**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 disposable 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 (2-30ºC/35.6-86ºF).

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**

<table>
<thead>
<tr>
<th>MATERIAL PROVIDED</th>
<th>MATERIAL REQUIRED BUT NOT PROVIDED</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 tests/kit Vitassay Campylobacter.</td>
<td>Specimen collection container.</td>
</tr>
<tr>
<td>Instructions for use.</td>
<td>Disposable gloves.</td>
</tr>
<tr>
<td>25 vials with diluent for the sample dilution.</td>
<td>Timer.</td>
</tr>
</tbody>
</table>
SPECIMEN COLLECTION
Collet 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).

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.

INTERPRETATION OF THE RESULTS
NEGATIVE
There is no Campylobacter presence. No infection caused by Campylobacter. Only one green line in the control zone (C).

POSITIVE
There is Campylobacter presence. Viral infection caused by Campylobacter. 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.

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

<table>
<thead>
<tr>
<th>Vitassay Campylobacter</th>
<th>qPCR: VIASURE Campylobacter Real Time PCR Detection Kit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
</tr>
<tr>
<td>Positive</td>
<td>59</td>
</tr>
<tr>
<td>Negative</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>63</td>
</tr>
</tbody>
</table>

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:

- Adenovirus
- Helicobacter pylori
- Shigella boydii
- Astrovirus
- Legionella
- Shigella dysenteriae
- Clostridium difficile
- Listeria monocytogenes
- Shigella flexneri
- Clostridium perfringens
- Norovirus GI
- Shigella sonnei
- Cryptosporidium
- Norovirus GII
- Staphylococcus aureus
- Entamoeba dispar
- Rotavirus
- Salmonella enteritidis
- S. flexneri
- Entamoeba histolytica
- Salmonella paratyphi A
- Yersinia enterocolitica
- Escherichia coli O111
- Salmonella paratyphi B
- Y. enterocolitica
- Escherichia coli O149
- Salmonella typhi
- Shigella sonnei
- Giardia
- Salmonella typhimurium

**References**

1. JAMES A. PLATTS-MILLS; JIE LIU; JEAN GRATZ; ESTO MDUMA; CAROLINE AMOUR; NDEALILLAI SWAI, MAI TANJUH; SHARMIN BEGUM; PABLO PEÑARATO YORI; DRAKE H. TILLEY; GWENYTH LEE; ZELI SHEN; MARK T. WHARY; JAMES G. FOX; MONICA MCGRATH; MARGARET KOSEK; RASHIDUL HAQUE; ERIC R. HOUPPT. "Detection of Campylobacter in stool and determination of significance by culture, Enzyme Immunoassay, and PCR in developing countries". Journal of Clinical Microbiology, April 2014, Volume 52, number 4, p. 1074-1080.

2. HIROSHI USHIJIMA; SHUICHI NISHIMURA; AKSARA THONGPRACHUM; YUKO SHIMIZU-ONDA; DINH NGUYEN TRAN; NGAN THI KIM PHAM; SAYAKA TAKANASHI; SHUVRA KANTI DEY; SHOKO OKITSU; WATARU YAMAZAKI, MASASHI MIZUYCHI; SATOSHI HAYAKAWA. “Sensitive and rapid detection of Campylobacter species from stools of children with diarrhea in Japan by the Loop-Mediated Isothermal Amplification Method”. Jpn. J. Infect. Dis., 67, 374-378, 2014.


### SYMBOLS FOR IVD COMPONENTS AND REAGENTS

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVD</td>
<td>In vitro diagnostic device</td>
</tr>
<tr>
<td></td>
<td>Keep dry</td>
</tr>
<tr>
<td>📚</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td></td>
<td>Temperature limitation</td>
</tr>
<tr>
<td>⚛️</td>
<td>Use by</td>
</tr>
<tr>
<td></td>
<td>Manufacturer</td>
</tr>
<tr>
<td>📋</td>
<td>Batch code</td>
</tr>
<tr>
<td></td>
<td>Contains sufficient for &lt;n&gt; test</td>
</tr>
<tr>
<td>🧴</td>
<td>Sample diluent</td>
</tr>
<tr>
<td></td>
<td>Catalogue number</td>
</tr>
</tbody>
</table>