

Antimicrobial Resistance Diagnostic Challenge selects 10 semifinalists in first phase of competition
Each will receive \$50,000 to develop prototypes of diagnostics to improve detection of drug resistant bacteria

Ten semifinalists have been selected in the first phase of the [Antimicrobial Resistance Diagnostic Challenge](#), a federal prize competition that will award up to a total of \$20 million in prizes, subject to the availability of funds, for innovative rapid, point-of-need diagnostic tests to combat the emergence and spread of drug resistant bacteria. The semifinalists were selected for their concepts for a diagnostic based on a technical and programmatic evaluation from among 74 submissions. While semifinalists will each receive \$50,000 to develop their concepts into prototypes, anyone can submit a prototype to compete in the second phase of the challenge to win up to \$100,000.

Antibiotic resistant bacteria are a rising public health threat and cause at least 2 million infections and 23,000 deaths each year in the United States, according to the Centers for Disease Control and Prevention. In addition, drug resistance can undermine the effectiveness of drugs provided as part of a medical response to bioterrorism, such as in an anthrax attack.

The diagnostic tests being sought are those that identify and characterize antibiotic resistant bacteria, and those that distinguish between viral and bacterial infections to inform treatment decisions and reduce unnecessary use of antibiotics, a major cause of drug resistance. With rapid detection, healthcare providers would be able to identify infecting pathogens and resistance factors within hours, rather than the hours to days that standard microbiological culture processes require, and prescribe an effective treatment the first time.

“We were quite pleased with the number of new and innovative concepts we received for this first phase of the competition,” said Robert W. Eisinger, Ph.D., Special Assistant for Scientific Projects in the National Institute of Allergy and Infectious Diseases Office of the Director. “The response underscores the level of importance the scientific community places on this critical issue.”

The prize is sponsored by two U.S. Department of Health and Human Services components, the National Institutes of Health and the Biomedical Advanced Research and Development Authority (BARDA) within the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), in support of the [National Action Plan for Combating Antibiotic-Resistant Bacteria](#).

“Diagnostics that are fast, accurate, and easy-to-use are critical to address antibiotic resistance that could imperil not only each person’s health but also our nation’s security from natural and

intentional threats,” said BARDA Director Rick Bright, Ph.D. “The exciting technology envisioned by our challenge’s semifinalists may help us put better tools at the patient’s side.”

The concept submissions for a diagnostic were evaluated by an independent panel of scientific and clinical experts based on the following criteria:

- Demonstrates novel and innovative technology and/or approaches outpacing the current state-of-the-science.
- Implementation supports improved clinical decision making, decreasing antibiotic resistance.
- Performance characteristics (e.g., sensitivity, specificity) relevant to its intended use and consistent with and support by proposed approaches and prior evidence.
- Likelihood of being successful as a commercial diagnostic system.
- Produces actionable results relevant to its intended use.
- Intended for use in inpatient and/or outpatient settings.

The semifinalists are:

- Antimicrobial Resistance Rapid, Point-of-Need Diagnostic Test Challenge
Richard Anderson, Becton, Dickinson and Company, Franklin Lakes, New Jersey
- Breath volatile metabolites for the rapid identification of pneumonia etiology
Sophia Koo, Brigham and Women's Hospital, Boston Massachusetts
- First Light's MultiPath platform
Don Straus, First Light Biosciences, Inc., Bedford, Massachusetts
- Host gene expression to classify viral and bacterial infection using rapid multiplex PCR
Ephraim Tsalik, Duke University, Durham, North Carolina
- Minicare HNL: Point-of-care detection of bacterial infections to curb unnecessary use of antibiotics
Joe Frassica, Philips North America, Cambridge, Massachusetts
- Patient-side, disposable, molecular PCR diagnostic device for STI and Antimicrobial Resistance Detection
Gregory Loney, Click Diagnostics, Inc., San Jose, California
- Rapid AMR Test using Spectral Platforms' Technology
Ravi Kent Verma, Spectral Labs, Inc., San Diego, California
- Ultra-Rapid Phenotypical AST by Microbe Mass Measurement
Ken Babock, Affinity Biosensor, Santa Barbara, California
- Transcriptional Profiling to Distinguish Bacterial and Viral Respiratory Infection
Ann Falsey, University of Rochester, Rochester, New York
- Yale's One Step, Rapid in vitro Diagnostic System
Ellen Foxman of Yale University, New Haven, Connecticut

More information on these concepts can be found [here](#).

Submissions of prototypes and analytical data for the second phase of the competition are due Sept. 4, 2018. Up to 10 finalists will be selected on Dec. 3, 2018. Each may receive up to \$100,000 and their submitted prototypes will be evaluated in the third phase of the competition by two [CLIA](#)-certified independent laboratories. Prototype performance in this evaluation will be the basis for selection of the final winners. Up to three winners are expected to be announced on July 31, 2020, to share an amount up to \$20 million, subject to the availability of funds. Funding for this challenge comes from NIH's National Institute of Allergy and Infectious Diseases and ASPR's BARDA. The CDC and the U.S. Food and Drug Administration provided technical and regulatory expertise to the design of the challenge competition. Technical criteria, objectives and performance characteristics of laboratory diagnostics that would be considered for the prize were informed by stakeholder input from a [public workshop](#) and a [request for information](#). Additional information on how to submit to phase two will be provided in the Federal Register and NIH Guide for Grants and Contracts, as well as found on the following websites www.challenge.gov and the [challenge website](#).

About the Biomedical Advanced Research and Development Authority (BARDA): BARDA, within the HHS Office of the Assistant Secretary for Preparedness and Response, makes available medical countermeasures to address public health emergencies arising from natural and intentional threats through an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies, and diagnostic tools. For more information about BARDA, visit www.phe.gov/about/BARDA/Pages/default.aspx.

About the Office of the Assistant Secretary for Preparedness and Response (ASPR): ASPR leads HHS in preparing the nation to respond to and recover from adverse health effects of emergencies, supporting communities' ability to withstand adversity, strengthening health and response systems, and enhancing national health security. For more information about ASPR and for expertise, tools, and resources to help your community prepare, respond and recover from public health emergencies, visit www.phe.gov.

About the National Institute of Allergy and Infectious Diseases (NIAID): NIAID conducts and supports research — at NIH, throughout the United States, and worldwide — to study the causes of infectious and immune-mediated diseases, and to develop better means of preventing, diagnosing and treating these illnesses. News releases, fact sheets and other NIAID-related materials are available on the NIAID website: <http://www.niaid.nih.gov/Pages/default.aspx>

About the National Institutes of Health (NIH): NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and

Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.