UNCLASSIFIED

Request for Information (RFI)

"Agnostic Metagenomic Next-Generation Sequencing (mNGS) for Clinical Diagnostics"

Issued by:
Advanced Technology International (ATI),
Medical CBRN Defense Consortium
315 Sigma Drive
Summerville, SC 29486

Request Issue Date: April 17, 2026

Responses Due Date: May 20, 2026
Noon Eastern Time

DISCLAIMER

This is an information request only. This request is issued solely for information and planning purposes – it does not constitute a Request for Proposal (RFP) or a promise to issue an RFP in the future. Solicitations are not available currently. This notice does not constitute a commitment by the United States Government to contract for any supply or service whatsoever.

Purpose:

The Capability Program Executive for Chemical, Biological, Radiological, and Nuclear Defense (CPE CBRND) invites you to collaborate on a critical mission: to develop a field-forward, threat-agnostic metagenomic next-generation sequencing (mNGS) capability for rapid identification of traditional, novel, emerging, and engineered infectious disease agents. This initiative seeks to address a critical gap in the current diagnostic portfolio by enabling hypothesis-free identification of pathogens that may be undetectable by standard targeted assays.

This RFI is your opportunity to help shape the future of military medical diagnostics and contribute directly to the health, readiness, and resilience of our Armed Forces in diverse operational environments.

This initiative is a critical component of a Medical Readiness and Response capability. Potential technologies will directly support Formation Based Layered Protection. By enabling early and accurate characterization of pathogens, agnostic metagenomic next-generation sequencing (mNGS) clinical diagnostics capability will help the Joint Force avoid being understood by disrupting adversary capabilities to identify, locate, and target. By enabling appropriate and timely treatment, they will help the warfighter avoid being hit and ensure they can survive if hit or attacked to sustain and regenerate combat power.

Requested Information of Interest:

CPE CBRND is conducting essential market research for a new initiative dedicated to identifying and advancing mature, portable, and integrated mNGS systems for clinical diagnostics. The program focuses on overcoming technical and regulatory hurdles currently preventing deployment of mNGS as a routine clinical diagnostic tool, particularly in resource-limited or austere settings.

Unlike targeted assays, mNGS offers comprehensive and unbiased detection of pathogens (i.e., viral, bacterial, fungal, and parasitic) from a human clinical sample (e.g. blood, respiratory sample, or other minimally invasive sample types). This capability is essential for diagnosing infections of unknown origin, traditional, novel or genetically modified threats, providing molecular data for outbreak investigations, and enabling informed decisions by Department of War (DoW) leadership.

We are seeking collaboration with innovative industry partners who are developing cutting-edge, end-to-end solutions that address the following critical challenges:

Integrated "Sample-to-Answer" System: Fully-automated and ruggedized platforms that minimize manual steps from nucleic acid extraction of clinical samples and library preparation, to sequencing and bioinformatic analysis, ideally, in a single system and workflow.

Host Nucleic Acid Depletion: Efficient and unbiased methods for removing the overwhelming background of human host DNA/RNA from complex human clinical samples (e.g., blood), when

targeting microbial species.

Field-Forward Bioinformatics: Computationally efficient, **offline analysis** with curated, regulatory-grade databases that can be securely updated. Systems must incorporate validated bioinformatics thresholds for confident pathogen identification.

Clinical Decision Support: Advanced interpretive tools to help distinguish true pathogens from contaminants or commensal organisms, and provide an output report for operators who may not be infectious disease specialists but can submit the results report to a physician or healthcare provider for appropriate action.

Host-Response Profiling ("Stretch Goal"): Capabilities for analyzing the host's transcriptomic response (e.g., mRNA sequencing) to identify unique gene expression "signatures" indicative of infection by a particular microbial genus or species. This represents a "next level" next-generation clinical diagnostic capability for instances where direct pathogen detection may fail.

Regulatory Path: This market research extends beyond the core technology to address the significant programmatic hurdles inherent in fielding a novel medical diagnostic. Therefore, CPE CBRND is equally interested in solutions that are supported by a viable and proactive regulatory strategy for achieving U.S. Food and Drug Administration (FDA) authorization (e.g., Emergency Use Authorization (EUA), 510(k) (Food, Drug, and Cosmetic Act), or *de novo*) and a scalable manufacturing plan that can support potential military requirements. A mature technical solution without a clear path to approval/authorization and production will be considered of limited value.

