UNCLASSIFIED

Request for Information (RFI)

"Host-Based Diagnostics for Acute Infections"

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

Request Issue Date: April 20, 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:

Capability Program Executive for Chemical, Biological, Radiological and Nuclear Defense (CPE CBRND) invites you to collaborate with us in a critical mission: to develop the next generation of host-based assays for diagnosis of disease etiology, prognostication of clinical outcomes, and directed administration of therapeutic treatments that will protect the warfighter from chemical, biological, radiological, and nuclear (CBRN) threats.

This RFI is your opportunity to help shape the future of military medicine and contribute directly to the readiness and resilience of our Armed Forces. The decade-long surge in tracking host responses to pathogens has spawned diagnostic technologies that utilize specific panels of host response molecules to differentially diagnose the class of pathogen (e.g., bacterial or viral), predict the likelihood of severe illness, and/or enable the selection of therapeutic regimen. The goal is to identify and develop a new generation of host-based tests to diagnose a warfighter's condition, predict clinical outcomes, and direct the optimum therapeutics for maximal disease recovery. This creates a prime opportunity for innovative companies to align their research and development pipelines with a forward-looking program.

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Requested Information of Interest:

CPE CBRND is conducting essential market research for the **Advanced Differential Diagnostics (ADD)** program, an existing Program of Record that is developing new diagnostic capabilities in a phased approach. This program is dedicated to identifying and advancing mature diagnostics that utilize the warfighter's early response to the pathogen. CPE CBRND will be focused on developing and delivering diagnostics that help meet operational and mission needs across the conflict continuum. The goal is to create a resilient force, capable of withstanding, mitigating, and recovering from the complex injuries caused by CBRN threats, some of which are outlined in the Medical Management of Biologic Casualties Handbook, Medical Consequences of Radiological and Nuclear Warfare, and Medical Aspects of Chemical Warfare.

We are seeking information from industry partners developing innovative solutions that diagnose infection based on measures of the body's response, rather than targeting specific pathogens. These tests will rely on host biomarkers to make diagnostic determinations; for example, peripheral blood cellular gene expression patterns, rather than direct detection of a pathogen. We are particularly interested in candidates that fall into the following categories:

- **Predictive Diagnostics for Infection Complications:** Diagnostic assays that are predictive for Sepsis, Systemic Inflammatory Response Syndrome (SIRS), respiratory destabilization, or other acute complications from infections of biowarfare agents, based on the patient's

current condition and measurable host biomarkers circulating in the peripheral blood, or other easily accessible sample types.

- **Diagnostics to Assist in Therapeutic Selection and Monitoring:** Diagnostics based on host biomarkers and endotypes that enable precision medicine for the most appropriate treatment, or that reveal proper response to therapeutics or ineffective therapeutics, such as in hyperinflammatory states or immune response paralysis that may occur due to biowarfare agent exposure or other infectious agents.

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

Example Target Product Profile (TPP) for Host-Directed Products

This profile targets products designed to enable rapid diagnostic decision-making in remote laboratories, or central clinical laboratories, for suspected acute infections that may also direct effective therapeutic treatments to prevent severe outcomes and/or monitor recovery.

Feature	Desired Characteristic
Intended Use	Used with clinical assessments and other laboratory findings as an aid to determine the likelihood of severe clinical outcome in adults with suspected acute infections; and/or enlighten the selection of appropriate therapeutics.
Device Size and Robustness	Since the device is intended for low resource sites, the ideal size should be relatively small (handheld or backpack-sized), battery-operable and/or externally powered, operable in tropical humidity and temperature environments, with an assay time of less than 70 minutes and ideally less than 10 minutes.
Clinical Efficacy	Diagnostic clinical sensitivity and specificity greater than 90% is desired. Diagnosis and appropriate treatment lead to reduced severity and duration of clinical manifestation; improvement in clinical symptoms, reduction in length of hospitalization, and enhanced return to duty.
Sample Types	Peripheral blood samples (Ethylenediaminetetraacetic acid (EDTA) or PAXgene®-stabilized), fingerstick blood samples, respiratory samples, other minimally invasive sample types.

Administration:

Respondents are requested to submit a white paper, not to exceed three (3) pages, that addresses the following areas: Technical Approach and Product Maturity; Regulatory and Clinical Status; Manufacturing and Supply Chain; and Company Profile and Vision (A through D, below, in the order presented.) A separate, one-page Quad Chart should also be included. It should contain the objective of the project and benefit of the product; a high-level development schedule with major goals/timelines; a Rough Order of Magnitude cost; and any associated Intellectual Property rights required for commercial marketing and use, patent coverage,

commercial market, or data rights assertions.

The government's primary interest is to identify scientifically mature and programmatically viable candidates. Therefore, when reviewing responses, the government will place the greatest emphasis on the "Technical Approach and Product Maturity" and "Regulatory and Clinical Status" sections. Responses that provide detailed, data-driven evidence in these areas will be considered most valuable.

A. Technical Approach and Product Maturity

1. Product Description: Describe the host-directed response(s) that your candidate diagnostic targets, the specific gene expression or physiological pathways, and its intended use.

2. Technology Readiness Level (TRL): State the product's current TRL using the harmonized Quantitative Technology Readiness Level (Q-TRL) rating scale for diagnostics (https://medicalcountermeasures.gov/trl/trls-for-medical-devices) and provide justification for this assessment.

3. Diagnostic Efficacy Data Summary: Please summarize significant performance data using banked, contrived, or clinical study samples. Specify the sample types, gene or other molecules targeted, and key outcomes (e.g., clinical sensitivity and specificity, outcome prediction efficacy, time-to-answer).

B. Regulatory and Clinical Status

1. U.S. Food and Drug Administration (FDA) Engagement: Provide a concise history of all interactions with the FDA regarding this candidate, highlighting any formal feedback that informs development risk or regulatory strategy. Please include the status of any applications and any special designations received (e.g., Pre-Submission, Emergency Use Authorization (EUA), 510(k) (Food, Drug, and Cosmetic Act)).

2. Clinical Data/Trial History: Please detail any completed or ongoing clinical trials, including the number of human subjects, and any available clinical data. Similarly, detail any completed or ongoing studies involving clinical specimens. Describe any studies conducted with intended users.

C. Manufacturing and Supply Chain

1. Current Capabilities: Describe your current manufacturing capacity (e.g., laboratory, pilot or full-scale current Good Manufacturing Practice (cGMP), Quality Management System), emphasizing capabilities that support rapid scale-up or surge production. Please state the location of the manufacturing facilities.

2. Scalability and Supply Chain: Briefly outline the strategy for scaling production to

meet potential Department of War (DoW) requirements. Identify the source of key starting materials (KSMs), stating the country sourced from, and noting if they are sourced within the U.S.

D. Company Profile and Vision

1. Corporate Experience: Describe your company's experience in advanced product development, including non-clinical, clinical, and manufacturing activities, and highlight any prior success transitioning products to advanced development or licensure.

2. Teaming Strategy: Identify any current or planned partners for development, manufacturing, or clinical research.

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