CE

IVD

Rapid-VIDITEST

Campylobacter jejuni Card

One step *Campylobacter jejuni* Card test.

Instruction manual

INTENDED USE:

The Rapid-VIDITEST *Campylobacter* Card is a rapid chromatographic immunoassay for the qualitative detection of *Campylobacter jejuni (C. jejuni)* in faeces specimens, which might be useful for the diagnosis of campylobacteriosis.

INTRODUCTION:

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:

The Rapid-VIDITEST *Campylobacter* Card is a qualitative immunochromatographic assay for the determination of *Campylobacter* in faeces samples. The membrane is pre-coated with monoclonal antibodies, on the test band region, against *C. jejuni* antigens.
During testing, the sample is allowed to react with the coloured conjugate (anti-*C. jejuni* 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.

MATERALS PROVIDED:

- Rapid-VIDITEST *Campylobacter* Card tests
- Instructions for use
- Specimen collection vial with buffer

MATERIALS REQUIRED BUT NO PROVIDED:

- Specimen collection container
- Disposable gloves
- Timer

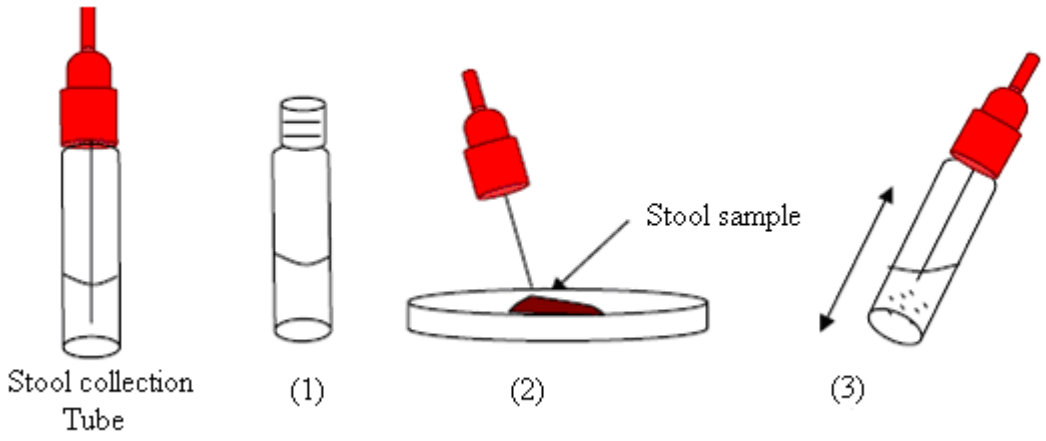
SPECIMEN COLLECTION AND PREPARATION:

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 (2-4ºC/36-40ºF) for 1-2 days prior to testing. For longer storage the specimen must be kept frozen at –20ºC/4ºF. More than three freezing and thawing cycles are not recommended.
The sample will be totally thawed, brought to room temperature and mix as thoroughly as possible before testing.

PROCEDURES:

Specimen preparation:

1. Take out the cap of the stool collection tube (1).
2. Use the stick to pick up enough quantity of sample (approx. 150mg), introduce the stick in 4 different parts of the sample. Add the sample into the stool collection tube. If the stool sample was liquid take 150 µl using a pipette (2).
3. Close the tube with the diluent and stool sample. Shake the tube in order to assure good sample dispersion (3).

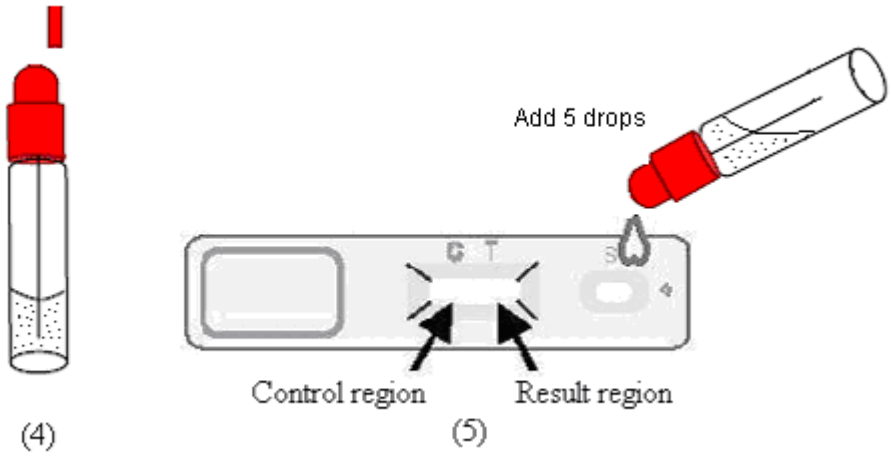


Test Procedure:

Allow the tests, stool samples and buffer to reach to room temperature (15-30ºC/59-86ºF) prior to testing. Do not open the pack with strips until ready to perform the assay.

