ImmunoCard STAT! CAMPY

Immunochromatographic Rapid Test for the Detection of Specific *Campylobacter* Antigens in Stool Specimens

REF **751530**

IVD

Rx Only

INTENDED USE

Immuno*Card* STAT! CAMPY is an immunochromatographic rapid test for the qualitative detection of specific *Campylobacter* antigens in human stool. Immuno*Card* STAT! CAMPY detects *C. jejuni* and *C. coli* in human stool, where stool may be either unpreserved or preserved in Cary-Blair-based transport media. Test results are to be used in conjunction with information available from the patient clinical evaluation and other diagnostic procedures.

In the US, Immuno*Card* STAT! CAMPY is not intended for point-of-care use. The device is intended for moderately complex laboratories. In Canada, this device is not intended for point-of-care use.

SUMMARY AND EXPLANATION OF THE TEST

Campylobacter is a gram-negative, microaerophillic bacterium. Virtually all human illness is caused by one or two species.[1] These two species are *C. coli* and *C. jejuni*. The Centers for Disease Control (CDC) reports that 99% of illness is caused by *C. jejuni* while other studies have shown that globally, more than 90% of *Campylobacter* infections are caused by *C. jejuni*, followed by *C. coli* with 5-10%.[1, 2] The disease caused by the genus *Campylobacter* is referred to as Campylobacteriosis. Most people with Campylobacteriosis get diarrhea, cramping, abdominal pain, and fever within two to five days after exposure to the organism. The diarrhea may be bloody and can be accompanied by nausea and vomiting. The illness typically lasts one week. Some persons who are infected with *Campylobacter* don't have any symptoms at all. In persons with compromised immune systems, *Campylobacter* occasionally spreads to the bloodstream and causes a serious life-threatening infection.

Campylobacter is one of the most common bacterial causes of diarrheal illness in the United States. Virtually all cases occur as isolated, sporadic events, not as a part of large outbreaks. Active surveillance through FoodNet indicates about 15 cases are diagnosed each year for each 100,000 persons in the population.[1, 2] Many more cases go undiagnosed or unreported, and Campylobacteriosis is estimated to affect over one million persons every year, or 0.5% of the general population. Campylobacteriosis occurs much more frequently in the summer months than in the winter. The organism is isolated from infants and young adults more frequently than from other age groups and from males more frequently than females. Although *Campylobacter* doesn't commonly cause death, it has been estimated that approximately 100 persons with *Campylobacter* infections may die each year.[2]

BIOLOGICAL PRINCIPLES

Immuno*Card* STAT! CAMPY is a lateral flow-based immunoassay for the direct detection of *Campylobacter* antigen in stool. Immuno*Card* STAT! CAMPY assay uses monoclonal antibodies specific for an antigen common to *C. jejuni* and *C. coli*. Stool sample is added to Sample Diluent buffer using the transfer pipette provided with the kit. The diluted sample is added to the sample port of the device. *Campylobacter* antigen in the diluted sample binds to the monoclonal antibody-colloidal gold conjugate as the sample moves through the device. The *Campylobacter*-capture monoclonal antibody bound to the assay membrane at the Test position of the device central window binds antigen-*Campylobacter* antibody-colloidal gold complex and yields a visible pink-red line. When no antigen is present, no complex is formed and no pink-red line will appear at the Test position of the device central window. The Control Line serves as the assay control by showing adequate flow of diluted sample through the test device, improper assay execution, and/or deterioration of test reagents. The Control Line is a goat anti-mouse antibody bound at the Control position of the reading window. A visible pink-red line at the Control position of the device central window should be present each time a sample or control is tested. If no pink-red Control Line is seen, adequate sample flow has not occurred and the test is considered invalid.

REAGENTS/MATERIALS PROVIDED

The maximum number of tests obtained in this test kit is listed on the outer box.

1. **Immuno*Card* STAT! CAMPY Test Device:** Plastic cassette containing a test strip with an immobilized monoclonal antibody specific to *C. jejuni* and *C. coli*. The Test Device is provided in a sealed foil pouch with desiccant
2. **Immuno*Card* STAT! CAMPY Sample Diluent/Negative Control:** A buffered protein solution containing 0.094% sodium azide and 0.03% gentamicin as preservatives
3. **Immuno*Card* STAT! CAMPY Positive Control:** Inactivated *Campylobacter jejuni* in a buffered protein solution containing 0.094% sodium azide and 0.03% gentamicin as preservatives
4. Transfer pipettes

MATERIALS NOT PROVIDED

1. Disposable latex gloves
2. Test tubes (eg, 10 x 75 mm or 12 x 75 mm)
3. Wooden applicator sticks

EQUIPMENT NOT PROVIDED

1. Vortex mixer
2. Interval timer

PRECAUTIONS

1. All reagents are for in vitro diagnostic use only.
2. Directions should be read and followed carefully.
3. Test devices are packaged in foil pouches that exclude moisture during storage. Inspect each foil pouch before opening. Do not use test devices from pouches that have holes in the foil or where the pouch has not been completely sealed. False negative reactions may result if test components and reagents are improperly stored.

