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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Correction for Announcement of Requirements and Registration for
“Antimicrobial Resistance Rapid, Point-of-Need Diagnostic Test” Challenge

The National Institutes of Health (NIH) is correcting a notice previously published in the Federal Register on September 8, 2016 (81 FR 62150), titled “Announcement of Requirements and Registration for “Antimicrobial Resistance Rapid, Point-of-Need Diagnostic Test” Challenge.” The notice announced the Antimicrobial Resistance Rapid, Point-of-Need challenge competition that may result in the awarding of \$20 million dollars for the successful development of new, innovative, accurate, and cost-effective in vitro diagnostic tests that would rapidly inform clinical treatment decisions and be of significant clinical and public health utility to combat the development and spread of antibiotic resistant bacteria and improve antibiotic stewardship.

The NIH is correcting and clarifying several components of Step 2 of the Challenge competition including:

- 1) The letter of intent must be submitted by August 3, 2018, at 11:59 p.m. ET, for all “Solvers” planning to submit for the Step 2 (Delivery of Prototype and Analytical Data) stage of the competition.

- 2) The prototype in vitro diagnostic device is not to be provided with the submission. The September 8, 2016, announcement incorrectly stated that the device was to be included as part of the submission for Step 2.
- 3) The Technical Evaluation Panel will use the following 4 criteria for evaluating the Step 2 submissions including: a) innovation; b) clinical significance; c) diagnostic performance and feasibility; and d) sample matrix/setting and ease of use/throughput. These criteria were defined in the September 8, 2016, announcement; however, the announcement incorrectly stated that the Panel will evaluate the solutions based on eight criteria.
- 4) A description sufficiently detailed and organized by sections for evaluation in the technical review and programmatic assessment of the proposed solution in 15 pages or less including the next 6 bullets, 8.5 x 11 inch page, 10-point or greater Arial, Palatino Linotype, or Georgia font and one inch margins including:
 - A title of the proposed solution;
 - A detailed description of the proposed in vitro diagnostic, and the development approach, challenges, and risks;
 - One section addressing each of the 4 criteria listed above;
 - One section providing a summary of the data, using the in vitro diagnostic device and the Standard Operating Procedures described in Appendix B, generated with either clinical or contrived samples compared to existing standard techniques demonstrating the performance characteristics (e.g., limits of detection, sensitivity,

specificity, and other characteristics that demonstrate test performance to support detection of biomarkers or analytes). The September 8, 2016, announcement incorrectly stated that diagnostic performance characteristics included positive predictive value and negative predictive value;

- Photographs of the in vitro diagnostic prototype device and a video not to exceed 5 minutes (in accordance with the NIH interim policy for submitting a video as NIH application materials (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-141.html>) demonstrating the status of the development and actual use of the device in testing contrived or clinical specimens;
- Address the NIH Human Subjects Protections and Inclusion of Women, Children, and Minorities policies, as well as biohazards policies (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-078.html>), if applicable.

- 5) An Appendix A, provide additional data and tables to support the data summary and performance claims based on the use of the proposed solution testing clinical or contrived samples in 15 pages or less.
- 6) An Appendix B with the standard operating procedures for the use of the solution submitted for Step 2 of the Challenge competition must be limited to 10 pages or less in length. If a longer Appendix is submitted, only the first 10 pages will be considered by the Technical Evaluation Panel and the Judging Panel.

- 7) Submissions for Step 2 of the Challenge competition can be submitted to <http://www.cccinnovationcenter.com/challenges/antimicrobial-resistance-diagnostic-challenge/> beginning June 1, 2018. Submissions received after the deadline of September 4, 2018, at 11:59 p.m. ET will be disqualified and not evaluated by the Technical Evaluation Panel or Judging Panel.
- 8) Solvers may submit corrections or additional materials in support of their Step 2 submissions so long as the NIH receives the materials by the deadline of September 4, 2018, at 11:59pm ET. Corrections or additional materials for Step 2 will not be accepted or evaluated by the Technical Evaluation Panel or Judging Panel if they are received after September 4, 2018, at 11:59pm ET.
- 9) The NIH will perform an initial review of all submissions to ensure they are complete and within the scope of the Challenge competition. Submissions that are incomplete will be administratively disqualified and will not be evaluated by the Technical Evaluation Panel or the Judging Panel.
- 10) A Solver may not be a federal employee of HHS (or any component of HHS) acting in their personal capacity.
- 11) A Solver employed by a federal agency or entity other than HHS (or any component of HHS), should consult with an agency Ethics Official to determine whether the federal ethics rules will limit or prohibit the acceptance of a prize under this challenge.
- 12) The NIH and Assistant Secretary for Preparedness and Response/Biomedical Advanced Research and Development Authority may determine that based on

the number of submissions received for Step 2 that less competitive submissions will not be discussed by the Technical Evaluation Panel during the Panel's meeting.

- 13) Members of the Technical Evaluation Panel for Step 1 are not eligible to participate in or contribute to any proposal for Step 2 and Step 3 of the Challenge competition.
- 14) Any Solver is eligible for Step 2 of this Challenge competition. For example, if a Step 1 "Solver" was not identified as a semifinalist, he/she may still submit for Step 2 of this competition and those who did not submit a Step 1 proposal may still submit a proposal for Step 2.
- 15) All submissions for Step 2 and 3 must be in English.

For further information about the Antimicrobial Resistance Diagnostic Challenge competition, please contact Robert W. Eisinger, Ph.D., NIH, 301-496-2229 or by email Robert.eisinger@nih.gov.

Dated: April 27, 2017

Lawrence A. Tabak

Deputy Director

National Institutes of Health

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