Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Invitation to Manufacturers of Pertussis Serological Kits

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

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) announces an opportunity for commercial manufacturers to work with CDC's National Center for Immunization and Respiratory Diseases (NCIRD) on the validation of pertussis serological kits prior to submission to the Food and Drug Administration (FDA) for marketing authorization. CDC is interested in the development of an assay that is an Immunoglobulin G (IgG) anti-pertussis toxin (PT) enzyme-linked immunosorbent assay (ELISA), calibrated to an international reference standard (such as FDA Reference Standard Lot #3, World Health Organization (WHO)

International Standard 06/140, or equivalents). The ELISA will be used for *in vitro* serological diagnosis of pertussis in clinical cases of selected age groups. CDC will be able to provide guidance, materials, and evaluation support for the manufacturer; however, the manufacturer will be responsible for submitting a premarket submission to FDA with adequate information, including any analytical or clinical data needed to support the submission, to demonstrate to FDA that FDA can grant marketing authorization to the product.

DATES: CDC is accepting information through [INSERT DATE 180 DAYS FROM PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit information by any of the following methods:

- E-mail: PertussisDL@cdc.gov
- Mail: Lucia Tondella, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., Mail Stop D-11, Atlanta, GA 30329

FOR FURTHER INFORMATION CONTACT:

For Technical Questions: Lucia Tondella, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., Mail Stop D-11, Atlanta, GA 30329. Phone: 404-639-1239, E-mail: PertussisDL@cdc.gov

For Business Questions: Jason Cloward, Technology Transfer Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., Mail Stop E-51, Atlanta, GA 30329. Phone: 404-639-2679, E-mail: wnv3@cdc.gov

SUPPLEMENTARY INFORMATION: CDC's National Center for Immunization and Respiratory Diseases (NCIRD), Division of Bacterial Diseases (DBD), Meningitis and Vaccine Preventable Diseases Branch (MVPDB) has lead technical responsibility for research, development and evaluation of diagnostic assays for their application in epidemiologic studies of pertussis. CDC uses epidemiologic, laboratory, clinical, and biostatistical sciences to control and prevent bacterial infectious disease such as pertussis. CDC also conducts applied research in a variety of settings, and translates the findings of this research into public health practice.

CDC is working closely with the Council of State and Territorial Epidemiologists (CSTE) to consider including serology as an appropriate diagnostic tool for confirming a pertussis case. Serology can be very useful for diagnosing pertussis in adolescents and adults during the later phases of disease when the current accepted diagnostic methods, culture and PCR, are no longer reliable. Sensitive and specific quantitative seroassays have been developed and are routinely used for diagnosis of pertussis world-wide; however, FDA marketing authorization is necessary before these seroassays can be made commercially available as in vitro diagnostics in the United States. To date, no quantitative pertussis serology kits are commercially available in the United States for diagnostic use.

Interested manufacturers that may have candidate products are invited to contact CDC to discuss potential opportunities for collaboration. At a minimum, discussions with CDC should include the following information 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. Detailed summary of data demonstrating suitable analytical and clinical test characteristics (i.e. precision, linearity, accuracy, sensitivity/specificity, etc.).

Any collaborations that result from these conversations will require that manufacturers enter into an appropriate agreement prior to the transfer of any material to or from CDC. Sample agreements may be viewed at the following web site: https://www.cdc.gov/od/science/technology/techtransfer/researchers/formsagreements/index.htm

All information submitted to CDC will be kept confidential as allowed by relevant federal law, including the Freedom of Information Act (5 USC 552) and the Trade Secrets Act (18 USC 1905).

Dated: December 13, 2017.

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Sandra Cashman,

Executive Secretary,

Centers for Disease Control and Prevention.

[FR Doc. 2017-27189 Filed: 12/15/2017 8:45 am; Publication Date: 12/18/2017]