CAMPYLOBACTER SPECIES Ag CARD

For in *Vitro* diagnostic use only

Immunochromatographic test for the detection of *Campylobacter spp* in faeces

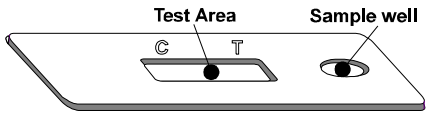
I. INTRODUCTION AND INTENDED USE

A rapid test for the qualitative detection of *Campylobacter spp* (identifies pathogenic species *Campylobacter jeiuni and Campylobacter coli)* in faeces specimens, which might be useful for the diagnosis of campylobacteriosis.
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.

II. 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.

III. REAGENTS AND MATERIALS



Each kit contains:
1. CAMPYLOBACTER SPECIES Ag CARD (25 card)
2. Extraction buffer (1.0 mL x 25 Tubes)
3. Instruction for use (1)

Required materials (not supplied)
Testing tubes. specimen collection container, Disposable gloves and container, Plastic pipette and Timer.

IV. SPECIAL 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 cards in accordance with GLP.
- Never use reagents from another lot.
- 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.

V. STORAGE AND STABILITY

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC/36-86ºF). 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.

VI. SPECIMENS COLLECTION

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). Samples collected in Cary Blair transport media can also be used (Transystem Cary Blair cod. 21132C). The samples can be stored in the refrigerator (2-4ºC/36-40ºF) for 1-2 days prior to testing. For longer storage the specimen must be kept frozen at –20ºC/4ºF. In this case, the sample will be totally thawed, and brought to room temperature before testing.

VII. 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 (15-30ºC/59-86ºF) 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 100uL into the specimen well. Start the timer.
4. Read the result at **10 minutes** after dispensing the sample.

VIII. INTERPRETING THE 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.

POSITIVE NEGATIVE INVALID

IX. INTERNAL 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.

X. PERFORMANCE

A. 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.

B. SENSITIVITY AND SPECIFICITY

It was performed an evaluation of CAMPYLOBACTER SPECIES Ag CARD. It was studied 35 stool samples and the results were confirmed by ImmunoCard STAT! CAMPY. CAMPYLOBACTER SPECIES Ag CARD showed >99% of sensitivity and >99% of specificity.
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 *Campylobacter* epitopes 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.

C. CROSS-REACTIVITY AND INTERFERENCES

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.*

XI. LIMITS OF THE KIT

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 some stool 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.

XII. REFERENCES

- 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.
- Fernández, H. and Farace, M.I. “Manual de Procedimientos *Campylobacter”*. *INEI*. 2003.

IVD	In Vitro Diagnostic Medical Device	LOT	Batch code (EXXX)
	Consult Instructions for Use	REF	Catalogue number
	Keep dry	NON STERILE	Non-sterile
	Temperature limitation		Manufacturer
	Use By (year/month)		Do not reuse
	Fragile, handle with care		Keep away from heat

CONTENT (25 tests)

CAMPYLOBACTER SPECIES Ag CARD
Extraction Buffer
Instruction for use

COD. VC1007

25 Device (Card)
25 vials
1item

EDMA Code 14 70 01 90 00 CE IVD