

Submission of Enteric Pathogens from Positive Culture-Independent Diagnostic Test Specimens to Public Health

Interim Guidelines

BACKGROUND

Laboratory tests that detect the molecular or antigenic signature of pathogens independent of generating an isolate are rapidly being adopted by clinical laboratories. These culture-independent diagnostic tests (CIDTs) represent a major shift in clinical microbiology practices and have important implications for physicians, patients and public health. CIDTs include PCR-amplified, antigen-based, and/or multi-analyte panel tests that are often ordered based on a clinical syndrome rather than a specific suspected pathogen. A GI Panel for enteric pathogens is often available from companies that develop and market CIDTs.

Enteric disease surveillance systems such as PulseNet have enhanced public health by enabling the rapid identification of foodborne outbreaks. PulseNet is a national, laboratory-based surveillance system that uses molecular subtyping methods to identify clusters of disease caused by bacterial pathogens including *Salmonella*, *Listeria* and *E. coli* O157, isolated from ill patients. Identification of disease clusters by PulseNet triggers epidemiological investigations into possible common sources, such as foods. The essential first step in the process is the isolation and availability of culture isolates from infected patients. Preservation of the flow of culture isolates from clinical laboratories to public health laboratories (PHLs) is essential for maintaining this and other laboratory-based surveillance systems and to limiting the spread of foodborne diseases. In the event that a clinical laboratory discontinues culture-based detection of gastrointestinal pathogens, it becomes critical that the patient sample be submitted to PHLs in lieu of an isolate (see recommendation 3).

Currently, nationally recommended practices for the public health submission of specimens that test positive using CIDTs are not available to clinical microbiologists. This absence of recommendations needs to be addressed, as clinical laboratories that have adopted CIDTs are interested in continuing their participation in public health surveillance efforts. The following interim recommendations have been developed by public health microbiologists working in collaboration with the Association of Public Health Laboratories (APHL) and the American Society for Microbiology (ASM), under consultation with scientists from the Centers for Disease Control and Prevention (CDC).

More specific recommendations will be provided following the analysis of results from an isolate recovery study being conducted by APHL and CDC.

INTERIM RECOMMENDATIONS

1. Prior to implementing a CIDT assay, clinical laboratories should contact their local and/or state public health laboratory to discuss specific regulations regarding culture-independent diagnostic tests, required organisms for public health submission and specimen type(s) preferred by their public health partner.
2. When a pathogen that requires public health submission is detected, clinical laboratories should continue to obtain isolates, as much as possible, and submit them to the local or state PHL to facilitate timely detection and investigation of outbreaks. PHLs will perform Pulsed-field Gel Electrophoresis (PFGE) and/or whole genome sequencing (WGS) along with virulence testing and susceptibility testing as warranted.
3. If clinical laboratories are unable to culture the isolates for public health surveillance, the CIDT-positive specimens should be submitted to the PHL within 24 hours of the CIDT result. Ideally, stools should be submitted in Modified Cary-Blair transport medium at ambient temperature even though viability will be compromised due to the elapsed time from collection to submission. If submission of stool specimens in Modified Cary-Blair transport medium is not feasible, specimens should be transported in GN broth and submitted to the PHL. Clinical laboratories should contact the public health laboratory for other organism-specific guidance.

SUGGESTED APPROACH

When a pathogen that requires public health submission is detected, isolation should be attempted using standard protocols, including selective and differential media as deemed cost-effective by the clinical laboratory. Acceptable specimen types for submission to public health laboratories include in preferred order: an isolate, stool in Modified Cary-Blair transport media or GN broth.

Adhering to these Interim Guidelines for Submission of Positive CIDT Specimens to Public Health will lead to important outcomes. These outcomes include accurate pathogen surveillance to monitor trends in disease, timely identification of outbreaks caused by enteric pathogens, removal of contaminated products from commerce and the ability to monitor industry changes designed to improve the safety of the food supply.

Additionally, we hope to further standardize specimen submission requirements. APHL intends to work with CDC and ASM in the coming year to update these Interim Guidelines based on the analysis of results from isolate recovery studies conducted in the summer of 2015.

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