We are seeking mature candidates (preference to systems at Technology Readiness Level (TRL) 4 or higher) that align with the following ideal product profile:

Example Target Product Profile (TPP) for Agnostic mNGS Clinical Diagnostics

This profile targets a portable, rapid, and easy-to-use mNGS system for the identification of causative agents of infectious diseases from human clinical samples by operators.

Feature	Desired Characteristics
Intended Use	Rapid, hypothesis-free identification of viral, bacterial, fungal, or parasitic pathogens in clinical samples to diagnose infections of unknown origin, and to identify traditional or novel/engineered threats in a far-forward field or forward-laboratory setting.
Platform	Ideally, system is a backpack-sized, battery-operable system with minimal footprint and proven environmental robustness. Preference is for platforms enabling real-time data analysis. At a minimum, system must be suitable for deployment at Role 3 (field hospital, or equivalent).
Workflow	**Fully automated "sample-to-answer" workflow is ideal**. Integrate nucleic acid extraction, host depletion (when targeting microbial

	species), library preparation, sequencing, and reporting in a closed or cartridge-based system with minimal hands-on time (< 15 minutes).
Time- Answer	Optimal: **< 6 hours from sample input to actionable report**. Solutions with varying run-times will be considered based on workflow complexity and data output.
Read Technology	**Long-read or ultra-long-read capability** is highly desirable to enable *de novo* assembly of novel pathogen genomes.
Bioinformatics	**Offline**, laptop-based analysis pipeline with a curated, secure, and updateable database. Must include automated quality filtering, host subtraction, and taxonomic classification with validated reporting thresholds and confidence metrics.
Host Biomarker (Stretch Goal)	Capability to analyze human host transcriptomic data (mRNA) to identify gene expression profiles or biomarkers indicative of infection, ideally by a specific pathogen class, genus or species. Ability to distinguish actual infection from colonization/normal flora or other inflammatory states, and the stage/severity of infection.
Regulatory Path	Experience with FDA pathways such as EUA, 510(k), and/or *de novo* classification is highly desirable. Familiarity with Clinical Laboratory Improvement Amendments (CLIA) waiver criteria is also of interest. **Must be willing to actively pursue a clinical diagnostics regulatory path** for the system and meet FDA and DoW requirements for clinical diagnostics of human samples. This will require generating a comprehensive data package through formal Test and Evaluation (T&E).

Administration:

Respondents are requested to submit a white paper, not to exceed five (5) pages, that addresses the following areas (A through F, below), in the order presented. A separate, one-page Quad Chart should also be included. It should contain the project objective and product benefit; a high-level development schedule with major goals/timelines; a Rough Order of Magnitude (ROM) cost to completion; and any associated Intellectual Property rights, patent coverage, or data rights assertions.

When reviewing responses, the government will place the greatest emphasis on the "Technical Approach & Product Maturity" and “Bioinformatics & Clinical Interpretation" sections. Responses that provide detailed, data-driven evidence of integrated, automated solutions with high confidence results will be considered most valuable.

A. Technical Approach & Product Maturity

1. System Description: Describe the complete "sample-to-answer" system, including sequencing platform, instrumentation for sample preparation, and key reagents. Describe system’s portability, ruggedization, and intended operational environment.
2. Technology Readiness Level (TRL): State the product’s current TRL using the Technology Readiness Levels (TRLs) for Medical Countermeasure Products

(Diagnostics and Medical Devices (https://medicalcountermeasures.gov/trl/trls-for-medical-devices), and provide justification for this assessment.

3. Sample Preparation & Host Depletion: Detail workflow from raw clinical specimen to sequence-ready library. Specify level of automation. Describe methodology for human host nucleic acid depletion (if targeting microbes), including efficiency across various sample types (especially blood), and data on potential taxonomic bias.
4. Efficacy Data Summary: Summarize all significant performance data using contrived or real-world clinical samples. Specify the sample types, organisms targeted, and key outcomes (e.g., Limit of Detection (LoD), inclusivity, exclusivity, and time-to-answer).

B. Bioinformatics & Clinical Interpretation

1. Analysis Pipeline: Describe bioinformatics workflow, including software for base calling, quality control, host subtraction, taxonomic classification, antimicrobial resistance (AMR) gene detection, and detection of traditional, novel, enhanced/advanced (genetically-engineered) pathogens. State if the pipeline can operate entirely offline.
2. Database Management: Detail the source, curation process, and update frequency for the microbial reference database (and human reference database for the host response profiling "stretch goal", if appropriate). Describe the security measures and the process for updating databases on deployed, offline systems.
3. Clinical Relevance & Reporting: Explain how the system aids in distinguishing true pathogens from contaminants or background organisms. Describe any clinical decision support features, confidence scoring, or validated reporting thresholds used to generate an actionable report for a non-specialist user.

