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Implications of Culture-Independent Panel-Based Detection of *Cyclospora cayetanensis*

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The Nebraska Medical Center (TNMC) was conducting an Institutional Review Board-approved research study utilizing the BioFire FilmArray gastrointestinal (GI) panel (BioFire Diagnostics, Salt Lake City, UT) when an outbreak of cyclosporiasis occurred in Iowa and Nebraska (1). The FilmArray GI panel is a culture-independent molecular test that simultaneously detects 14 bacterial, 5 viral, and 4 protozoal targets (including *Cyclospora cayetanensis*) directly from stool specimens, irrespective of physician ordering practices or laboratory ordering policies. For the research study, deidentified residual stool specimens, originally submitted to the laboratory based on a health care provider's suspicion of gastrointestinal illness, were tested with the FilmArray GI panel. All specimens were tested fresh (not frozen) and within 4 days of the collection date.

In the clinical microbiology laboratory, *Cyclospora* testing is typically conducted using a specifically ordered, modified-acid-fast-stained fecal smear. Prior to recognition and during the early stages of the cyclosporiasis outbreak, deidentified specimens that tested positive for *Cyclospora* using the FilmArray GI panel in the research study were undetected by the clinical laboratory because modified acid-fast staining was not ordered. In total, *Cyclospora* was detected by the FilmArray GI panel in 19 deidentified specimens collected between 18 June and 25 July 2013. As shown in Table 1, *Cyclospora* testing was not ordered for 8 of these specimens, of which three were collected before the outbreak became known (prior to 28 June) and five early in the outbreak investigation (prior to 13 July). Importantly, the first *Cyclospora*-positive specimen detected in our study was collected on 18 June, 1 week prior to the first reported positive case in Nebraska and 3 days prior to the first reported positive case in Iowa (2). As the medical community became aware of the outbreak, direct analysis of stools for *Cyclospora* became a common practice, and stool specimens enrolled in the clinical study later in the outbreak timeline were more likely to have had *Cyclospora* testing ordered (Table 1). Our results indicate that routine utilization of the FilmArray GI panel as a screening tool would have led to more-rapid detection of the cyclosporiasis outbreak, since *Cyclospora* would have been detected before anyone was specifically looking for this parasite.

There are recognized challenges associated with the utilization of culture-independent molecular testing and the concomitant need for isolation of enteric bacteria for further public health characterization or antimicrobial susceptibility testing (3). Our experiences during a *Cyclospora* outbreak, however, showed that culture-independent technologies have the potential to positively affect the detection and management of patients with infectious diseases. Isolates are invaluable resources to public health surveillance and outbreak investigations, and clinical laboratories should not abandon the practice of obtaining isolates whenever appropriate. Accordingly, our laboratory personnel look forward to utilizing the FilmArray GI panel as a screening tool for enteric pathogens (upon FDA clearance of the product) and plan to use culture or other isolation procedures as reflexive tests for positive specimens when applicable. We believe that appropriate laboratory implementation strategies are essential to ensure that culture-independent technologies are used to elevate our capabilities and enhance public health surveillance.

TABLE 1 Ordering practices related to the stool specimens positive for *Cyclospora* using the BioFire FilmArray GI panel[a]

Time of specimen collection in relation to outbreak[b]	No. of specimens for which *Cyclospora* testing was or was not ordered by provider	
	Ordered	Not ordered
Before (before 28 June)	0	3
Early (between 28 June and 12 July)	3	5
After outbreak established (after 12 July)	8	0

[a] For investigational use only.
[b] The Centers for Disease Control and Prevention became aware of two domestically acquired, laboratory-confirmed cases of *Cyclospora* infection on 28 June (1).

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