

VITASSAY

Campylobacter

Rapid test for the qualitative detection of Campylobacter in human stool samples.

IUE-7355028 Ed01 June 2018



For professional *in vitro* diagnostic use only.

INTENDED USE

Vitassay Campylobacter is a rapid one step immunochromatographic assay for the qualitative detection of campylobacter in human stool samples.

Simple, non-invasive and highly sensitive screening assay to make a presumptive diagnosis of campylobacter infection (campylobacteriosis).

INTRODUCTION

Campylobacter is a fastidious Gram-negative bacterium considered to be a common cause of acute, self-limiting gastroenteritis in the developed world.

Campylobacter jejuni and Campylobacter coli are the predominant causative agents of campylobacteriosis. The symptoms of gastroenteritis are sometimes severe in infants and at the elderly and bacterial culture is required for the diagnosis.

In developed countries, consumption of contaminated chicken, red meat, water, milk, and contact with pets and farm animals have been implicated as potential sources of Campylobacter infection.

Disease is associated with fever, bloody diarrhea, headache and severe abdominal pain. Campylobacteriosis is a self-limiting disease and antimicrobial therapy is not generally required. However, timely treatment can reduce the duration and severity of the infection. Most people who develop campylobacteriosis recover completely within 2-5 days, although sometimes recovery can take up to 10 days.

PRINCIPLE

Vitassay Campylobacter is a qualitative immunochromatographic assay for the detection of campylobacter in human stool samples.

The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against campylobacter.

During the process, the sample reacts with the antibodies against campylobacter, forming conjugates. The mixture moves upward on the membrane by capillary action. If the sample is positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible. Although the sample is positive or negative, the mixture continues to move across the membranes and the green control line always appears.

The presence of this green line (in the control zone (C)) indicates that sufficient volume is added; proper flow is obtained and serves as an internal control for the reagents.

PRECAUTIONS

- For professional *in vitro* use only.
- Do not use after expiration date.
- Do not use the test if its pouch is damaged.
- Specimens should be considered as potentially hazardous and handle in the same manner as an infectious agent. A new test must be used for each sample to avoid contaminations errors. Single use device.
- Tests should be discarded in a proper biohazard container after testing.
- Reagents contain preservatives. Avoid any contact with the skin or mucous membrane. Consult safety data sheet, available on request.
- Components provided in the kit are approved for use with the **Vitassay Campylobacter**. Do not use any other commercial kit component.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, goggles and mask. Do not eat, drink or smoke in the working area.
- The presence of yellow lines in the result window (control line zone and test line zone), before using the test, is completely normal and does not imply failure of the test functionality.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30°C/35.6-86°F).

The test is stable until the expiration date printed on the sealed pouch.

The test must remain in the sealed pouch until use.

Do not freeze.

MATERIALS

MATERIAL PROVIDED	MATERIAL REQUIRED BUT NOT PROVIDED
<ul style="list-style-type: none"> • 25 tests/kit Vitassay Campylobacter. • Instructions for use. • 25 vials with diluent for the sample dilution. 	<ul style="list-style-type: none"> • Specimen collection container. • Disposable gloves. • Timer.

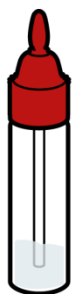
SPECIMEN COLLECTION

Collect sufficient quantity of feces: 1-2g or mL for liquid samples. Stool samples should be collected in clean and dry containers.

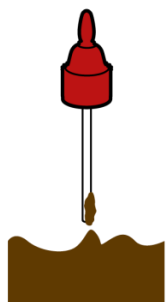
Samples can be stored in the refrigerator (2-8°C/35.6-46.4°F) for 1-2 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen at -20°C (-4°F). Samples must be brought to room temperature before testing.

SPECIMEN PREPARATION

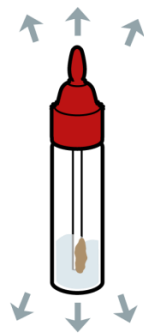
1. Remove the cap of the vial with diluent for the sample dilution (figure 1).
2. Use the stick to collect sufficient sample quantity. For solid stool, insert the stick in 4 different areas of the stool sample (figure 2), and add it into the vial with diluent for sample dilution. For liquid stool, take 125µL of the sample using a micropipette and transfer it into the vial with diluent for the sample dilution.
3. Close the vial with the diluent and stool sample. Shake vigorously the vial in order to assure good sample dispersion (figure 3).



Vial for sample dilution.



Insert the stick in 4 different areas of the stool.



Put the sample into the vial, close the cap and shake.

PROCEDURE

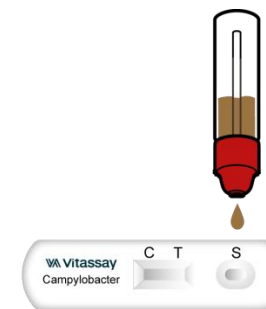
Allow the test, stool sample, controls and diluent to reach room temperature (15-30°C/59-86°F) prior to testing. Do not open pouches until the performance of the assay.

1. Shake the stool collection tube to obtain a good sample dilution.
2. Remove the **Vitassay Campylobacter** from its sealed bag just before using it.
3. Take the stool collection tube containing the diluted sample, cut the end of the cap (figure 4) and dispense 3 drops in the circular window marked with the letter S (figure 5).
4. Read the results at **10 minutes**. Do not read the results later than 10 minutes.

If the test does not run due to solid particles, stir the sample added in the sample window with the stick. If it does not work, dispense a drop of diluent until seeing the liquid running through the reaction zone.



Cut the end of the cap.



Dispense 3 drops in the circular window marked with the letter S.

