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[FR Doc. 2014–20477 Filed 8–27–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Announcement of Requirements and Registration for the Culture-Independent Straintyping and Characterization Challenge

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

Authority: 15 U.S.C. 3719.

Award Approving Official: Thomas R. Frieden, MD, MPH, Director, Centers for Disease Control and Prevention, and Administrator, Agency for Toxic Substances and Disease Registry.

SUMMARY: The Centers for Disease Control and Prevention (CDC) located within the Department of Health and Human Services (HHS) launches a challenge competition for the development of a method or process to accurately and efficiently identify, subtype, and characterize pathogenic microorganisms directly from clinical or environmental samples without the need for culture or culture-based enrichment.

Laboratory-based infectious disease surveillance programs, such as PulseNet, the National Tuberculosis Surveillance System, and the Active Bacterial Core Surveillance program, rely on primary culture and microbiologic testing in community hospital and clinical laboratories. A new generation of non-culture-based diagnostic tests are now beginning to enter the marketplace offering physicians faster results and, in some cases, more types of information than were previously available. Unfortunately, these new tests do not typically result in isolates being available for public health purposes, and, as their use continues to grow, it will likely become increasingly difficult or impossible to detect and investigate outbreaks or other important infectious disease trends. New laboratory approaches that do not depend on isolates or culture for subtyping and characterization of microbes are needed to maintain and improve important public health activities across a range of pathogenic organisms.

The Culture-Independent Straintyping and Characterization Challenge is an opportunity to develop novel approaches to identifying and characterizing pathogens similar to normal flora in a complex matrix in a process that does not require any culture, including pre-enrichment. Straintyping and characterization of the Shiga toxin-producing Escherichia coli (STEC) from clinical stool samples represents a significant challenge and has been selected as the target organism for this challenge. STEC are similar in most respects to the commensal E. coli that are carried in the intestinal tract of nearly everyone. Consistent identification, straintyping, and characterization of pathogenic STEC directly from a complex matrix, such as stool, requires the consistent identification of both a variable marker that can be used for subtyping and a second, more stable marker that can be used for definitive identification.

How To Enter

- Sign up for a Challenge.gov account and become a follower of the Culture-Independent Straintyping and Characterization Challenge at *http://www.cdc.gov/amd/cidtchallenge.*
- Review the rules and guidelines of this contest listed below and at *http://www.cdc.gov/amd/cidtchallenge.*

DATES: Contestants can submit solutions between September 2, 2014 and November 30, 2014. Judging will take place between December 1 and 10, 2014, during which time additional information, clarification or documentation may be requested. The winner will be notified and prize awarded by December 15, 2014.

Contest Prizes: We will choose one winning proposal and award $200,000 by electronic funds transfer. The winner may need to pay Federal income taxes on any prize money. We will follow Internal Revenue Service withholding and reporting requirements, where applicable.

How Winners Will Be Selected: An expert panel of CDC program staff with expertise in diagnostic testing, bioinformatics, and biotechnology who meet the requirements of the America COMPETES Act will evaluate all entries. The judging panel will use the following criteria to select a single winning submission:

(1) Resolution and typeability: Ability to accurately straintype and characterize STEC at high resolution from a stool sample matrix, without the need for culture-based amplification.

(2) Reproducibility and stability: Ability to return consistent, unambiguous results from three or more replicate specimens.

(3) Throughput parameters: Proposed solutions should have a feasible sample-to-answer turnaround time of under 48 hours, and a per-sample reagent and consumables cost of $100 per sample or less. Methods should be scalable to accommodate high-throughput testing.

(4) Portability: Data should be objective, based on open or established standards, and amenable for computerized analysis and easily disseminated between laboratories.

(5) Generalizability: While the subject organism for this challenge is STEC, special consideration will be given to proposals that may be readily adapted to a range of other pathogenic microorganisms.

(6) Epidemiologic concordance: Consistency of the resultant data with the known epidemiologic context of the specimen.

Contest Rules and Guidelines

Subject of Contest Competition: Your entry for the Culture-Independent Straintyping and Characterization Challenge should describe a novel or innovative method to straintype and characterize pathogenic organisms, such as STEC, directly from a complex clinical sample, without the need for culture or culture-based amplification.

