CDC update on non-culture methods for direct detection of *Campylobacter* in stool

Background

The use of non-culture methods as standalone tests for the direct detection of *Campylobacter* in stool appears to be increasing, which may have important implications for both patient management and public health surveillance efforts. There is currently limited data available about the performance characteristics of these assays. Some laboratories are noting a significant increase in the number of *Campylobacter* positive stools using these assays. This may be due to superior performance of these assays or it may be due to a specificity problem with the assays (i.e. false positive results). As isolates are not recovered using these assays, some laboratories have begun sending *Campylobacter* positive EIA broths to their state public health laboratory for culture confirmation, similar to the situation for STEC positive EIA broths. However, this is more problematic for *Campylobacter* as there is currently no data upon which to base recommendations for transport and culture of EIA positive broths, or for interpretation and reporting of EIA/culture discrepancies. Current CSTE and FoodNet *Campylobacter* case definitions require culture confirmation. Better information about assay performance characteristics is urgently needed to reassess these case definitions to assure the validity of public health surveillance data.

CDC in collaboration with state public health and clinical laboratory representatives and APHL are planning a *Campylobacter* laboratory workgroup to develop clinical and public health laboratory best practice guidelines for *Campylobacter* testing. However, without further evaluation of these non-culture assays, it will not be possible to develop such guidelines.

What non-culture tests are available?

There are currently three different antigen-based, non-culture methods commercially available in the United States for direct detection of *Campylobacter* in stool and a fourth assay will soon go into clinical trial.

i) **ProSpecT *Campylobacter* assay** (Remel). This is an EIA test that has been on the market for several years; takes about two hours to perform. When compared to culture, the ProSpecT EIA has been shown to vary in sensitivity from 80-96% and has a specificity ≥ 97% .

ii) **PREMIER™ CAMPY assay** (Meridian Biosciences). This EIA test received FDA approval in Feb 2009; it take approx four hours to perform.

iii) **ImmunoCard STAT! CAMPY** (Meridian Biosciences). This is a rapid (20 minutes) lateral flow monoclonal antibody-based immunoassay that received FDA approval in June 2009.

The following shows the performance characteristics of the Meridian assays according to manufacturer's instructions:

	Sensitivity	Specificity
PREMIER™ CAMPY assay	**96.7%**	**95.6%**
ImmunoCard STAT! CAMPY	**98.1%**	**95.9%**

iv) **Xpect *Campylobacter* assay (Remel)**. This is a rapid test equivalent to the Meridian ImmunoCard STAT! CAMPY test. No performance data is currently available for this assay as it is still in development; it is due to go into clinical trial soon.

What are the immediate data gaps related to non-culture methods for *Campylobacter*?

i) Real-world performance characteristics of these non culture methods is not available.
ii) Feasibility and optimal transport and processing conditions of EIA positive broths to maximize recovery of *Campylobacter* is unknown.
iii) Discordant results between non-culture test and culture result for a given specimen have not been analyzed; guidelines for reporting discordant results do not exist.

How will this data be subsequently used?

i) Review, and update if appropriate, current *Campylobacter* case definition.
ii) Develop clinical and public health laboratory best practice guidelines for *Campylobacter.*

How can we address these data gaps?

To begin to address the laboratory data gaps described above, we are planning a collaborative study with APHL, state public health laboratory and clinical laboratory partners, to evaluate the four non culture methods described above with the current gold standard, bacterial culture. This data is essential before best practice guidelines can be written.

What should I do in the meantime?

We suggest that your laboratory continue to culture for *Campylobacter* if at all possible, until the performance of these non-culture methods has been further evaluated. At a minimum, we recommend non-culture test positive specimens should be culture confirmed and a reporting plan developed to address discrepant results. In the long term once these non-culture methods have been evaluated, we can consider secondary confirmation tests such as PCR, but these are not currently validated for direct detection in stool.