **Proposed Solution Technical Overview**
   - Clear description of your high-performance antigen assay/platform. Sensitivity is a higher priority than multiplexing capability. Ideal solutions address both sensitivity and multiplexing. Include discussion of these points:
     - Clear description of detection technology, signal amplification methods, sample processing/concentration approaches, or other approaches that contribute to sensitivity gains
     - Address the maturity of your platform/solution (see https://medicalcountermeasures.gov/trl/trls-for-medical-devices; e.g., concept, R&D, prototype, commercial)
     - Include intended workflow, including sample input, sample processing steps (if applicable), detection method, and output/readout
     - Feasibility data demonstrating performance comparable to NAATs (ideally approaching ~1-10 pg/mL or better). Clearly identify sample types and relevant testing conditions.
     - Data demonstrating multiplexing capability
     - Description of any development work required to integrate into a sample-to-answer diagnostics system; provide high-level expected timelines and key milestones
   - Manufacturing and scalability considerations:

- Strategy for scaling production (reagents, devices, consumables)
- Supply chain considerations and potential constraints

3. **Infrastructure & Capabilities**
   - Brief description of existing facilities, infrastructure, and capabilities

Responses

Interested parties should respond to this RFI with a written response consisting of a cover page and a technical response (PDF or Word; no smaller than 10-point font). The cover page should provide administrative and contact Information (contact name, title, email address, phone number) and organizational information of the responder (entity name, headquarters, mailing address). The technical response should be no longer than 5 pages and include the following:

1. Executive Summary (≤0.5 page)
2. Technical Overview (≤4 pages)
3. Capabilities and Infrastructure (≤0.5 page)

Add references as necessary but be sure to include all relevant information in the response. Cited publications or attachments may not be read.

Respondents must clearly mark all copyrighted information, data, and materials with appropriate restrictive legends (e.g., confidential, privileged, proprietary, trade secret). To aid in protecting your information, please segregate proprietary information. DO NOT SUBMIT ANY CLASSIFIED INFORMATION.

Please note that non-federal employees performing advisory and assistance services will have access to any submission under this RFI. All non-federal employees are required to sign a non-disclosure agreement prior to accessing the RFI responses.