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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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

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

ACTION: General notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), announces an opportunity for industry and the public to collaborate on a project to evaluate nucleic acid and serologic tests. CDC is interested in evaluating serologic and nucleic acid tests that can be used to aid in the diagnosis of HIV–1 infection, including serologic tests that can secondarily differentiate recent infection, and nucleic acid tests for the quantitation or semi-quantitation of HIV RNA. Tests of interest include those that use whole blood, serum, plasma, or dried blood spots. Performance will be evaluated relative to Food and Drug Administration (FDA)-approved qualitative and quantitative nucleic acid tests as well as serologic immunoassays. More than one collaborator may be selected.

DATES: Letters of interest must be received on or before Friday, September 15, 2023. Formal proposals must be received on or before Friday, November 10, 2023.

ADDRESSES: Send Letters of Interest and Formal Proposals to Division of HIV Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop H18-2, Atlanta, Georgia 30329. Attn: HIV Serologic and Nucleic Acid Tests Evaluation Project.

FOR FURTHER INFORMATION CONTACT: Jeffrey Johnson, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and

Prevention, 1600 Clifton Road NE., Mailstop 18-2, Atlanta, GA 30329; Telephone 404-639-4976; Email: jlj6@cdc.gov.

SUPPLEMENTARY INFORMATION:

Background

Priority for technical evaluations are rapid tests or mail-in sample collection methods that can be self-administered outside of clinic settings. Secondarily, tests or collection methods that have the potential for both HIV-1 diagnostic and prognostic use for monitoring responses to therapy are preferred.

The objective of the collaboration is timely collection of data to evaluate the performance characteristics of simplified nucleic acid and serologic tests or protocols when used in their intended applications. Only tests that are under or near production (i.e., not first-generation prototypes) will be eligible for the collaboration. Companies that are interested in collaborating must be planning to market a test protocol for distribution in the United States and to seek FDA approval for diagnostic or prognostic use.

Currently, nucleic acid testing conducted as part of CDC's laboratory algorithm has 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. Moreover, there are significant financial stability, geographic isolation, and stigma barriers to accessing testing in clinical settings that prevent sustained continuum of care for many populations, including the most vulnerable. Methods to support rapid identification of HIV–1 infection or viral suppression using a simplified nucleic acid or serologic test, or use of self-collection methods, may have a significant impact on individuals by allowing them to obtain care and services more quickly.

Tests should be simple to use on unprocessed specimens (e.g., whole blood) or include specimen processing in the design of the test. For nucleic acid tests, preference may also

be given to tests that are capable of both qualitative and quantitative applications. Key benchmarks are the ability to demonstrate improved sensitivity of diagnostic tests over current FDA-approved laboratory-based tests and nucleic acid monitoring test protocols that are suitable for lower complexity settings.

CDC and Collaborator Roles and Responsibilities

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 assistance with project management and data analysis;

(3) Providing testing support as determined by CDC as needed; and

(4) Publishing research results.

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 Prevention access to necessary data about the diagnostic tests in support of the evaluation 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, DNA, antibody, or antigen.

(3) Information on:

a. the time required to perform the test or sample collection method;

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 or sample collection method;

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

(5) Plans, capability, and clinical trial designs 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, for appropriate tests, if FDA approved.

Letters of interest

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.

Formal Proposals:

Confidential proposals, preferably six pages or less (excluding appendices), are solicited from companies which have a product that is suitable for regulatory approval and commercialization. This collaboration will have an expected duration of 1 to 4 years.

Dated: June 7, 2023.

Tiffany Brown,
Executive Secretary,
Centers for Disease Control and Prevention.

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