



APHL Position Statement

Establishing Legal Requirements for the Submission of Enteric Disease Isolates and/or Clinical Material to Public Health Laboratories

A. Statement of Position

The Association of Public Health Laboratories (APHL) recommends that all public health departments establish legal requirements for the submission of enteric bacterial disease isolates and/or clinical specimens by hospital and clinical laboratories; in jurisdictions with applicable requirements in place, APHL encourages a review of the legal language to ensure continued submissions of enteric bacterial disease isolates and/or clinical specimens by hospital and clinical testing laboratories as foodborne culture-independent diagnostic tests (CIDTs) are implemented.

B. Implementation

1) Through its Culture Independent Diagnostics (CID) Subcommittee, APHL will continue to collaborate closely with CDC, other federal agencies, sister associations, diagnostic manufacturers and clinical laboratory partners regarding the rapid implementation of CIDTs and address the impacts of the increased use of such technologies.

2) APHL will participate on CDC's CIDT Steering Committee that is considering issues related to costs to both clinical and public health laboratories, including CPT coding and federal grant opportunities.

3) APHL will develop suggested language for legal submission requirements. This language will complement the CIFOR Law Project Documents that include an Analysis of State Legal Authorities, a Practitioners' Handbook on Legal Authorities and a Menu of Legal Options.

4) APHL will request data from states that have enacted mandatory submission rules to demonstrate positive outcomes on surveillance and response activities to state officials and policymakers.

5) APHL will connect members with experience in developing and implementing rules with those members planning to develop new language or review/revise pre-existing language.

C. Background/Data Supporting Position

The recovery of cultured isolates, whether by clinical or public health laboratories, remains an essential component to public health efforts to monitor trends and detect and respond to foodborne illness outbreaks. The rapidly increasing availability of CIDTs for foodborne pathogens poses serious challenges for public health and is threatening to derail current laboratory-based surveillance systems. CIDTs do not produce isolates.

Without such isolates, information on foodborne pathogen serotype, subtype, virulence factors, and antimicrobial susceptibility will be scant, if available at all. Loss of culture-based DNA fingerprinting will make outbreak detection and source trace back nearly impossible.

Surveillance data has been used for decades to monitor the burden of disease and trends in antibiotic resistance, to detect and respond to outbreaks, to inform and evaluate programmatic activities and national policies aimed at reducing the burden of foodborne illness, and to conduct special studies.

- PulseNet is the most successful national laboratory-based surveillance system in the United States. In 2013, PulseNet detected over 250 foodborne disease clusters (Centers for Disease Control and Prevention (CDC), unpublished data). Without this network, many large national foodborne outbreaks would never be detected. Historic examples include: Salmonella infections linked to organic sprouted chia powder (2014), raw chicken (2013), a raw scraped ground tuna product (2012), and shell eggs (2010), and Listeria infections linked to fresh, artisanal cheese & cheese products (2013 & 2014).
- Public health uses comprehensive surveillance data on the 30 most prevalent Salmonella serotypes through CDC's "An Atlas of Salmonella in the United States, 1968-2011" to better define and understand the epidemiology of Salmonellosis (1).
- Federal regulatory agencies rely on public health laboratory surveillance data for the control of foodborne pathogens in meat and poultry establishments and for animal and environmental surveillance activities such as those through the National Veterinary Services Laboratories (NVSL) within the United States

Department of Agriculture (USDA)-Food Safety and Inspection Service (FSIS)(2).

- The National Antimicrobial Resistance Monitoring System (NARMS) tracks changes in antimicrobial susceptibility for several enteric bacteria found in ill people, retail meats, and food animals. Due in large part to data collected on fluoroquinolone-resistant Campylobacter isolates at the Minnesota Department of Health (3) and through NARMS, the U.S. Food and Drug Administration (FDA) proposed the withdrawal of fluoroquinolone use in poultry in 2000 (4).

The critical information gathered from NARMS has been influential in shaping policy around the use of antimicrobial drugs in food animals. None of the aforementioned programs would have been possible without the availability of cultured isolates.

State-specific isolate submission requirements for the most prevalent foodborne pathogens vary considerably and, in some cases, are non-existent. In a survey conducted by APHL in 2011, the number of state public health laboratories who reported having mandatory isolate submission laws in place for Campylobacter, Listeria monocytogenes, non-Typhoidal Salmonella, and Shiga toxin-producing Escherichia coli (STEC) ranged between 11 and 31 states (APHL, unpublished data). Successful state submission laws currently in place have taken into consideration pathogens of concern to the community, the impact of timeliness of submission on effective public health actions, the types of material that are preferred and acceptable, and where to send the required materials.

Many public health departments rely on the voluntary submission of foodborne disease isolates by clinical laboratories. Clinical laboratories are under ever-increasing, intense pressure to offer faster, more highly-sensitive, efficient and cost-effective tests for the physicians they serve. Uniform mandatory isolate and/or specimen submission guidance across the nation will not only preserve critical public health laboratory surveillance systems, but will also encourage clinical laboratories to preserve specimens and provide an impetus to justify reflex culture. Furthermore, properly worded submission rules will allow CLIA and CAP to enforce submission guidelines in the product inserts of FDA cleared CIDTs.

As public health laboratories race to adapt to the new testing methods used in the clinical laboratories, the cornerstone of surveillance will remain the preservation of culture isolates. While whole genome sequencing appears to be the forerunning technology for pathogen characterization, obtaining the sequence information from the etiologic agent still relies on cultured isolates. For the near term, both pulse-field gel electrophoresis (PFGE) and whole genome sequencing methods require pure cultured isolates, and it is critical that this essential component remains available to public health laboratories until future technologies no longer require them. APHL strongly encourages public health departments to ensure continued surveillance capabilities in individual jurisdictions by pursuing legal submission requirements for enteric disease isolates and/or clinical material.

D. References

1. Centers for Disease Control and Prevention (CDC). An Atlas of Salmonella in the United States, 1968-2011: Laboratory-based Enteric Disease Surveillance. Atlanta, Georgia: US Department of Health and Human Services, CDC, 2013.
2. Serotypes Profile of Salmonella Isolates from Meat and Poultry Products January 1998 through December 2011. USDA-FSIS, <http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/annual-serotyping-reports>
3. Smith KE, Besser JM, Hedberg CW, Leano FT, Bender JB, Wicklund JH, Johnson BP, Moore KA, Osterholm MT. Quinolone-resistant *Campylobacter jejuni* infections in Minnesota, 1992-1998. Investigation Team. *N Engl J Med*. 1999 May 20;340(20):1525-32.
4. Nelson, J.M., Chiller, T.M., Powers, J.H., and Angulo, F.J. (2007) Fluoroquinolone-Resistant *Campylobacter* Species and the Withdrawal of Fluoroquinolones from Use in Poultry: A Public Health Success Story. *Clinical Infectious Diseases*, 44 (7)977-980. Doi: 10.1086/512369.
5. Centers for Disease Control and Prevention (CDC). National Salmonella Surveillance Annual Report, 2011. Atlanta, Georgia: US Department of Health and Human Services, CDC, 2013.

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