### TECHLAB<sup>®</sup>

TRUSTED RESULTS

# Campylobacter Testing

## Offers accurate results, fast

- Detects more pathogenic species of Campylobacter, including C. jejuni, C. coli, C. lari, and C. upsaliensis, than any other commercially-available assay
- Provides excellent accuracy and results within minutes without the downsides of culture
- Compatible with multiple specimen types, including fresh, frozen, and samples in transport media



### Campylobacter Test Kits

<b>Product Order Information</b>				
Product Name	Cat. No.	Sample Type	Time to Result	Format
CAMPYLOBACTER QUIK CHEK™	T31025	Fresh, frozen, transport media (Cary Blair or C&S)	30 minutes	Rapid EIA
CAMPYLOBACTER CHEK™	T31096	Fresh, frozen, transport media (Cary Blair or C&S)	60 minutes	Automatable 96-well plate

#### CAMPYLOBACTER QUIK CHEK™ Performance

N = 1552	Culture Positive	Culture Negative
CAMPYLOBACTER QUIK CHEK™ Positive	34	13*
CAMPYLOBACTER QUIK CHEK™ Negative	1*	1504

		95% Confidence Limits
Sensitivity	97.1%	85.5% - 99.9%
Specificity	99.1%	98.5%- 99.5%

<sup>\*</sup> The 14 discrepant specimens were further characterized by additional testing at TECHLAB. This testing included a US FDA-cleared commercial Microassay well EIA, a US FDA-cleared commercial molecular test, in-house PCR (detecting the 16S rRNA gene of Campylobacter spp., and species-specific identification), and bidirectional sequencing. All of the discrepant specimens resolved in favor of the CAMPYLOBACTER QUIK CHEK™ test.

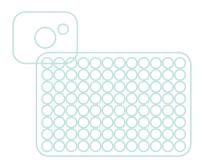
#### CAMPYLOBACTER CHEK™ Performance

N = 1552	Culture Positive	Culture Negative
CAMPYLOBACTER CHEK™ Positive	32	14*
CAMPYLOBACTER CHEK™ Negative	3**	1503

		95% Confidence Limits
Sensitivity	91.4%	75.8% - 97.8%
Specificity	99.1%	98.5%- 99.5%

The 17 discrepant specimens were further characterized by additional testing at TECHLAB. This testing included a US FDA-cleared commercial Microassay well EIA, a US FDA-cleared commercial molecular test, in-house PCR (detecting the 16S rRNA gene of Campylobacter spp., and species-specific identification), and bidirectional sequencing.

<sup>\*\*</sup>One of the three specimens that were culture positive and CAMPYLOBACTER CHEKTM test negative was confirmed to be negative with all tests.



 $\textit{CAMPYLOBACTER QUIK CHEK}^{\intercal} \ \text{Package Insert and CAMPYLOBACTER CHEK}^{\intercal} \ \text{Package Insert}.$ 

TECHLAB, Inc. is a leading developer and manufacturer of infectious disease diagnostics products worldwide. Since 1989, the company has offered a quality portfolio of diagnostic tests which now includes assays for *C. difficile*, *Campylobacter*, Shiga toxin producing *E. coli*, *H. pylori*, protozoan parasites, and biomarkers of intestinal inflammation.



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<sup>\*</sup> All of the 14 culture negative and CAMPYLOBACTER CHEK™ positive resolved in favor of the CAMPYLOBACTER CHEK™ test.