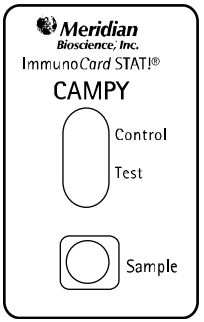
4. Do not use reagents that are discolored or precipitated. Discoloration or precipitation may be a sign of microbial contamination.
5. Stool must be mixed thoroughly, regardless of consistency, to ensure a representative sample prior to pipetting.
6. Do not use kit components beyond labeled expiration date.
7. Do not use vials that lack a label, a lot number, or an expiration date.
8. Allow reagents and samples to warm to 20–25 C before use.
9. All reagents should be mixed gently and thoroughly before use.
10. The transfer pipettes provided with this kit must be used for specimen preparation and transfer. Use one per specimen.
11. Any deviation below or above set incubation times may affect sensitivity and specificity and should be avoided.

WARNINGS
1. The Immuno*Card* STAT! CAMPY Positive Control Reagent contains inactivated *C. jejuni*. Handle as a potentially biohazardous material.
2. Patient specimens may contain infectious agents and should be handled and disposed of as potential biohazards.
3. Dispose of all used test materials in an appropriate container. Treat waste as a potential biohazard.

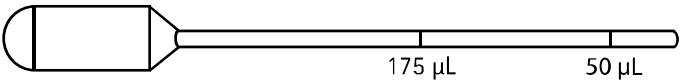
HAZARD and PRECAUTIONARY STATEMENTS
There are no known hazards associated with this product.

SHELF LIFE AND STORAGE
Expiration date is provided on the kit box. Store the kit at 2-8 C and return the kit promptly to the intended storage condition after use.

PROCEDURAL NOTES
The Immuno*Card* STAT! CAMPY device is shown below:



The Immuno*Card* STAT! CAMPY transfer pipette is diagrammed below:



Pipettes supplied with the kit should be marked at the intervals shown in the diagram. Do not use transfer pipettes with markings that differ from the diagram.

SPECIMEN COLLECTION AND PREPARATION
Human stool specimens, unpreserved: Specimens should be received in an air-tight transport container and stored at 2-8 C prior to testing. Specimens may be held at 2-8 C for up to 96 hours. Specimens that will not be tested within 96 hours should be frozen immediately upon receipt and stored at ≤ -20 C. Specimens may be frozen and thawed twice.

Human stool specimens, preserved in Cary-Blair-based media: Specimens should be stored at 2-8 C prior to testing. Specimens may be held at 2-8 C for up to 96 hours. Specimens that will not be tested within 96 hours should be frozen immediately upon receipt and stored at ≤ -20 C. Specimens may be frozen and thawed twice.

REAGENT PREPARATION
1. Bring test reagents, including the appropriate number of Immuno*Card* STAT! CAMPY Test Devices to 20-25 C before use.
2. One Immuno*Card* STAT! CAMPY Test Device is required for each patient specimen to be tested.
3. One Immuno*Card* STAT! CAMPY Test Device is required for each external Positive Control to be tested.
4. One Immuno*Card* STAT! CAMPY Test Device is required for each external Negative Control to be tested.

SPECIMEN PREPARATION
Bring specimens to 20-25 C. Mix stool as thoroughly as possible prior to pipetting.
1. **Human stool specimens, unpreserved:**
   a. **Mix Sample Diluent/Negative Control thoroughly prior to use.** Using the dropper assembly provided with the Sample Diluent/Negative Control, add 1400 µL (1.4 mL) of Sample Diluent to a test tube. The 1400 µL is equivalent to 700 µL (second mark from the tip of the dropper assembly barrel) x 2 (times two). Alternatively, a calibrated pipette may be used to add the 1400 µL.