C. Regulatory & Clinical Status

1. U.S. Food and Drug Administration (FDA) Engagement: Provide a concise history of all interactions with the FDA regarding this system. Include the status of any submissions (e.g., Pre-Submission, EUA, 510(k)) and a summary of any formal feedback received.
2. Clinical/Usability Data**:** Detail any completed or ongoing studies involving clinical specimens. Describe any human factors or usability studies conducted with intended users in simulated operational environments.

D. Manufacturing & Supply Chain

1. Current Capabilities: Describe your current manufacturing capacity (e.g., laboratory, pilot, or full-scale current Good Manufacturing Practice (cGMP)) for instruments and consumables/reagents.
2. Scalability & Shelf Life: Briefly outline the strategy for scaling production. State the demonstrated stability and shelf-life of reagents, noting any cold-chain requirements.

E. Company Profile & Vision

1. Corporate Experience: Describe your company's experience in developing and

commercializing regulated medical diagnostic devices, particularly those involving molecular methods or instrumentation.

2. Teaming Strategy: Specific mention of partnerships with T&E organizations capable of supporting analytical and clinical validation for FDA submission and to meet DoW requirements is strongly encouraged.

F. Information Requested from Test & Evaluation (T&E) Partners

In parallel with identifying primary system developers, CPE CBRND is seeking to understand the landscape of independent T&E organizations capable of validating mNGS clinical diagnostic systems. T&E organizations are invited to submit a separate white paper, not to exceed two (2) pages, that details their capabilities in the following areas:

1. Corporate Experience: Describe your organization's experience in the T&E of regulated medical devices, particularly molecular diagnostics. Highlight any specific experience with NGS platforms and bioinformatics pipeline validation.

2. Laboratory Capabilities: Detail your facility's capabilities, including relevant Biosafety Levels, and experience handling complex human clinical matrices (e.g., whole blood).

3. Regulatory & Validation Experience: Describe your experience conducting analytical and clinical validation studies intended for FDA submissions (EUA, 510(k), *de novo*). Highlight experience with establishing performance characteristics such as LoD, inclusivity, and cross-reactivity for sequencing-based assays.

4. Past Performance: Briefly describe past T&E programs conducted for government or industry partners in relevant diagnostic areas.

As part of this Request for Information (RFI), the Government will host in-person, one-on-one engagement sessions during the Annual Membership Meeting, scheduled for May 12–13, 2026, at the Gaylord in National Harbor. Interested organizations will need to submit a separate response to request an in-person meeting to mcdc@ati.org no later than May 1, 2026 by Noon EST and must submit their RFI by May 7th. Additional details and scheduling information will be provided upon receipt and review of requests.

Virtual one-on-one sessions will also be offered following the closing of this RFI for respondents who are unable to attend in person. Please submit your request for a virtual engagement session to mcdc@ati.org or indicate this request in your RFI response. Additional details and scheduling information will be provided upon receipt and review of requests.

Responses must be sent to mcdc@ati.org with the subject line denoting the Responding organization and RFI Title. Material that is advertisement-only in nature is not desired.

MCDC membership is NOT required for the submission to this RFI. However, should this RFI result in a formal solicitation through the MCDC Consortium, membership will be required for

submission of an Enhanced White Paper.

Note: This RFI is issued solely for information and planning purposes and does not constitute a solicitation. Neither unsolicited proposals nor other offers will be considered in response to this RFI. Responses to this notice are not offers and will not be accepted by the government to form a binding contract. Responders are solely responsible for all expenses associated with responding to this RFI. Request for Information papers should NOT include proprietary or classified information.

Points of Contact:

For inquiries, please direct your correspondence to the following contacts:

- Government Technical questions should be directed to CPE CBRND - Joint Product Lead - Diagnostics, Jason Opdyke, jason.a.opdyke.civ@army.mil
- ATI Technical questions should be directed to the Technical Project Analyst, Seth Tomblyn, seth.tomblyn@ati.org
- Any general or administrative questions about the process for submitting responses to this information request may be directed to MCDC Program Manager, Robert Harwell, mcdc@ati.org