

Clinical Evaluation and Validation of Laboratory Methods For The Diagnosis of Bordetella Pertussis Infection.

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Principal Investigator: Heidi Flori, MD, MPH

Synopsis:

1. To evaluate the clinical sensitivity, specificity and predictive values of:
 - a. the CDC/FDA anti pertussis toxin IgG (PT-IgG) ELISA,
 - b. the anti pertussis toxin secretory IgA (sIgA-PT) ELISA,
 - c. the CDC's combined PCR (that amplifies a section of the IS481 insertion sequence and a sequence of the pertussis toxin promoter region (PTXS1)),
 - d. culture and clinical diagnosis of pertussis.
2. If CDC identifies one or more commercial serology ELISA kits to clinically validate, the sensitivity, specificity and predictive values will be estimated.
3. Evaluate the sensitivity and specificity of various serological diagnostic cutoff points, including values that were recently established using NHANES specimens.

The results of this study will ensure that validated laboratory assays (particularly, PCR and serology) are available at both the state level and at CDC. The results will also help assess and manage pertussis outbreaks, to measure the real burden of adolescent and adult pertussis disease, and to perform future pertussis vaccine efficacy studies.

If the study results indicate the CDC/FDA ELISA kit or a commercial ELISA kit is adequately sensitive and specific, the results may be included in an application for FDA licensure.

The individual site laboratories may request CDC serological and PCR results in order to conduct secondary validations to meet Clinical Laboratory Improvement Amendments (CLIA) requirements for their in-house pertussis diagnostic tests.