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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice to Announce of Requirements and Registration for "Antimicrobial Resistance Rapid, Point-of-Need Diagnostic Test" Challenge

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) is supplementing and amending a Notice previously published in the Federal Register on September 8, 2016 titled "Announcement of Requirements and Registration for "Antimicrobial Resistance Rapid, Point-of-Need Diagnostic Test" Challenge." This Notice serves to provide additional details to Step 2 Semi-finalists of the submission requirements and review criteria for Step 3 (Performance Testing in CLIA-certified Laboratories) of this Challenge.

DATES: On or before Monday, November 4, 2019, 11:59 pm ET: Step 3 Letter of Intent is due. Only Step 2 Semi-finalists are eligible to submit a Letter of Intent. On or before Friday, January 3, 2020, 5:00 pm ET: The submissions from the Step 2 Semi-finalists for Step 3 are due. Submissions received after the deadline of January 3, 2020, at 5:00 p.m. ET will be disqualified and not evaluated by the CLIA-certified laboratories, the Technical Evaluation Panel, or Judging Panel.

Important note: The Step 3 submission must be received by January 3, 2020. Plan to send the submission so it arrives on or before January 3, 2020. In effect, a post-mark date of January 3, 2020, is not sufficient; the submission must be received by that date.

ADDRESSES: The Letter of Intent and Step 3 submission must be submitted to Capital Consulting Corporation no later than the due dates cited above. The letter of intent must be submitted on http://www.cccinnovationcenter.com/challenges/antimicrobial-resistance-diagnostic-challenge/

FOR FURTHER INFORMATION CONTACT: Robert W. Eisinger, Ph.D., NIH, 301-496-2229 or by email Robert.eisinger@nih.gov.

SUPPLEMENTARY INFORMATION: On September 8, 2016, the National Institutes of Health (NIH) published a Notice in the Federal Register 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 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 Notice provided information on submission requirements for Step 3 of the Challenge and indicated that additional details on submission requirements for Step 3 will be made available after the Step 2 Semi-finalists are announced. This Notice serves to provide additional details to Step 2 Semi-finalists of the submission requirements and review criteria for Step 3 (Performance Testing in CLIA-certified Laboratories) of this Challenge.

The NIH is supplementing and amending several components of Step 3 of the Challenge including:

1) The letter of intent must be submitted by Monday, November 4, 2019, at 11:59 p.m. ET, for all Step 2 Semi-finalists planning to submit for the Step 3 (Performance Testing in CLIA-certified

Laboratories) stage of the Challenge. A list of Step 2 Semi-finalists can be found at http://www.cccinnovationcenter.com/challenges/antimicrobial-resistance-diagnostic-challenge/.

2) The Technical Evaluation Panel will use the following 4 criteria for evaluating the Step 3 submissions and the test results from the two CLIA-certified laboratories' analysis of the Step 3 prototype 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 in vitro diagnostics (solution) based on six criteria.

3) Each solution will be tested by two CLIA-certified laboratories against standard FDA-approved in vitro assays using a panel of reference (or well-characterized) pathogens, clinical specimens, and/or contrived samples to demonstrate usability, stated time to result, appropriate analytical sensitivity/specificity, as well as confirmation of analytical performance (e.g., limit of detection, interference, inclusivity, reproducibility, etc.) reported in the data submitted by the Step 2 Semi-finalist.

4) Step 2 Semi-finalists will submit:

a. sufficient numbers of their diagnostic tests based on the Step 2 solutions for independent testing by both CLIA-certified laboratories, as well as methodology/protocols to perform diagnostic testing using the prototypes. These materials must be received on or before January 3, 2020, at 5:00 p.m. ET by Capital Consulting Corporation, Suite 100, 11821 Parklawn Drive, Rockville MD 20852. At a future date, the NIH will provide additional information about the specific number of test kits that each Step 2 Semi-finalist will need to provide for CLIA-certified laboratory testing. Submissions received after the deadline of January 3, 2020, at 5:00pm ET will be disqualified and not evaluated by the CLIA-certified laboratories, the Technical Evaluation Panel, or the Judging Panel.

b. A description sufficiently detailed and organized by sections for evaluation in the technical evaluation and programmatic assessment of the proposed solution in 10 pages or less including the next 8 bullets, 8.5 x 11inch page, 10-point or greater Arial, Palatino Linotype, or Georgia font and one-inch margins including:

- A title of the proposed solution;
- A one-paragraph executive summary that will be posted on the Challenge website after the "Winners" are announced in July 2020. The Executive Summary must not contain any proprietary information since the website is open to the public;
- A statement as to the source of funds that were used to develop their solution submitted for Step 3 of the Challenge;
- A detailed description of the proposed in vitro diagnostic and the claims of performance using specific types of biospecimens/samples;
- A description of any changes from the original design (Step 2 solution) must be documented and explained;
- One section providing a summary of the data, using the in vitro diagnostic device and the Standard Operating Procedures described in Appendix A, 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;
- A video not to exceed 15 minutes demonstrating the status of the development and actual use of the device in testing contrived or clinical specimens;

- A section addressing applicable HHS Human Subjects Protections regulations and NIH Inclusion of Women, Children, and Minorities policies, as well as biohazards policies (https://grants.nih.gov/grants/guide/notice-files?NOT-OD-12-141.html), if applicable.

5) An Appendix A with the standard operating procedures for the use of the solution submitted for Step 3 of the Challenge must include all steps to prepare test specimen/sample, perform the assay, and interpret the results.

6) An Appendix B 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 5 pages of less.

7) Each Step 2-Semi-finalist may submit corrections in support of their Step 3 submission within the page limitations cited above as long as Capital Consulting Corporation receives the materials by the deadline of January 3, 2020, at 5:00 p.m. ET. Corrections for Step 3 will not be accepted or evaluated by the CLIA-certified laboratories, Technical Evaluation Panel, or Judging Panel if they are received after January 3, 2020, at 5:00 p.m. ET.

8) The NIH will perform an initial review of all submissions to ensure they are complete and within the scope of the Challenge. Submissions that are incomplete or outside of the scope of the Challenge will be administratively disqualified and will not be evaluated by the CLIA-certified laboratories, the Technical Evaluation Panel, or the Judging Panel. Disqualified submissions will not be returned to the Step 2 Semi-finalist.

9) 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 3 that less competitive submissions will not be discussed by the Technical Evaluation Panel during the Panel's meeting.

10) Members of the Technical Evaluation Panel for Step 1 or Step 2 are not eligible to participate in or contribute to any proposal for Step 3 of the Challenge.

11) Only Step 2 Semi-finalists are eligible for Step 3 of this Challenge.

12) All submissions for Step 3 must be in English.

13) No submissions will be returned to the submitters.

14) The remainder of the provisions from the September 8, 2016, Federal Register Notice (81 FR 62150) not amended here still apply.

Dated: January 11, 2019.

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Lawrence A. Tabak,

Deputy Director,

National Institutes of Health.

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