ORDERING INFORMATION	Test Size	Meridian#
Premier™ CAMPY	96 Microwells	618096

REFERENCES

[1] *Premier™ CAMPY Package Insert.*

[2] *Hurd, S. et al. "Clinical Laboratory Practices for the Isolation and Identification of Campylobacter in FoodNet Sites: Do Differences Explain Variation in Incidence Rates?" Abstract 2004.*

[3] *www.fda.gov/CVM/Documents/RRASec2.pdf, pages 2-5.*

[4] *Nachamkin, I. "Campylobacter and Acrobacter – Chapter 57". Manual of Clinical Microbiology, 8th Edition, Volume 1. pg. 905.*

[5] *Goosens, H. et al. "Modified selective medium for isolation of Campylobacter spp from feces: comparison with Preston medium, a blood-free medium and filtration system". Journal of Clinical Microbiology. 24:840-843.*

[6] *Ng, L.K., et al. "Characterization of freshly isolated Campylobacter coli strains and suitability of selective media for their growth". Journal of Clinical Microbiology. 26:518-523.*

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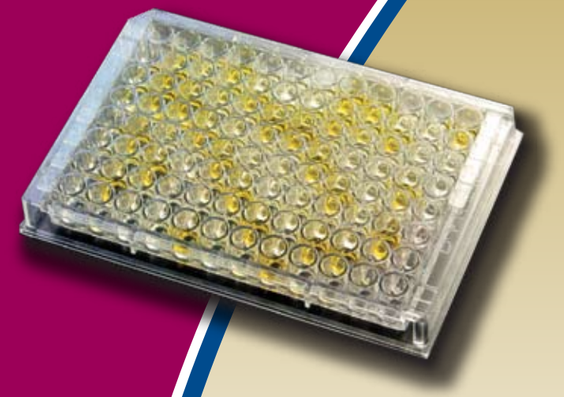

Meridian Bioscience®, Inc.

PREMIER™ CAMPY

Rapid EIA for the detection of *Campylobacter*

Optimized Detection
For *Campylobacter* Testing

OPTIMIZED PERFORMANCE:

- 96.7% Sensitivity, 95.6% Specificity [1]
- Provides detection without lengthy and variable culture procedures which avoids pitfalls associated with culture methods. [2]
- Greater sample flexibility than culture [3]
  - Culture detects only viable organisms
  - Premier™ CAMPY detects microbial antigen expressed on both nonviable and viable organisms.
- Antibiotics in *Campylobactor* culture media can suppress growth [4]

FASTER TURNAROUND TIME:

- Improved Turnaround Time from 48-72 hours to 2 hours
- Allows for triage of patient for earlier therapy

Accurate and early diagnosis provides improved patient care.

For more information, contact a Premier™ CAMPY specialist at 1-888-763-6769, or visit us online at **www.meridianbioscience.com**

Meridian Bioscience,® Inc. Inspired Science. Trusted Solutions.®

Premier™ CAMPY
Optimized Detection for *Campylobacter* Testing

ELIMINATES VARIABILITY

The different methods utilized to culture *Campylobacter* lead to a potential reduction in the sensitivity of routine culturing.

- Hurd, et al noted that, "The [Foodborne Disease Active Surveillance Network survey] showed differences in methods such as routine culturing, length of incubation, and use of transport media that might explain the regional variation in incidence rates among FN [FoodNet] sites." [2]

NOT AFFECTED BY ORGANISM VIABILITY

Campylobacter is fragile and difficult to grow in culture. However, the antigen remains present for detection which maintains specimen viability for Premier™ CAMPY versus traditional culture methods.

- "Stool culture techniques lack sensitivity as *Campylobacter* are fastidious microaerophillic organism that, when exposed to oxygen or other stress, may enter a non-culturable state." [3]
- "Sub-optimal specimen handling and storage may allow competitive growth by other bacteria or result in low numbers of *Campylobacter* in the stool that could reduce the likelihood that *Campylobacter* will be identified during culture." [3]

ANTIBIOTICS IN CULTURE MEDIA CAN SUPPRESS GROWTH

The utilization of an EIA detection test reduces the potential negative growth impact of inhibitory antibiotics in culture media specific for *Campylobacter*.