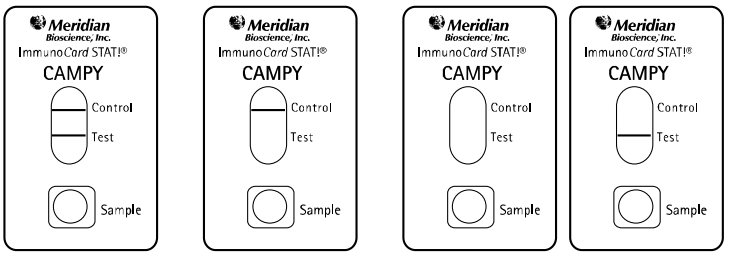
b. **Formed/Solid stools:**
   i. Add a small portion (3-4 mm diameter) of thoroughly mixed stool to the Sample Diluent test tube.
   ii. Emulsify the stool using the wooden applicator stick.
   iii. Vortex for a minimum of 15 seconds.
c. **Liquid/Semi-Solid stools:**
   i. Using a transfer pipette provided with the kit, add 50 µL of thoroughly mixed stool (first mark from pipette tip) to the Sample Diluent test tube.
   ii. Vortex for a minimum of 15 seconds.
   iii. Save the transfer pipette in the sample for later use.

2. **Human stool specimens, preserved in Cary-Blair-based media:**
   a. **Mix Sample Diluent/Negative Control thoroughly prior to use.** Using the dropper assembly provided with the Sample Diluent/Negative Control, add 350 µL of Sample Diluent to test tube. Alternatively, a calibrated pipette may be used to add the 350 µL.
   b. Using a transfer pipette provided with the kit, add 50 µL of thoroughly mixed stool (first mark from pipette tip).
   c. Vortex for a minimum of 15 seconds.
   d. Save the transfer pipette in the sample for later use.
3. **Stool diluted in Sample Diluent:** If needed, stool diluted in Sample Diluent can be held at 2-8 C for up to 24 hours before testing provided the tube is sealed.

TEST PROCEDURE
1. Remove the Immuno*Card* STAT! CAMPY test device from its foil pouch and label with the patient identification.
2. Using the transfer pipette provided in the kit, add 175 µL of the diluted specimen (second mark from tip of pipette) to the sample port of the device.
3. Incubate the test at 20-25 C for 20 minutes.
4. Read the results within 1 minute of the end of incubation.

External Control Tests
1. Remove the Immuno*Card* STAT! CAMPY test device from its foil pouch. Label the device with the control to be tested.
2. Add exactly 6 drops of the Immuno*Card* STAT! CAMPY Positive Control to the sample port of the device marked for the Positive Control.
3. With the transfer pipette provided in the kit add 175 µL of the Immuno*Card* STAT! CAMPY Sample Diluent/Negative Control (second mark from tip of pipette) to the sample port of a device marked for the Negative Control.
4. Incubate the test at 20-25 C for 20 minutes.
5. Read the results within 1 minute of the end of incubation.

INTERPRETATION OF RESULTS



Positive test for *Campylobacter*:
PINK-RED bands at the Control and Test Line positions. The appearance of a Test Line, even if very weak, indicates the presence of *Campylobacter* antigen. The intensity of the Test Line can be less than that of the Control Line.

Negative test:
PINK-RED band at the Control Line position. No other bands are present.

Invalid Test Results:
1. No band at the designated position for the Control Line. The test is invalid as the absence of a control band indicates the test procedure was performed improperly or that deterioration of reagents has occurred.
2. PINK-RED band appearing at the Test Line position of the device after the defined incubation limit. Falsely positive results may occur if tests are incubated too long.
3. Band of any color other than PINK-RED. Bands with colors other than PINK-RED may indicate reagent deterioration.

If any result is difficult to interpret, the test should be repeated with the same sample to eliminate the potential for error. Obtain a new sample and retest when the original sample repeatedly produces unreadable results.

QUALITY CONTROL
This test should be performed per applicable local, state or federal regulations or accrediting agencies.
At the time of each use, kit components should be visually examined for obvious signs of microbial contamination, freezing or leakage. Do not use contaminated or suspect reagents.

Internal controls:
Internal controls are contained within the test strip and therefore are evaluated with each test.

1. A PINK-RED band appearing at the Control Line serves as an internal positive control and indicates the test has been performed correctly, that sample flowed properly and that test reagents were active at the time of use.
2. A colorless background around the Control or Test Lines serves as a negative procedural control. Control or Test Lines that are obscured by heavy background color may invalidate the test and may be an indication of reagent deterioration, use of an inappropriate sample or improper test performance.

