



# QuickVue® TLI

## Campylobacter

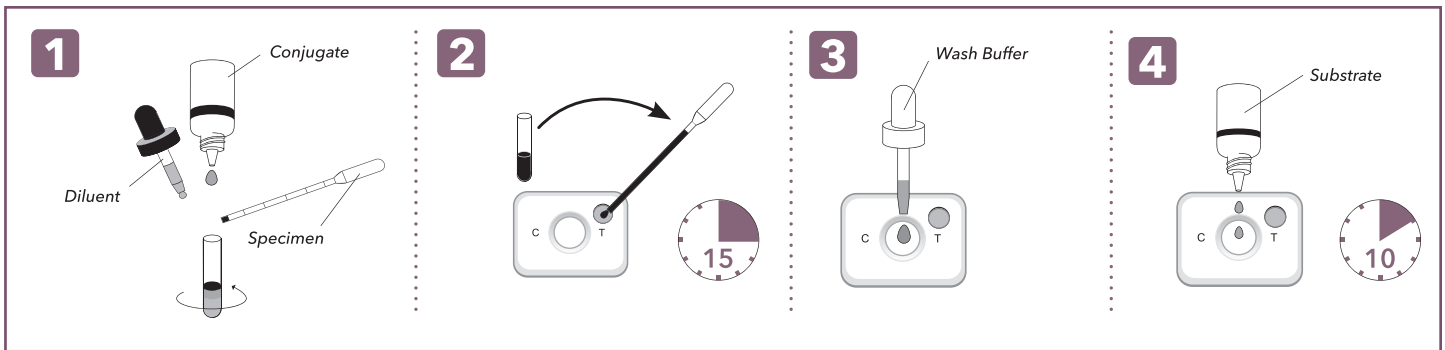


### Test and Treat Today®!

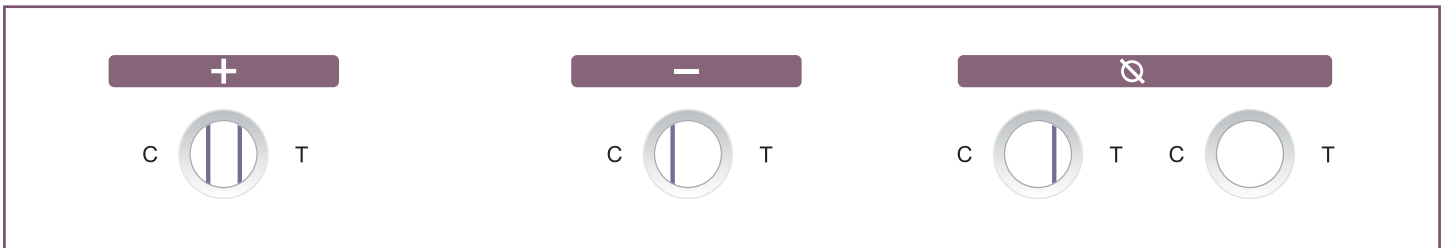
Timely Results You Can Trust

- Results in 30 minutes compared to culture, which requires 72 hours and is prone to false negative results due to stringent sample or specimen transport and growth requirements.
- Can be performed with fresh, frozen, Cary Blair or C&S samples or specimens.
- Detects *C. jejuni*, *C. coli*, *C. upsaliensis*, and *C. lari*.
- Has been shown to cross react with other clinically relevant pathogenic species including *C. helveticus* in clinical and analytical studies.

## Procedure:



## Results:



## Performance:

n= 1552	Culture Positive	Culture Negative
Pos	34	13*
Neg	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 an FDA-cleared commercial Microassay well EIA, an FDA-cleared commercial molecular test, in-house PCR (detecting the 16s rRNA gene of *Campylobacter* spp., and species-specific identification), and bidirectional sequencing.

\*Nine of the 13 specimens that were culture negative and QuickVueTLI Campylobacter Test positive were confirmed to be positive for *C. jejuni* with all test methods.

Two of the 13 specimens that were culture negative and QuickVueTLI Campylobacter Test positive were confirmed to be positive with the commercial EIA, in-house PCR, and bidirectional sequencing.

One of the 13 specimens that was culture negative and QuickVueTLI Campylobacter Test positive was confirmed to be positive with an FDA-cleared commercial molecular test, in-house PCR and bidirectional sequencing.

One specimen that was culture negative and QuickVueTLI Campylobacter Test positive was confirmed to be positive for *C. upsaliensis* (an important pathogen) by species-specific PCR and sequencing.

\*\*The one specimen that was culture positive and QuickVueTLI Campylobacter Test negative was confirmed to be negative for *C. jejuni* or *C. coli* with all test methods.

The performance of any rapid *Campylobacter* test is dependent on sample collection and handling and the adherence to the Package Insert. Refer to our website at [quidel.com](http://quidel.com) for additional performance claims.