- "Most [*Campylobacter*] selective media have one or more antimicrobial agents, mainly cefoperazone, as the primary inhibitor of enteric bacterial flora. The antimicrobial agents, such as cephalothin, colistin, and polymixin B, present in some selective medium formations are inhibitory to some strains of *C. jejuni* and *C. coli*." [4,5,6]

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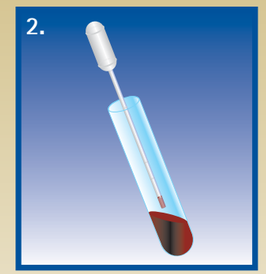
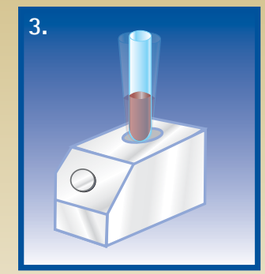
Premier™ CAMPY Test Procedure

SPECIMEN PROCESSING

Measure 200 µL of Sample Diluent/Negative Control into a test tube.



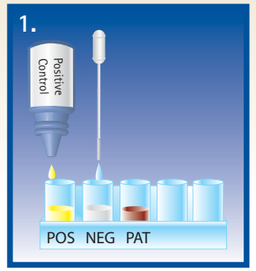
Mix sample thoroughly. Using a transfer pipet, add 50 µL of unpreserved stool (or 200 µL if preserved in Cary Blair-based media) to the tube. Gently expel and withdraw the suspension several times.



Vortex for 15 seconds.

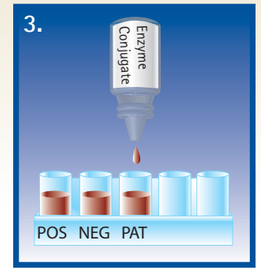
Detach microwells needed, place in holder. Using transfer pipette, add 100 µL (2nd mark from tip) of the diluted stool to the appropriate wells.

SAMPLE / ENZYME CONJUGATE INCUBATION

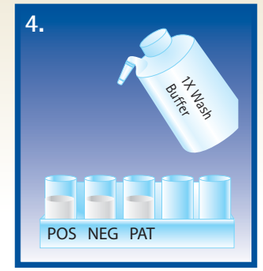


Add 2 drops of Positive Control and 100 µL Sample Diluent/ Negative Control to the appropriate wells. Seal the plate and incubate for 1 hour at 21-27 C.
- or - STAT Fax™ 2200 Alternative Incubation. Incubate and shake plate for 30 minutes at 21 - 27 C (Mix Setting 5)

Wash 5 times with 1X Wash Buffer. See Package Insert for proper wash procedure.

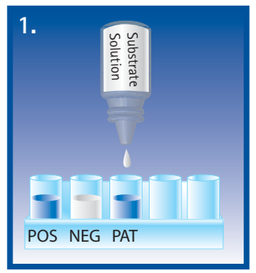


Add 2 drops of Enzyme Conjugate to all wells and shake firmly for 30 seconds. Seal the plate and incubate for 30 minutes at 21-27 C.
- or - STAT Fax™ 2200 Alternative Incubation. Incubate and shake plate for 15 minutes at 21 - 27 C (Mix Setting 5)

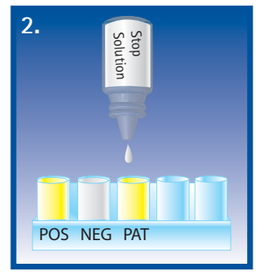


Repeat wash procedure:
Wash 5 times with 1X Wash Buffer. See Package Insert for proper wash procedure.

SUBSTRATE INCUBATION



Add 2 drops of Substrate to all wells. Shake firmly for 30 seconds. Incubate for 10 minutes at 21-27 C.



Add 2 drops of Stop Solution to all wells and shake firmly for 30 seconds.

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Interpretation of Results

Visual:
Negative = Colorless to very faint yellow
Positive = Definite yellow color
A very faint yellow color must be evaluated by a spectrophotometric reading.

Spectrophotometric Single Wavelength (450 nm)
Negative: < 0.150
Positive: ≥ 0.150
Negative Control: < 0.150
Positive Control: ≥ 0.600

Spectrophotometric Dual Wavelength (450/630 nm)
Negative: < 0.100
Positive: ≥ 0.100
Negative Control: < 0.100
Positive Control: ≥ 0.600

*NOTE: *This chart does not contain complete instructions for use. For further information, please refer to the package insert.*