

infectious diseases, regulatory and other federal agencies, professional societies, and other stakeholders. This new draft Guideline will not be a federal rule or regulation.

Dated: January 22, 2014.

Stacey Hoffman,

Acting Director, Division of Executive Secretariat Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Influenza Diagnostic Testing and Reporting

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) located within the Department of Health and Human Services (HHS) is seeking to assess new technologies that improve rapid influenza diagnostic testing and supplement national laboratory-based surveillance for human influenza infections. In particular, the Influenza Division within the National Center for Immunization and Respiratory Diseases (NCIRD) at HHS/CDC proposes to evaluate new or improved point of care diagnostic tests for influenza virus detection that incorporate the capability to transmit influenza diagnostic test results electronically, such as through wireless communication technology, for more timely diagnosis of human influenza and/or other respiratory pathogen infections in outpatient/ambulatory and emergency room healthcare practices.

DATES: HHS/CDC will accept inquiries/proposals until December 31, 2015.

ADDRESSES: You may submit your inquiry/proposal by email: FluDiagnosticTests@cdc.gov.

All information submitted to HHS/CDC will be kept confidential as allowed by relevant federal law, including the Freedom of Information Act (5 U.S.C. 552) and the Trade Secrets Act (18 U.S.C. 1905). Responses are preferred in electronic format. CDC does not intend to publish the results of these evaluations.

FOR FURTHER INFORMATION CONTACT: Influenza Division, Centers for Disease Control and Prevention. Email: FluDiagnosticTests@cdc.gov.

SUPPLEMENTARY INFORMATION: HHS/CDC uses epidemiologic, laboratory, clinical, and biostatistical sciences to prevent and control vaccine preventable infectious diseases. HHS/CDC also conducts applied research in a variety of settings, and translates the findings of this research into public health practice. HHS/CDC/NCIRD Influenza Division has lead technical responsibility for research, development, and evaluation of diagnostic tools for influenza and application of these to national surveillance and epidemiologic studies of influenza. Improving influenza diagnostic testing is part of HHS/CDC/NCIRD Influenza Division's strategic plan and includes support of the development of expanded respiratory pathogen tests on existing test platforms; development of advanced sequence detection methods for identifying novel influenza strains with pandemic potential; rapid identification of antiviral resistant influenza strains; rapid identification of influenza immunological response to determine the presence or absence of circulating antibodies specific for influenza viruses; and the development and characterization of stable diagnostic reagents or reference material and controls, for application with existing diagnostic test systems on established platforms.

HHS/CDC/NCIRD Influenza Division seeks to collaborate on evaluations of any new or improved diagnostic tests for the detection of human influenza viruses. The tests may range from high complexity molecular assays providing genetic sequence information to point of care type tests that facilitate more timely diagnosis of human influenza infections and/or other respiratory pathogen infections in ambulatory and emergency room healthcare practices. Assays should present sensitivity and specificity higher than currently available products.

For commercial products with approval for use by the US Food and Drug Administration (FDA), HHS/CDC/NCIRD Influenza Division is seeking to evaluate the potential supplementation of current national laboratory-based influenza surveillance data with influenza test result data that can be transmitted directly to a public health entity (state, local, or CDC) from the test platform electronically, such as through wireless technology. Direct test platform-based reporting capability has been newly established. Current surveillance incorporates data from healthcare provider offices and laboratories through manual or automated reporting functions; however, most of the current testing

platforms do not have the capacity to directly transmit reports. Such reports represent a new data source and thus require evaluation and determination of appropriate data use agreements.

HHS/CDC/NCIRD Influenza Division is also interested in collaborating with organizations working on validation of novel and improved respiratory specimen collection materials and methods that can enable reliable and consistent self-collection or collection by non-expert personnel. Data obtained from the evaluation can be compared through analytical assessments and be used by HHS/CDC in making recommendations and decisions for diagnosis of influenza in the health setting. Products may be evaluated at HHS/CDC and/or at collaborating laboratories and if appropriate, may be used in epidemiologic validation studies.

Interested organizations that have candidate products are invited to approach the HHS/CDC/NCIRD Influenza Division to assess whether the available product(s) are at a sufficient stage of development and how HHS/CDC can collaborate on evaluations and comparative analysis.

Information To Submit

At a minimum, submitted information should include the following for each candidate product: (a) Product package insert or detailed instructions for use; (b) Detailed information to determine if the product is calibrated to a recognized standard; (c) Preliminary data demonstrating suitability for validation studies and clinical trial data on sensitivity and specificity; (d) Whether the product is FDA approved; and (e) Statement of how HHS/CDC/NCIRD Influenza Division could collaborate on product evaluation or further development.

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Stacey Hoffman,

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