

# STATE OF COLORADO

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Dedicated to protecting and improving the health and environment of the people of Colorado

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Colorado Department  
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## Recommendations for the Detection of *Campylobacter* in Stool

### KEY POINTS

- New antigen-based non-culture methods for detection of *Campylobacter* are being adopted by laboratories, many of which have ceased to use culture for *Campylobacter* testing.
- A multicenter study involving the CDC and 7 states, including Colorado, found that currently available antigen-based non-culture tests for *Campylobacter* demonstrated poor real-world performance characteristics.
- CDPHE recommends that culture be used as the primary method for the detection of *Campylobacter* in stool and that culture be performed for confirmation of *Campylobacter* in all stool specimens that yield positive findings by antigen-based methods.
- The CDPHE laboratory will perform culture confirmation for *Campylobacter* for a fee as it has been determined that using state funds to perform confirmation testing for methods with demonstrated poor performance would be inappropriate.
- Any specimen with positive findings for *Campylobacter*, whether by culture or by antigen-based testing, should continue to be reported within 7 days to the state or local health department.

### BACKGROUND INFORMATION

In early 2010 CDPHE became aware that several laboratories in Colorado had switched their method of *Campylobacter* testing from culture to antigen-based non-culture methods. Due to the limited data available about the performance characteristics of these assays, on March 8, 2010 CDPHE sent a memo to laboratories providing "Interim Guidance on Testing and Reporting *Campylobacter* Cases for Laboratories Using EIA Testing for *Campylobacter*." In this memo, CDPHE requested that laboratories, if possible, perform culture on all stools that are antigen-test (+) for *Campylobacter* and indicated that if laboratories were unable to perform *Campylobacter* culture, to please forward all antigen-based (+) stools to the CDPHE laboratory for culture confirmation at no charge.

The CDPHE laboratory participated in a multicenter study with the CDC and 7 other states to evaluate the real-world performance of stool antigen-based assays in comparison to culture and PCR for detection of *Campylobacter* in stool. Stool specimens collected between July and October 2010 from patients who were being evaluated for GI illness were tested with the following methods: *Campylobacter* culture, four antigen-based assays (ProSpecT™ *Campylobacter*, PREMIER™ CAMPY, ImmunoCard STAT! (ICS) and Xpect Campy) and PCR (Seegene). When compared to culture and PCR, the antigen-based assays demonstrated poor performance characteristics in Colorado (Table 1), and at all other test sites (see attached poster) where the real-world prevalence of *Campylobacter* is low. The CDC will be considering the results of this multicenter evaluation study in the development of best practice laboratory guidelines for *Campylobacter* diagnosis.

**Table 1: Performance Characteristics in Colorado<sup>1</sup>:**

<b>Antigen-Based Tests</b>						
	<b><i>Culture</i></b>	<b><i>A</i></b>	<b><i>B</i></b>	<b><i>C</i></b>	<b><i>D</i></b>	<b><i>PCR</i></b>
<b><i>Sensitivity</i></b>	100%	100%	100%	80%	100%	100%
<b><i>Specificity</i></b>	100%	94.5%	98.2%	95.2%	98.9%	100%
<b><i>PPV*</i></b>	100%	25%	50%	23.5%	62.5%	100%
<b><i>NPV*</i></b>	100%	100%	100%	99.6%	100%	100%

<sup>1</sup>A total of 277 stool specimens were tested of which 5 were confirmed to be positive for *Campylobacter*.

\*PPV= positive predictive value, NPV= negative predictive value

### **RECOMMENDATIONS AND GUIDANCE**

Given the low incidence of *Campylobacter* disease in Colorado, and the performance data generated by the multicenter evaluation study, CDPHE recommends that antigen-based tests should not be used as stand-alone tests for direct detection of *Campylobacter* in stool. Culture is recommended as the most reliable primary test for the detection of *Campylobacter*. Furthermore, culture should be performed for confirmation of *Campylobacter* in all stool specimens that are antigen-test (+) for *Campylobacter*. The CDPHE laboratory will perform culture confirmation for *Campylobacter* for a fee (\$90) as using laboratory funds to perform confirmation testing for methods with demonstrated poor performance would be inappropriate. **Any specimen with positive findings for *Campylobacter*, whether by culture or by antigen-based testing, should still be reported within 7 days to the state or local health department.**

These recommendations are specifically for *Campylobacter*; please continue to submit bacterial isolates and other clinical material to CDPHE as outlined in the attached “Guidance for Clinical Microbiology Laboratories on Isolate Submission.” We will continue to evaluate other culture-independent tests, as they are developed, based on real-world performance characteristics.

For questions, please contact the CDPHE laboratory at 303-692-3480 or the Communicable Disease Epidemiology Program at 303-692-2700.