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## 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](http://www.cdc.gov/amd/cidtchallenge).

- Review the rules and guidelines of  
this contest listed below and at [http://  
www.cdc.gov/amd/cidtchallenge](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 Strainotyping 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](http://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.*

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## 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