

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

| Product Order Information | | | | |
|---------------------------------|----------|--|----------------|---------------------------|
| Product Name | Cat. No. | Sample Type | Time to Result | Format |
| CAMPYLOBACTER QUIK CHEK™ | T5047 | Fresh, frozen, transport media (Cary Blair or C&S) | 30 minutes | Rapid EIA |
| CAMPYLOBACTER CHEK™ | T5052 | 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% |

* 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

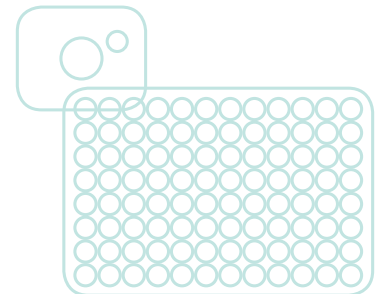
| N = 1552 | Culture Positive | Culture Negative |
|-------------------------------------|------------------|------------------|
| CAMPYLOBACTER CHEK™ Positive | 32 | 14* |
| CAMPYLOBACTER CHEK™ Negative | 3** | 1503 |

| | 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.

* All of the 14 culture negative and **CAMPYLOBACTER CHEK™** positive resolved in favor of the **CAMPYLOBACTER CHEK™** test.

One of the three specimens that were culture positive and **CAMPYLOBACTER CHEK™ test negative was confirmed to be negative with all tests.



CAMPYLOBACTER QUIK CHEK™ Package Insert and CAMPYLOBACTER CHEK™ Package Insert.

Distributed by



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Developed and manufactured by



PROVEN DIAGNOSTIC PERFORMANCE

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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.