Eligibility Rules for Participating in the Competition: The contest is open to everyone, with the exceptions noted below. Participants may submit individual proposals or work as teams.

To have a chance to win a prize in this contest you must—

(1) Register for the contest at CHALLENGE.GOV and follow posted contest rules;

(2) Meet all of the requirements in this section;

(3) Enter the contest as an individual or as a team in which a you or all members of the team are citizen(s) or permanent resident(s) of the United States; or as an entity where entities are limited to those that are incorporated and maintain a primary place of business in the United States; and

(4) Federal employees may not participate in this contest in their official capacity. Federal employees seeking to participate in this contest should talk with their ethics official before submitting a proposal.

(5) Federal grantees cannot use Federal funds to develop *COMPETES Act* challenge applications unless consistent with the purpose of their grant award.

(6) Federal contractors cannot use Federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge submission.

You can use Federal facilities (e.g., laboratories) or speak with Federal employees during the contest only if those same Federal facilities and employees are equally available to everyone participating in the contest (for example, such availability could be announced on a public Web site).

If laboratory work is required to support your submission, all work should be performed under appropriate biosafety level 2 (BSL2) conditions, and in accordance with standard precautions for the handling and processing of clinical specimens.

By participating in this contest, contestants agree to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from participation in this prize contest, whether the injury, death, damage, or loss arises through negligence or otherwise. By participating in this contest, contestants agree to indemnify the Federal Government against third party claims for damages arising from or related to contest activities.

Contestants warrant that their submissions are wholly original and do not infringe upon any rights of any third party of which Contestants are aware.

Registration Process for Participants: All participants for the Culture-Independent Straintyping and Characterization Challenge must register before submitting a proposal. Registration instructions are available at *http://www.cdc.gov/amd/cidtchallenge.* Deadline for registration is October 1, 2014.

Additional Information: More information on or about CDC's Advanced Molecular Detection and Response to Outbreaks of Infectious Diseases initiative can be found at: *www.cdc.gov/amd.*

Regarding Copyright/Intellectual Property: When you submit your entry, you must certify that you are the person who developed the submission and that you maintain intellectual property rights to the process and solution that you propose. You also must ensure that you did not use any copyrighted material or affect the rights of any third party to the best of your knowledge.

Submission Rights: Once you submit your solution, you give HHS/CDC permission to review and evaluate your submission, and to post and share information about your solution in the context of the contest, its participants and its awardee. You cannot take this permission back or ask us for money to use your submission for these purposes. You can, however, give other people permission to use your method or solution to this challenge while the contest is ongoing, and may keep all other intellectual property rights to your solution and your work.

Compliance With Rules and Contacting Contest Winners: In order to win the contest, you must meet all terms and conditions of these Official Rules. You can be named a winner only if you meet all the requirements. We will contact the winner using the contact information provided (by email, telephone, or mail after the date of the judging). You may need to pay Federal income taxes on any prize money. The Department of Health and Human Services will follow the Internal Revenue Service withholding and reporting requirements, where applicable.

Privacy: If you provide personal information to use when you register for the contest at the Challenge.gov Web site, we will use that information to contact you about your entry, and to announce updates and the final contest winner. We will not use the information for commercial marketing.

General Conditions: HHS/CDC can cancel, suspend, or change the contest, or any part of it, for any reason.

Dated: August 22, 2014.

Ron A. Otten,

Acting Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2014–20428 Filed 8–27–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2003–D–0128 (Legacy ID: FDA–2003D–0236)]

Guidance for Industry: Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis,'' dated September 2014. The guidance document provides recommendations for screening and testing of donors and management of donations based on screening tests for syphilis. The guidance is intended for blood establishments that collect Whole Blood or blood components, including Source Plasma. The guidance announced in this notice finalizes the draft guidance of the same title, dated March 2013 (2013 draft guidance), and supersedes the memorandum of December 12, 1991, entitled ''Clarification of FDA Recommendations for Donor Deferral and Product Distribution Based on the Results of Syphilis Testing.''

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., Center for Biologics Evaluation and Research, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled, ''Guidance for Industry: Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis,'' dated September 2014. The guidance document provides recommendations for screening and testing of donors and management of