External controls:
External control reagents should be tested according to the requirements of the laboratory or those of applicable local, state or national accrediting agencies.

1. The reactivity of Immuno*Card* STAT! CAMPY should be verified with each new kit lot or each new shipment using Positive and Negative Control reagents. The external controls are used to monitor reagent reactivity.
2. Failure of the controls to produce the expected results can mean that one of the reagents or components is no longer reactive at the time of use, the test was not performed correctly or that reagents were not added.

The results expected with the External Controls are described in the section on Interpretation of Results. The kit should not be used if control tests do not produce the correct results. Repeat the control tests as the first step in determining the root cause of the failure. If control failures are repeated please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor.

EXPECTED VALUES

The performance of Immuno*Card* STAT! CAMPY was evaluated during 2009 using retrospective positive and negative samples collected during 2008 and prospective positive and negative samples which were collected in 2009. The samples were collected from different geographic regions in the United States. The incidence of positive samples was approximately 1.5% during the 2008 and approximately 1.2% during the 2009 sample collection seasons. The incidence for an individual laboratory may differ from this number since it is dependent on factors such as locale, the time of year and whether an outbreak has occurred.

LIMITATIONS OF THE PROCEDURE

1. The test is qualitative and no quantitative interpretation should be made with respect to the intensity of the positive line when reporting the result.
2. Test results are to be used in conjunction with information available from the patient clinical evaluation and other diagnostic procedures.

SPECIFIC PERFORMANCE CHARACTERISTICS

Immuno*Card* STAT! CAMPY was evaluated by three independent laboratories located in different geographical regions of the United States. A total of 421 qualified samples were tested. Of these samples 189 (45%) were retrospective frozen samples. 51% of the samples (216/421) were collected without a preservative. The remaining samples (205/421) were collected in a Cary-Blair medium. Samples were collected from males (44%) and females (52%). In the case of 4% of the patients, gender was not recorded. The age groups of the patients from whom samples were collected ranged from one month of age to 95 years. No differences in test performance were observed based on patient age or gender. The following tables show assay performance by clinical site, patient age and sample type.

Table 1 – Performance characteristics by site

	Positive Samples			Negative Samples		
Site	**ICS/ Culture**	**Sensitivity %**	**95% CI**	**ICS/ Culture**	**Specificity %**	**95% CI**
Site 1	17/17	100%	81.6-100%	92/95	96.8%	91.1-98.9%
Site 2	18/19	94.7%	75.4-99.1%	130/135	96.3%	91.6-98.4%
Site 3	17/17	100%	81.6-100%	131/138	94.9%	89.9-97.5%
Combined Sites	52/53	98.1%	90.1-99.7%	353/368	95.9%	93.4-97.5%

Table 2 – Performance characteristics by patient age

	Positive Samples			Negative Samples		
Patient Age	**ICS/ Culture**	**Sensitivity %**	**95% CI**	**ICS/ Culture**	**Specificity %**	**95% CI**
Birth to 1 month	0/0	N/A	N/A	1/1	100%	20.7-100%
> 1 month to 2 years	2/2	100%	34.2-100%	66/68	97.1%	89.9-99.2%
> 2 years to 12 years	5/5	100%	56.6-100%	88/93	94.6%	88.0-97.7%
> 12 years to 21 years	1/1	100%	20.7-100%	40/42	95.2%	84.2-98.7%
> 21 years	27/28	96.4%	82.3-99.4%	158/164	96.3%	92.2-98.3%
Not Defined	17/17	100%	81.6-100%	0/0	N/A	N/A

Table 3 – Performance characteristics by sample type (preserved vs unpreserved)

	Positive Samples			Negative Samples		
Specimen Type Preserved	**ICS/ Culture**	**Sensitivity %**	**95% CI**	**ICS/ Culture**	**Specificity %**	**95% CI**
Site 1	12/12	100%	75.8-100%	92/95	96.8%	91.1-98.9%
Site 2	13/14	92.9%	68.5-98.7%	61/66	92.4%	83.5-96.7%
Site 3	17/17	100%	81.6-100%	1/1	100%	20.7-100%
Specimen Type Unpreserved	**ICS/ Culture**	**Sensitivity %**	**95% CI**	**ICS/ Culture**	**Specificity %**	**95% CI**
Site 1	5/5	100%	56.6-100%	0/0	N/A	N/A
Site 2	5/5	100%	56.6-100%	69/69	100%	94.7-100%
Site 3	0/0	N/A	N/A	130/137	94.9%	89.8-97.5%

