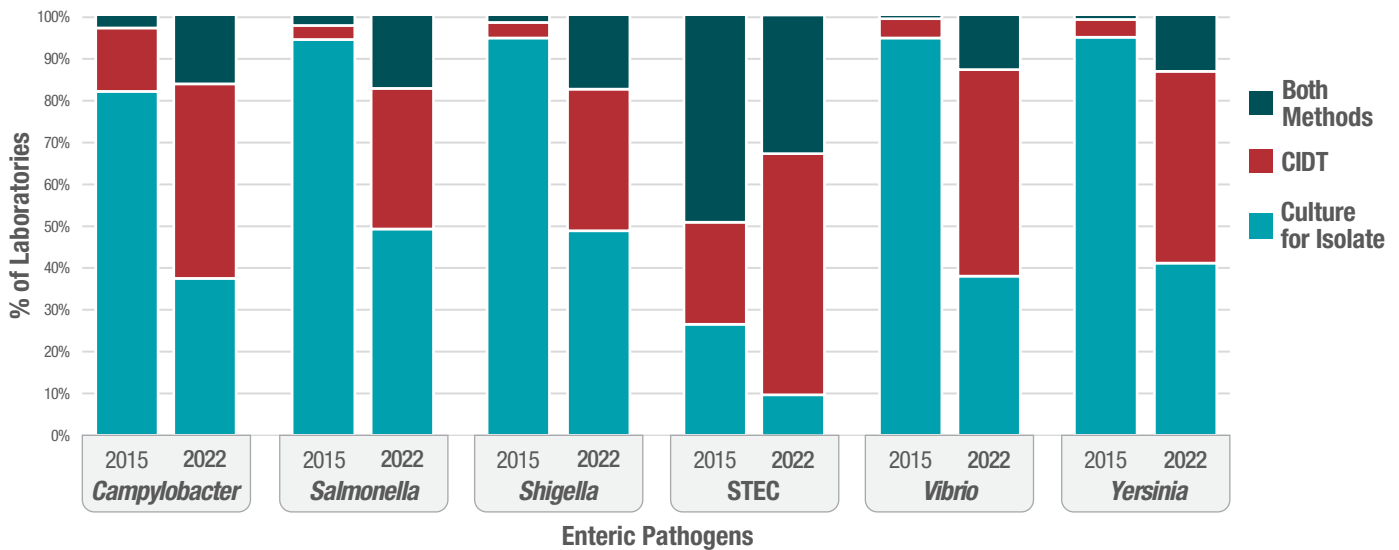


CULTURE-INDEPENDENT DIAGNOSTIC TESTS

and the Future of Foodborne Disease Surveillance

Over the past decade, the use of culture-independent diagnostic tests (CIDTs) in disease detection and surveillance has been steadily increasing (Figure 1). CIDTs do not provide bacterial isolates, so this shift in microbiology practice has important implications for physicians, patients and public health. This resource outlines the benefits and challenges of widespread CIDT use and provides recommended actions that laboratories, federal agencies and test manufacturers can take to preserve critical public health surveillance infrastructure.

Figure 1. Test Methods Used by Diagnostic Laboratories to Detect Enteric Pathogens*



Benefits and Challenges of CIDTs

Many foodborne disease surveillance systems—such as PulseNet—rely on isolates for rapid, accurate foodborne outbreak identification. PulseNet is a national laboratory-based surveillance system that uses whole genome sequencing of isolates to identify human disease outbreaks caused by bacterial pathogens, such as *Salmonella* and *E. coli*. Continued preservation of isolates is crucial to maintaining laboratory-based surveillance systems for early detection and identification of foodborne diseases. While the use of CIDTs can more rapidly diagnose patient illness at a reduced cost, the loss of cultured isolates causes a consequential burden for both clinical and public health laboratories.

Benefits

- **Cost Effective:** Can test for multiple pathogens at once reducing need for multiple microbiology procedures.
- **Rapid Identification:** Fast and syndrome-based, can detect multiple pathogens including organisms traditionally challenging to cultivate.
- **Easy to Use:** Easy onboarding and training can reduce labor needs.

Challenges

- **No Isolate Recovery:** Many CIDTs do not allow for the recovery of bacterial isolates required for further characterization.
- **Burden of Reflex Culture:** Reflex bacterial culture incurs additional costs and labor in both clinical and public health laboratories.
- **Difficult Result Interpretation:** Difficult to interpret polymicrobial infections and viability, possibly resulting in unnecessary treatment and costs for patients.

Recommended Actions

Clinical Laboratories

- Maintain effective communication with your jurisdiction's public health laboratory on what CIDs your laboratory uses for foodborne pathogen detection.
- Continue to obtain and submit isolates or clinical material (stools, broths) promptly to your public health laboratory according to your jurisdiction's sample submission regulations.
- Report discrepancies or abnormal CIDT results to the manufacturer, US Food and Drug Administration (FDA) MedWatch and state/local public health laboratory.
- Monitor pathogen volume and recovery rates and share that information with your public health laboratory, if allowed.

Public Health Departments

- Regularly communicate with clinical laboratories in your jurisdiction about isolate submission guidelines and outbreak information.
- Consider implementing pathogen-specific workflows developed by the Association of Public Health Laboratories (APHL) to help with isolate recovery.
- Collaborate with state and local epidemiologists to review and recommend updates to state regulations to include mandatory submission of clinical material and/or isolates from clinical partners.
- Monitor pathogen recovery rates from CIDT-positive specimens received for testing to allow for identification, investigation and reporting of testing anomalies.
- Report discrepancies or abnormal CIDT results to the manufacturer, FDA MedWatch, US Centers for Disease Control and Prevention (CDC) and clinical laboratories.
- Advocate for funding to help assist with costs of isolation and recovery of foodborne pathogens.

CDC

- Communicate with CIDT manufacturers during assay development to ensure specimen and process compatibility with isolate recovery efforts.
- Continue to develop and evaluate metagenomic culture-independent surveillance testing workflows to maintain subtyping ability in the absence of isolates.
- Implement the national CIDT workplan and support public health laboratories with the burden of increased isolate recovery.
- Help to identify and overcome barriers to reflex culture in clinical laboratories and isolate recovery in public health laboratories, considering funding opportunities to offset the increased cost and labor of culturing.

Manufacturers

- Consider both clinical and public health needs when creating new CIDs.
- Maintain open communication with public health laboratories and CDC about planned instrument and test kit discontinuation and product recalls.
- Include in package insert requirements for clinical laboratories to follow local jurisdiction rules on isolate submission guidelines.

Additional Resources

- [APHL CIDT Dashboard](#)
- [APHL Food Safety Tools and Resources](#)