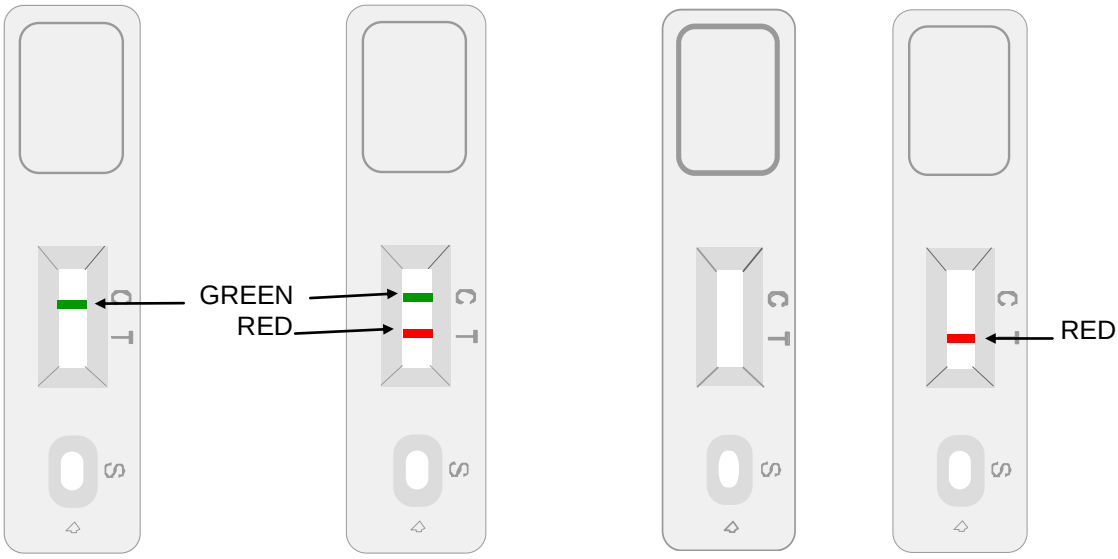
Only bring to room temperature the number of tests required to assay before opening it. Do not remove strip test from pack until test sample has reached room temperature. Bring patient sample to room temperature (15-30ºC/59-86°F).

1. Proceed to shake the stool collection tube in order to assure good sample dispersion. Cut the end of the top (4).
2. Remove the Rapid-VIDITEST *Campylobacter* Card device from its sealed bag just before using.
3. Use a separate stool collection tube and device for each sample or control. Dispense exactly 5 drops or 150 µL into the circular window marked with an arrow (5).
4. Read the result at **10 minutes** (the coloured bands appear).



(4) (5)

INTERPRETATION OF RESULTS:



NEGATIVE: Only one GREEN band appears across the control line region marked in the illustration with the letter C (control line).

POSITIVE: In addition to the GREEN control band, a RED band (test line) also appears in the site marked with the letter T (result line).

INVALID: A total absence of the control coloured band (GREEN) regardless the appearance or not of the result line (RED). Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact your local distributor.

NOTES ON THE INTERPRETATION OF RESULTS:

The intensity of the red coloured band in the result line region (T) will vary depending on the concentration of antigens in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

QUALITY CONTROL:

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

LIMITATIONS:

1. The test must be carried out within 2 hours of opening the sealed bag.
2. An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
3. Some stool samples can decrease the intensity of the control line.
4. Freeze and thaw several times stool samples with *Campylocbater* 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.

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.

PERFORMANCE CHARACTERISTICS:

Sensitivity and specificity

It was performed an evaluation of Rapid-VIDITEST *Campylobacter* Card. It was studied 35 stool samples and the results were confirmed by ImmunoCard STAT! CAMPY.
Rapid-VIDITEST *Campylobacter* Card showed >99% of sensitivity and >99% of specificity.
The use of a mouse monoclonal antibody in Rapid-VIDITEST *Campylobacter* Card assures high degree of specificity for the detection of these bacteria. The antibodies used to elaborate this test recognise 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.

Cross-reactivity

It was performed an evaluation to determine the cross reactivity of Rapid-VIDITEST *Campylobacter* Card. There is not cross reactivity with common intestinal pathogens, other organisms and substances occasionally present in feces: *H. pylori, E. coli, Listeria monocytogenes, Salmonella.*

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.

PRECAUTIONS:

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not use the test if pouch is damaged.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test should be discarded in a proper biohazard container after testing.
- The test must be carried out within 2 hours of opening the sealed bag.

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.

SYMBOLS FOR IVD COMPONENTS AND REAGENTS:

IVD	*In vitro* diagnostic device	LOT	Batch code
	Use by		Manufacturer

Distribuito in ITALIA da
Li StarFish S.r.l.
Via Cavour, 35
20063 Cernusco S/N (MI)
telefono 02-92150794
fax 02-92157285
info@listarfish.it
www.listarfish.it