Table 4 – Performance characteristics of fresh and frozen samples

	Positive Samples			Negative Samples		
Specimen Type Fresh	**ICS/ Culture**	**Sensitivity %**	**95% CI**	**ICS/ Culture**	**Specificity %**	**95% CI**
Site 1	0/0	N/A	N/A	91/94	96.8%	91.0-98.9%
Site 2	2/3	66.7%	20.8-93.9%	130/135	96.3%	91.6-98.4%
Site 3	0/0	N/A	N/A	0/0	N/A	N/A
Total Fresh	2/3	66.7%	20.8-93.9%	221/229	96.5%	93.3-98.2%
Specimen Type Frozen	**ICS/ Culture**	**Sensitivity %**	**95% CI**	**ICS/ Culture**	**Specificity %**	**95% CI**
Site 1	17/17	100%	81.6-100%	1/1	100%	20.7-100%
Site 2	16/16	100%	80.6-100%	0/0	N/A	N/A
Site 3	17/17	100%	81.6-100%	131/138	94.9%	89.9-97.5%
Total Frozen	50/50	100%	92.9-100%	132/139	95.0%	90.0-97.5%

ANALYTICAL SENSITIVITY

The analytical sensitivity of this assay for *C. jejuni* and *C. coli* was based on 45 tests for each measurand and with a stated probability (e.g. 95%) of obtaining positive responses at the following levels of the measurands: *C. jejuni* 1.2 x 10^7 CFU/mL; *C. coli* 3.0 x 10^7 CFU/mL.

REPRODUCIBILITY

Coded panels of 10 samples were supplied to three independent laboratories for precision studies. Samples were randomly sorted within each panel to mask sample identities. The panels included contrived samples manufactured at the assay limit of detection (n=3) and just below the limit of detection (eg, high negative samples, n=3). The panels also included moderately positive (n=2) and negative (n=2) samples. Testing was performed by different operators at each site on the same day (intra-assay variability) for five days (inter-assay variability). The expected results were obtained with all but one low positive sample.

ASSAY REACTIVITY

The following *Campylobacter* stock cultures from different sources were tested and produced positive reactions at 1.1 x 10^7 or 1.1 x 10^8 CFU/mL with Immuno*Card* STAT! CAMPY: *C. coli* strains 10956, 17755, 36994 and 53138 and *C. jejuni* strains 6951, 10940, 12081, 29411 and 38106.

CROSSREACTIVITY

Crossreactivity studies were performed with positive and negative stool specimens inoculated with bacterial or fungal organisms to a final concentration of 1.1 x 10^8 CFU/mL or virus ranging from 1.3 x 10^4 to 3.1 x 10^6 $TCID_{50}$/mL. None of the following organisms in stool reacted with Immuno*Card* STAT! CAMPY:

Aeromonas hydrophila, Bacteroides fragilis, Campylobacter fetus, Candida albicans, Citrobacter freundii, Clostridium difficile, Clostridium perfringens, Enterobacter cloacae, Enterococcus faecalis, Escherichia coli, Escherichia coli O157:H7, *Escherichia fergusonii, Escherichia hermannii, Helicobacter pylori, Klebsiella pneumoniae, Lactococcus lactis, Listeria monocytogenes, Peptostreptococcus anaerobius, Plesiomonas shigelloides, Proteus vulgaris, Pseudomonas aeruginosa, Pseudomonas fluorescens,* Salmonella Groups B-E, *Serratia marcescens, Shigella boydii, Shigella flexneri, Shigella sonnei, Staphylococcus aureus, Staphylococcus epidermidis, Vibrio parahaemolyticus, Yersinia enterocolitica,* Adenovirus Types 40 and 41, Coxsackievirus, Echovirus, Rotavirus.

TESTS FOR INTERFERING SUBSTANCES

The following substances, at the specified saturated solvent/diluent concentrations, do not interfere with test results in the final concentrations listed: Barium sulfate (5 mg/mL), fecal fat (equivalent to 2.65 mg stearic plus 1.3 mg palmitic acids per mL), hemoglobin (as methemoglobin) (3.2 mg/mL), Imodium AD® (0.00667 mg/mL), Kaopectate® (0.87 mg/mL), mucin (3.33 mg/mL), Mylanta® (4.2 mg/mL), Pepto-Bismol® (0.87 mg/mL), Prilosec® (0.5 mg/mL), Tagamet® (0.5 mg/mL), TUMS® (0.5 mg/mL), urine (5% v/v), whole blood (5% v/v).