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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Opportunity to Collaborate in the Evaluation of Simplified Nucleic Acid Tests for Detecting and Quantifying HIV

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

ACTION: General Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS) announces an opportunity for industry and the public to collaborate on a project to evaluate simplified nucleic acid tests. HHS/CDC is interested in evaluating simplified nucleic acid tests that (1) can be used near a patient with rapid turn-around of results (2) can be used to aid in the diagnosis of HIV-1 infection, and (3) have the potential to be used in moderately complex and/or waived laboratories as defined under the Clinical Laboratory Improvement Amendment (CLIA) regulations. Tests of interest include those that use whole blood, serum, plasma, or dried blood spots.

Performance will be evaluated relative to HHS/Food and Drug Administration (FDA)-approved qualitative and quantitative nucleic acid tests as well as antibody immunoassays. More than one collaborator may be selected.

DATES: Formal proposals must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: Formal proposals should be submitted to Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road N.E., Mailstop E-46, Atlanta, Georgia 30329, Attn: Simplified Nucleic Acid Tests Evaluation Project. If you are interested in submitting a proposal, please send a letter of interest to Dr. Michele Owen at smo2@cdc.gov by [INSERT DATE 30 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]. The letter of interest is not considered a formal proposal and is not required; however, it is highly recommended, as it will assist CDC in planning for the review process. The formal proposal will still need to be submitted according to the instructions in this notice.

FOR FURTHER INFORMATION CONTACT: Questions on the project should be addressed to: Laura Wesolowski, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., Mailstop E-46, Atlanta, GA 30329, telephone: (404) 639-6007, email: lig7@cdc.gov.
Scientific questions should be addressed to Michele Owen, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road N.E., Mailstop A-25, Atlanta, GA 30329; Phone 404-639-1046, e-mail smo2@cdc.gov.

SUPPLEMENTARY INFORMATION: HHS/CDC seeks to collaborate with one or more companies that have developed a simplified nucleic acid test that can detect acute or established HIV-1 infection. Acute HIV infection is the early infection period associated with high viral load that occurs before the development of HIV antibodies, and established infection is that which occurs once antibodies are detectable.

The objective of the collaboration is timely collection of data to evaluate the performance characteristics of simplified nucleic acid tests when used in their intended applications. The evaluation will be

conducted in phases. The first round of evaluation will be done on well characterized stored or mock laboratory specimens. Following the initial round of evaluation, a subset of tests with high performance will be evaluated with prospectively collected specimens. Only tests that are near production (i.e., not first generation prototypes) will be eligible for the collaboration. Companies that are interested in collaborating must be planning to produce a simplified nucleic acid test for distribution in the United States and to seek FDA approval for diagnostic or prognostic use (priority given to tests with both applications). Confidential proposals, preferably six pages or less (excluding appendices), are solicited from companies which have a product that is suitable for commercial distribution. This collaboration will have an expected duration of 1 to 6 years.

Currently, nucleic acid testing conducted as part of HHS/CDC's laboratory algorithm is associated with a delay in returning results because testing is often conducted in referral laboratories. Likewise, pooled nucleic acid testing causes delays due to the time required to create and break down pools in the event of a positive pool. Rapid identification of acute and established HIV-1 infection using a simplified nucleic acid test may have a

significant impact on patients with positive test results obtaining care and services more quickly. Therapeutic monitoring could also be conducted more efficiently using a simplified nucleic acid test.

For this project, preference may be given to manufacturers that have produced rapid nucleic acid tests that can aid in HIV-1 diagnosis, and be used for monitoring responses to therapy. Tests should be simple to use on unprocessed specimens (e.g., whole blood) or include specimen processing in the design of the test. Preference will also be given for tests that can be performed in 60 minutes or less, that have the potential to be designated moderately complex or waived under the Clinical Laboratory Improvement Amendments (CLIA), and that are capable of both qualitative and quantitative applications.

HHS/CDC and Collaborator Responsibilities

HHS/CDC's role may include, but will not be limited to, the following:

(1) Providing scientific and technical expertise needed for the research project;

(2) Providing appropriate panels of specimens, and conducting the tests;

(3) Planning and conducting research studies of the diagnostic tests and interpreting results; and

(4) Publishing research results.

HHS/CDC anticipates that the role of the successful collaborator(s) will include the following:

(1) Providing tests and finalized protocols that can be used in the evaluation; and

(2) Providing the CDC Division of HIV/AIDS Prevention access to necessary data about the diagnostic tests in support of the research activities.

Selection Criteria

Proposals submitted for consideration should address, as fully as possible and to the extent relevant to the proposal, each of the following:

(1) Data available on the performance of the test in persons with acute and established HIV-1 infection.

(2) Information on the technology used for the test and its basic operating principals for detecting HIV RNA and/or DNA.

(3) Information on:

a. the time required to perform the test;

b. whether the test is performed on whole blood, serum, plasma, or dried blood spots; and

c. the steps involved in performing the test on each specimen type;

(4) Information on the storage requirements and stability of the test.

(5) Plans and capability of the company to seek HHS/FDA approval and whether the company intends to seek a diagnostic claim, a prognostic claim (for patient monitoring) or both.

(6) Plans the company has for seeking CLIA waiver status, if FDA approved.

Dated: February 6, 2015

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Centers for Disease Control and Prevention

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