TITLE: ImmunoCard STAT Campy

PRINCIPLE / PURPOSE:

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.

SCOPE:

This procedure applies to all tests ordered for *Campylobacter* antigen testing in stool.

SPECIMEN:

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.

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).

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.

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.

EQUIPMENT AND MATERIALS:

REAGENTS/MATERIALS PROVIDED

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.*

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

Storage Requirements:

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.

CALIBRATION: None

QUALITY CONTROL:

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: - used to monitor reagent reactivity and test performance

External controls: External control reagents should be run on opening a kit from each new lot number and/or shipment. If the kit is open for >30 days, external QC must be performed.

The results expected with the controls are described in the INTERPRETATION OF

RESULTS.

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 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.

1. Bring all Test Devices and reagents to (20-25 C) before testing.

2. 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.

3. Remove the Immuno*Card* STAT! CAMPY test device from its foil pouch. Label the device with the control to be tested.

4. Add exactly 6 drops of the Immuno*Card* STAT! CAMPY Positive Control to the

sample port of the device marked for the Positive Control.

5. 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.

6. Incubate the test at 20-25 C for 20 minutes.

7. Read the results within 1 minute of the end of incubation.



PROCEDURE:

1. Bring all Test Devices, reagents and samples to room temperature (20-25 C) before

testing, approximately one hour.

2. Remove the Immuno*Card* STAT! CAMPY test device from its foil pouch and label

with the patient identification.

3. 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.

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.*

REPORTING RESULTS:

Reference Ranges:

Negative

Procedures for Abnormal Results:

Positive Campy results must be called to the physician or RN. If the patient is in-house, notify infection control, and report to the Alamance County Health Department.

Reporting Format:

NEG - Negative - Campylobacter antigen NOT dectected.

POS - Positive - Campylobacter antigen DETECTED.

INV - Invalid

PROCEDURE NOTES:

1. Directions should be read and followed carefully.

2. 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.

3. Do not use reagents that are discolored or precipitated. Discoloration or

precipitation may be a sign of microbial contamination.

4. Stool must be mixed thoroughly, regardless of consistency, to ensure a

representative sample prior to pipetting.

5. Do not use kit components beyond labeled expiration date.

6. Do not use vials that lack a label, a lot number, or an expiration date.

7. Allow reagents and samples to warm to 20–25 C before use.

8. All reagents should be mixed gently and thoroughly before use.

9. The transfer pipettes provided with this kit must be used for specimen preparation

and transfer. Use one per specimen.

10. Any deviation below or above set incubation times may affect sensitivity and

specificity and should be avoided.

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.

REFERENCES:

1. Coker, AO; Isokpehi, RD; Thomas, BN, et. al. Human Campylobacteriosis in developing countries. EID 2002; 8:237-43.
2. Friedman, CR; Hoekstra, RM; Samuel, M. et. al. Risk factors for sporadic *Campylobacter* infection in the United States: A case-controlled study in FoodNet sites. CID 2004; 38:S285-96.

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SOP HISTORY PAGE

SOP Number: MIC-706

SOP Title: ImmunoCard STAT! Campy

Written By: Jacee Farmer

Manual in which Hard Copy of this SOP is located:

Distribution:

Supersedes Procedure:

SOP CHANGE CONTROL

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|  | Approvals | |  | Action | In |
| Mgmt. | Date | Director | Date |  | Effect |
| √ | 11/26/14 |  |  | Added QC requirement for kits open for >30 days. | 11/26/14 |
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