

14-06

## STATEMENT OF POLICY

### Enteric Disease Testing

#### Policy

Knowledge of the clinical and epidemiologic features of acute gastroenteritis (AGE) such as salmonellosis, campylobacteriosis, and shiga-toxin-producing *Escherichia coli* (STEC) eg, O157, has been developed through the study of culture-confirmed infections.<sup>1</sup> These infections are mainly foodborne and therefore preventable. Successful control of such illnesses may be at risk because AGE diagnostics are moving away from culture and are being replaced by culture-independent diagnostic tests (CIDT). The capacity for culture-based diagnostic testing or their equivalent must be retained in the medical care and public health sectors.

The National Association of County and City Health Officials (NACCHO) advocates that all positive results from non-culture assays used by clinical laboratories to detect bacterial foodborne disease pathogens of public health concern be confirmed through culture-based (or their equivalent) identification methods and that isolates should be fully characterized. Therefore, NACCHO strongly urges that the federal government sustain the capacity for culture-based or equivalent testing for AGE through financial support for laboratories to retain such capacity and through policies and rules-making that promote such testing.

#### Justification

Foodborne illnesses are a serious public health and economic issue in the United States. There are an estimated 48 million cases of illness each year; approximately 128,000 hospitalizations and 3,000 deaths. It is estimated that foodborne illnesses cost the United States \$125 billion each year.<sup>2</sup> Prevention and control measures depend upon coordination between public health regulations, investigations, and (currently) culture-based laboratory services. The proliferation of rapid CIDT is economically inviting (less costly) and clinically sound (results are available sooner and are actionable). An unfortunate consequence of the increasing use of non-culture diagnostic tests is that such diagnostics do not provide isolates critical for public health purposes. These isolates, which are used for further microbiologic and nucleic acid sub-type testing that can link cases to exposures and to each other, are essential for disease prevention and public health disease investigation.

Implementation of CIDT methods introduces a bias in surveillance of AGE. For example, public health surveillance for STEC has been based on culture-confirmed cases of *E. coli* O157.<sup>3</sup> Moving to CIDT will affect the numbers of cases being reported, and will compromise not only investigations, but also any analysis of trends over time, as well as an inability to distinguish specific strains of bacteria, such as STEC due to *E. coli* O157 from *E. coli* O26.<sup>4,5</sup> In addition, the sensitivity, specificity, and the associated positive and negative predictive values of antigen tests will differ from those of culture. This can influence decisions about whether to include the



results of such tests in the reportable disease roster and could lead to the underreporting or overreporting of cases.

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 supporting 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,<sup>6</sup> National Antimicrobial Resistance Monitoring System (NARMS),<sup>7</sup> 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. New policies are needed to address this risk to the public's health. Decisions about implementing new tests in clinical laboratories are usually based on cost, ease of use, sensitivity, and specificity. The test results' relevance to public health purposes are less likely to be emphasized when making decisions on which tests to use. All of these aspects need to be considered before new diagnostic tests and methods are implemented in clinical laboratories.<sup>8,9</sup> If laboratories are not submitting isolates (or their equivalents) to public health labs for a more complete set of characterizations, there is a risk that surveillance, prevention, and control of foodborne diseases will become unreliable and unsuitable for eliminating such threats to the health of the community.

## **References**

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**Record of Action**

*Proposed by NACCHO Epidemiology, Infectious Disease Prevention and Control, and Food Safety Workgroups*

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