INTERPRETATION OF THE RESULTS

C T	NEGATIVE	
		Only one green line in the control zone (C).
C T	POSITIVE	
		In addition to the green line (control line C), a red line appears (test line T).
ANY OTHER RESULTS		Invalid result, we recommend repeating the assay using the sample with another test. Note: Wrong procedural techniques or deterioration of the reagents are mostly the main reasons for control line failure. If the symptoms or situation still persist, discontinue using the test kit and contact your local distributor.

Notes: The intensity of the red colored test line in the result line zone (T) will vary depending on the concentration of antigens in the specimen.

QUALITY CONTROL

Internal procedural control is included in **Vitassay Campylobacter**. Green line appearing in the results window is an internal control, which confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS

- **Vitassay Campylobacter** must be carried out within 2 hours of opening the sealed bag.
- An excess of stool sample could cause wrong results (brown bands appear). Dilute the sample with the diluent and repeat the test.
- The intensity of test line may vary depending on the concentration of antigens.
- Freezing and thawing cycles for the samples are not recommended, it could be affect the results.
- The use of other samples different from human samples has not been established.
- The quality of **Vitassay Campylobacter** depends on the quality of the sample; Proper fecal specimens must be obtained.
- Positive results determine the presence of Campylobacter in fecal samples. A positive result should be followed up with additional laboratory techniques (biochemical and serological methods or by PCR) to confirm the results. A confirmed infection should only be made by a physician after all clinical and laboratory findings have been evaluated and must be based in the correlation of the results with further clinical observations.
- Negative results should not be considered as conclusive; it is possible that the concentration of antigens is lower than the detection limit. If symptoms or situation still persist, a Campylobacter determination should be carried out, on a sample from an enrichment culture.
- Bloody stool samples and/or mucous stool samples can be cause non-specific reactions in the test. These types of samples whose result is positive should be followed up with other techniques of diagnosis to confirm the result.

EXPECTED VALUES

A strong association between Campylobacter infection and diarrhea has also been described in the developed world. In developing country settings, Campylobacter infection has been most clearly implicated as a cause of diarrhea only in the first 6 months of life. Campylobacter is often shed for extended periods following such episodes, and asymptomatic excretion is common.

Campylobacter gastroenteritis is especially common in children during the first 5 years of life with reported isolation rates of up to 46%.

In developed and developing countries, Campylobacter cause more cases of diarrhoea than food borne Salmonella.

Campylobacteriosis occurs much more frequently in the summer months than in the winter.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity (detection limit)

Detection limit values for the different species are:

For *Campylobacter jejuni* and *Campylobacter coli* detection:

The typical detection limit value is: 0.78 ng/mL of *Campylobacter jejuni* recombinant protein and 0.78 ng/mL of *Campylobacter coli* recombinant protein.

Clinical sensitivity and specificity

An evaluation with fecal samples was performed using **Vitassay Campylobacter** and qPCR technique (VIASURE Campylobacter Real Time PCR Detection kit, CerTest). The results were as follows:

		qPCR: VIASURE <i>Campylobacter</i> Real Time PCR Detection Kit		
		Positive	Negative	Total
Vitassay Campylobacter	Positive	59	1	60
	Negative	4	49	53
	Total	63	50	113

Vitassay Campylobacter vs VIASURE <i>Campylobacter</i> Real Time PCR Detection Kit		
	Mean Value	95% confidence interval
Sensitivity	93.7%	84.5-98.2%
Specificity	98.0%	89.4-99.9%
PPV	98.3%	91.1-97.9%
NPV	92.5%	81.8-97.9%

The results showed that **Vitassay Campylobacter** has a high sensitivity and specificity to detect Campylobacter.

Cross reactivity










No cross reactivity was detected against gastrointestinal pathogens that are occasionally present in feces:

<i>Adenovirus</i>	<i>Helicobacter pylori</i>	<i>Shigella boydii</i>
<i>Astrovirus</i>	<i>Legionella</i>	<i>Shigella dysenteriae</i>
<i>Clostridium difficile</i> antigen GDH	<i>Listeria monocytogenes</i>	<i>Shigella flexneri</i>
<i>Clostridium perfringens</i>	Norovirus GI	<i>Shigella sonnei</i>
<i>Cryptosporidium</i>	Norovirus GII	<i>Staphylococcus aureus</i>
<i>Entamoeba dispar</i>	Rotavirus	<i>Streptococcus pneumoniae</i>
<i>Entamoeba histolytica</i>	<i>Salmonella enteritidis</i>	<i>Streptococcus pyogenes</i>
<i>Escherichia coli</i> O111	<i>Salmonella paratyphi</i> A	<i>Yersinia enterocolitica</i> O:3
<i>Escherichia coli</i> O149	<i>Salmonella paratyphi</i> B	<i>Yersinia enterocolitica</i> O:9
<i>Escherichia coli</i> O157:H7	<i>Salmonella typhi</i>	
<i>Giardia</i>	<i>Salmonella typhimurium</i>	

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3. P. RAJENDRAN; S. BABJI; AT GEORGE, DP RAJAN; G. KANG; SS. AJJAMPUR. "Detection and species identification of Campylobacter in stool samples of children and from Vellore, south India". Indian J. Med Microbiol. 2012; 30(1): 85-88.
4. SM SALIM; J MANDAL; SC PARIJA: "Isolation of Campylobacter from human stool samples". Indian Journal of Medical Microbiology, 2014, volume 32, Issue 1, pp. 35-38.

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

	<i>in vitro</i> diagnostic device		Keep dry
	Consult instructions for use		Temperature limitation
	Use by		Manufacturer
	Batch code		Contains sufficient for <n> test
DIL	Sample diluent		Catalogue number

