

Campylobacter Species Ag Rapid Test

Cat. No.:DTS606

Pkg.Size:20 T

Intended use

A rapid test for the qualitative detection of Campylobacter spp. in faeces specimens, which might be useful for the diagnosis of campylobacteriosis.

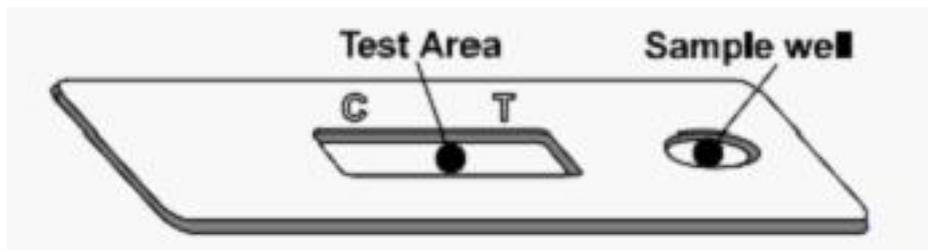
General Description

Campylobacteriosis is an infectious disease caused by bacteria of the genus Campylobacter. Most people who become ill with campylobacteriosis get diarrhoea, cramping, abdominal pain, and fever within two to five days after exposure to the organism. The diarrhoea may be bloody and can be accompanied by nausea and vomiting. The illness typically lasts one week. Some infected persons do not have any symptoms. In persons with compromised immune systems, Campylobacter occasionally spreads to the bloodstream and causes a serious life-threatening infection.

Principle Of The Test

The CAMPYLOBACTER SPECIES Ag CARD is a qualitative immunochromatographic assay for the determination of Campylobacter spp. in faeces samples. The membrane is pre-coated with monoclonal antibodies, on the test band region, against Campylobacter antigens.

During testing, the sample is allowed to react with the coloured conjugate (anti-Campylobacter monoclonal antibodies-red polystyrene microspheres) which was pre-dried on the test strip. The mixture then moves upward on the membrane by capillary action. As the sample flows through the test membrane, the coloured particles migrate. In the case of a positive result the specific antibodies present on the membrane will capture the coloured conjugate. The mixture continues to move across the membrane to the immobilized antibody placed in the control band region, a green coloured band always appears. The presence of this green band serves as 1) verification that sufficient volume is added, 2) that proper flow is obtained and 3) as an internal control for the reagents.



Reagents And Materials Provided

Each kit contains:

1. CAMPYLOBACTER SPECIES Ag CARD (20 card)
2. Extraction buffer (1.0 mLx20 Tubes)
3. Instruction for use

Materials Required But Not Supplied

Testing tubes, specimen collection container, Disposable gloves and container, Plastic pipette and Timer.

Storage

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30°C/36-86°F). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze.

Specimen Collection And Preparation

Collect sufficient quantity of faeces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-4°C/36-40°F) for 1-2 days prior to testing. For longer storage the specimen must be kept frozen at -20°C/4°F. In this case, the sample will be totally thawed, and brought to room temperature before testing.

Assay Procedure

Process the collected stool samples

Use a separate swab or stick, dropper and testing tube or vial for each sample. Unscrew the top of the extraction buffer tube. Collect the stool sample with the tip of the collection device by dipping in three different places of the same stool specimen. Verify to transfer a small portion (150 mg) of stool. Put the collection device back into the plastic test tube. Shake the extraction tube in order to get an homogeneous solution. For liquid or semi-solid stools using a separate pipette, draw stool of the sample itself. Dispense 150 µl of each stool into a extraction tube. Mix carefully, then vortex 15 seconds.

Test Procedure

Allow the tests, stool samples and buffer to reach to room temperature (15-30°C/59-86°F) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the CAMPYLOBACTER SPECIES Ag CARD from its sealed pouch and use it as soon as possible.
2. Use a separate device for each sample. Extract some liquid from the topside with a dropper.
3. Dispense 4 drops or 100 µL into the specimen well. Start the timer.
4. Read the result at 10 minutes after dispensing the sample.

Quality Control

Internal procedural controls are included in the test. A GREEN line appearing in the control region (C) is an internal control. It confirms sufficient specimen volume and correct procedural technique.

Interpretation of Results

NEGATIVE: Only one GREEN control band appears across the central window in the site marked with the letter C (control line).
POSITIVE: In addition to the GREEN control band across the central window in the site marked with the letter C (control line), a RED band (test line) also appears in the site marked with the letter T (result region).
INVALID: A total absence of the control coloured band. Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are likely the reasons for control line failure. Review the procedure and repeat the tests using a new test.



Expected Values

Campylobacter spp. are bacteria that are a major cause of diarrhoeal illness in humans and are generally regarded as the most common bacterial cause of gastroenteritis worldwide. In developed and developing countries, they cause more cases of diarrhoea than, for example, foodborne Salmonella bacteria. In developing countries, Campylobacter infections in children under the age of two years are especially frequent, sometimes resulting in death. In almost all developed countries, the incidence of human Campylobacter infections has been steadily increasing for several years. The reasons for this are unknown.

Sensitivity

The test showed >99% of sensitivity.

Specificity

It was performed an evaluation of CAMPYLOBACTER SPECIES Ag CARD. It was studied 35 stool samples and the results were confirmed by Immun°Card STAT! CAMPY. CAMPYLOBACTER SPECIES Ag CARD showed >99% of sensitivity. The use of a mouse monoclonal antibody in CAMPYLOBACTER SPECIES Ag CARD assures high degree of specificity for the detection of these bacteria. The antibodies used to elaborate this test recognise Campylobacterepitopes found in stool of patients, as well as in preparations from the bacteria cultures in vitro.

This preliminary values has to be taken with precaution until more evaluation data will be available.

Cross-Reactivity

It was performed an evaluation to determine the cross reactivity of CAMPYLOBACTER SPECIES Ag CARD. There is not cross reactivity with common intestinal pathogens, other organisms and substances occasionally present in faeces: H. pylori, E. coli, Listeria monocytogenes, Salmonella.

Precautions

All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices.

The kit is for in vitro diagnosis only.

Avoid touching the nitrocellulose with your fingers.

Wear gloves when handling the samples.

Disposable gloves, swabs, test tubes, and sensitized strips in accordance with GLP.

Never use reagents from another lot.

The tube containing the sensitized strips must be recapped as soon as the necessary number of strips for the operation has been removed, since the strips are sensitive to humidity. Make sure that the desiccant is present.

Discard the dilution buffer if it is contaminated with bacteria or mould.

The reagents' quality cannot be guaranteed beyond their shelf-life date or if the reagents are stored under inappropriate conditions.

Limitations

1. The test must be carried out within 2 hours of opening the sealed bag.
2. An excess of stool sample could result in wrong results (brown bands appear or absence of the control coloured band).
3. Stool from somestool samples can decrease the intensity of the control line.
4. Freezing and thawing cycles for the sample are not recommended, it could cause wrong results.
5. This test provides a presumptive diagnosis of Campylobacteriosis. A confirmed infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated must be based in the correlation of the results with further clinical observations.

REFERENCES

1. Kawatsu, K. et al. "Development and Evaluation of Immunochromatographic Assay for Simple and Rapid Detection of Campylobacter jejuni and Campylobacter coli in Human Stool Specimens". Journal of Clinical Microbiology Apr. 2008 Vol 46, No. 4, p. 1226-1231.
2. Fernández, H. and Farace, M.I. "Manual de Procedimientos Campylobacter". INEI. 2003.