APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

APHL Position Statement

Use of Non-Culture Assays to Detect Foodborne Infectious Agents

A. Statement of Position

APHL advocates that all positive results from non-culture assays used by clinical laboratories to detect foodborne disease agents of public health concern be confirmed through culture-based identification methods, with a focus on increasing specimen submissions to public health laboratories. Isolates should be fully characterized to enable public health practitioners the ability to trace disease sources, develop intervention strategies, monitor changes to virulence patterns, and examine therapy regimens, thereby eliminating threats to the health of the community. To this end, APHL supports current Centers for Disease Control and Prevention (CDC) culture confirmation recommendations for Shiga toxin-producing *E. coli*[1] (STEC) published in October of 2009 and encourages CDC to develop similar recommendations for other foodborne disease agents, such as *Campylobacter sp*. and *Salmonella sp*.

B. Background/Data Supporting Position

The public health laboratory system is a network of local, state, and national laboratories, working in partnership with epidemiologists that play a key role in the prevention and control of communicable infectious diseases. The laboratory staff who support this system do so by providing epidemiologists with population-based laboratory surveillance data to detect and investigate outbreaks of infectious diseases and to monitor significant trends in the development of antibiotic resistance and altered pathogenicity. Several national surveillance programs are built on this laboratory network, including PulseNet,[1] National Antimicrobial Resistance Monitoring System (NARMS),[2] and other non-food related pathogen-tracking systems. They all require the continuous availability of microbial culture isolates for analysis. Without adequate numbers of such isolates as the starting material for the laboratory findings that populate relevant databases, the effectiveness of these national surveillance systems will be severely compromised.

Advances in technology have allowed faster detection of pathogens in both clinical specimens and food samples without the need to isolate the organism. These non–culture based methods include an array of biochemical, nucleic acid, and serologic based tests which are marketed as diagnostic kits for clinical use. While these “rapid” tests are becoming increasingly sensitive and specific, limitations still exist[3]. False-positive non-culture assay results and poor or incomplete isolate characterizations lead to unnecessary and sometimes costly public health interventions.[4] CDC has generated standard of practice guidelines for the testing and submission of STEC isolates and clinical materials to public health laboratories as outlined in an MMWR Recommendations and

Reports.[5] Clinical laboratories should culture samples that signal positive in a non-culture assay and consult with their state authority to determine whether isolates and/or clinical material should be sent to the PHL in support of epidemiological investigations.

The PulseNet[1] program has provided critical support to national laboratory surveillance of foodborne pathogens. PulseNet is a national network of laboratories using standardized molecular methods to detect clusters of foodborne illness which are then investigated by epidemiologists to determine if patients can be linked in space or time. Efficient control measures can be implemented when targeted by enhanced laboratory findings derived from culture isolates. The use of PulseNet data has been extremely effective in epidemiologic investigations of local, national, and international outbreaks.[6,7] Its effectiveness depends on the active participation of public health laboratories around the nation that use this technology to characterize isolates all operating in a cooperative partnership with clinical laboratories. Early identification of foodborne illness clusters using PulseNet has made it possible to respond rapidly on a national level to prevent further cases of disease by facilitating "trace back" to sources, so that production, distribution, and sale of implicated foods may be halted.[8] Many PulseNet laboratories also contribute isolates to NARMS.

An essential feature of PulseNet, NARMS, and other national surveillance networks is the need for constant access to a broad spectrum of culture-confirmed bacterial pathogens specifically identified and thoroughly characterized by members of the public health laboratory system. To detect communicable disease outbreaks early and focus epidemiologic investigations, culture isolates must be available for characterization and sub-typing by serological, biological, or molecular methods to demonstrate critical point-source relationships within a community, a state, or the nation. Such isolates are also essential for conducting in-depth analyses required to monitor trends in antibiotic resistance and the emergence of new or altered pathogens.

C. Implementation

On behalf of its members, APHL will collaborate with CDC and the Council of State and Territorial Epidemiologists (CSTE) to educate health-care providers and clinical laboratories about the importance of culture confirmation of non-culture based test results, in-depth epidemiological characterization, and continuous surveillance of foodborne infectious diseases via published updated recommendations. APHL will continue developing guidelines for public health laboratories regarding best practices for laboratory identification and characterization of STEC and other foodborne pathogens. APHL will also work with CDC and CSTE to assist the US Food and Drug Administration in responding to the issue of approval of new tests that affect public health laboratory-based surveillance.

APHL members will seek speaking opportunities whenever possible to address the need for isolate retention and submission.

APHL will continue to meet with CDC and clinical laboratory partners and their representative body, the American Clinical Laboratory Association (ACLA), and The American Society for Microbiology (ASM). Specifically, APHL will work with ACLA and ASM members, CDC and CSTE to:

- Develop results interpretation guidelines for clinicians
- Assist clinical laboratories in decreasing time interval for submitting PulseNet-tracked isolates to PulseNet laboratories

- Create physician education materials regarding foodborne illness diagnosis
- Assist regulatory agencies in developing policies and accreditation rules that reflect the standard of care guidelines proposed by CDC[5]

D. References

1. CDC. PulseNet: The National Molecular Subtyping Network for Foodborne Disease Surveillance, 2011. Information may be found at: http://www.cdc.gov/pulsenet/
2. CDC. NARMS: National Antimicrobial Resistance Monitoring System, 2011. Information may be found at: http://www.cdc.gov/narms/
3. Robinson TJ, Cebelinski EA, Taylor C, and KE Smith. Evaluation of the Positive Predictive Value of Rapid Assays Used by Clinical Laboratories in Minnesota for the Diagnosis of Cryptosporidiosis. 2010;50:e53-e55.
4. CDC. Importance of Culture Confirmation of Shiga Toxin-producing *Escherichia coli* Infection as Illustrated by Outbreaks of Gastroenteritis --- New York and North Carolina, 2005. MMWR Morb Mortal Wkly Rep. 2006 Sep 29;55(38):1042-5
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6. Tauxe, R. Molecular Subtyping and the Transformation of Public Health. Foodborne Pathog Dis.2006 3(1): 4-8
7. Hedberg, C. and J. Besser. Commentary: Cluster Evaluation, PulseNet, and Public Health Practice. Foodborne Pathog Dis.2006 3(1): 32-5
8. Laine, ES. et al. Outbreak of Escherichia coli O157:H7 infections associated with nonintact blade-tenderized frozen steaks sold by door-to-door vendors. J Food Prot. 2005 Jun;68(6):1198-202

Recommended by: The Food Safety Committee, Approved by Board of Directors for Interim Use: January 2012, Approved by Membership: February 2012, Sunset Date: February 2017

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