Proflow™ Campylobacter

(for *In Vitro* Diagnostic use only)

PRODUCT CODE PL.3016 **20 Tests**

INTENDED USE

The Proflow™ Campylobacter test is a single use rapid membrane immunoassay for the qualitative detection of *Campylobacter* spp. in human faeces samples, to aid in the diagnosis of campylobacteriosis. For *In Vitro* Diagnostic Use.

SUMMARY AND EXPLANATION

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 2-5 days after exposure to the organism. The diarrhoea may be bloody and can be accompanied by nausea and vomiting. The illness typically lasts for one week. Some infected individuals do not have any symptoms. In those with compromised immune systems, Campylobacter occasionally spreads to the bloodstream and causes a serious life-threatening infection.

PRINCIPLE OF THE TEST

The Proflow™ Campylobacter test is a single use rapid membrane immunoassay for the qualitative detection of Campylobacter antigen in human faeces samples. Monoclonal antibodies to Campylobacter antigen are coated onto the test line region of the strip. During testing the sample migrates along the membrane by capillary action and is allowed to react with the conjugate on the test strip. In the case of a positive result the specific antibodies present on the membrane will capture the coloured conjugate.

A green line should always appear in the control line region to show that sufficient volume was added, proper flow was obtained and the reagents functioned correctly. Failure of the control line to appear, whether or not test lines are present, indicates an invalid assay.

The test is interpreted by the presence or absence of visibly detectable coloured lines in the test region at 10 minutes or less depending on the concentration of antigen present.

A positive result will show a pink/red test line and a green control line, indicating that Campylobacter antigen is present in the sample. A negative test result, read at 10 minutes, will show only a green control line, indicating that Campylobacter antigen was not detectable in the sample.

MATERIALS PROVIDED

- PL.3116 Proflow™ Campylobacter Test Devices: 20 devices
- PL.3216 Proflow™ Campylobacter Sample Preparation Devices: 20 devices
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Sample collection container
- Timer or stopwatch
- Biohazard disposal container
- Disposable gloves

STABILITY AND STORAGE

- Store all components at 2-30ºC.
- Do not freeze or overheat.
- Do not use beyond the expiration date printed on the outer package label.
- The test kits should be kept away from direct sunlight, moisture and heat.

PRECAUTIONS

- For *In Vitro* Diagnostic Use only.
- For professional use only.
- Directions should be read and followed carefully.
- Tests are for single use only. Do not reuse.
- Reagents are provided at the necessary working strength. Do not dilute reagents.
- Do not interchange reagents between kits with different lot numbers.
- Do not use kits or reagents beyond the stated expiration dates.
- Microbial contamination of reagents may decrease the accuracy of the assay.
- Treat all materials as if they were infectious and dispose of all material in accordance with local regulation.
- The test must be carried out within 2 hours of opening the sealed bag.

SAMPLE STORAGE AND COLLECTION

- Collect sufficient quantity of faeces (1-2g or mL for liquid samples).
- Faecal samples should be collected in clean and dry containers (no preservatives or transport media).
- Samples may be stored at 2-8°C for 1-2 days or at -20°C for longer periods before testing.
- Allow all samples to equilibrate to room temperature before testing.
- Freezing and thawing cycles are not recommended.

TEST PROCEDURE

Use a separate sample collection vial and test for each sample or control. Allow the tests, faeces samples and buffer to reach room temperature prior to testing.

1. Introduce the swab or stick four times into the faeces up to the thread of the stick to pick up approx. 50 mg, and put back into the sample preparation device with buffer. For liquid faeces, aspirate with a dropper and add 50 µL into the sample preparation device.
2. Shake the sample preparation device to ensure good sample dispersion.
3. Remove the Proflow™ Campylobacter test from its sealed pouch.
4. Break off the top of the vial on the sample preparation device.
5. Dispense 3 drops (100 uL) into the sample well on the test (S).
6. Read the result at 10 minutes.

QUALITY CONTROL PROCEDURE

It is recommended that a positive and negative control be used to ensure that the test is performing as expected.

The control line (C) is a procedural control and will show that the test has been performed correctly; proper flow occurred and that the test reagents functioned as expected. When a green line appears at the control line position this indicates the test has been performed correctly. The control line will appear on all valid tests, whether or not the sample is reactive or non-reactive (refer to the Interpretation of Results section).

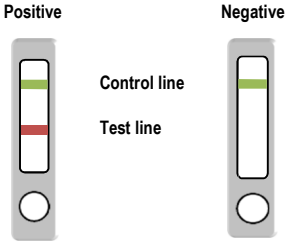
INTERPRETATION OF RESULTS

Positive

A pink/red line of any intensity appears in the test window at the test line position; a green line appears at the control line position. This indicates a reactive result that is interpreted as positive for Campylobacter antigen.

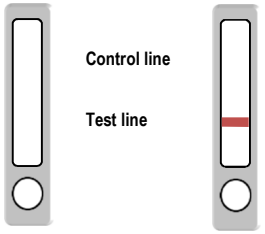
Negative

A single green line of any intensity appears in the test window at the control line position. There is no line at the test line position. This indicates a non-reactive result that is interpreted as negative for Campylobacter antigen.



Invalid

No line appears in the test window at the control line position. This is an invalid result and cannot be interpreted. This is irrespective of whether or not a pink/red line appears in the test window at the test line position. If either condition below occurs, the test should be repeated with a new test.



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LIMITATIONS OF THE PROCEDURE

- The Proflow™ Campylobacter test will only indicate the presence of Campylobacter in the sample (qualitative detection) and should be used for the detection of Campylobacter antigen in faeces samples only. Neither the quantitative value nor the rate of increase in Campylobacter antigen concentration can be determined by this test.
- An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
- Some faeces samples can decrease the intensity of the control line.
- The test must be carried out within 2 hours of opening the sealed bag.
- Avoid antimicrobials, proton pump inhibitors and bismuth for 10 days prior to testing.
- Mucous and/or bloody faecal samples can cause non-specific reactions. A positive result with a mucous or bloody sample should be confirmed with other techniques.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Campylobacter infection.
- This test provides a presumptive diagnosis of campylobacteriosis. All results must be interpreted together with other clinical information and laboratory findings available to the clinician.

PERFORMANCE CHARACTERISTICS

EXPECTED VALUES

Campylobacter spp. are a major cause of diarrhoeal illness in humans and are generally regarded as the most common bacterial cause of gastroenteritis worldwide. In both developed and developing countries, this group of bacteria cause more cases of diarrhoea than foodborne Salmonella bacteria. In developing countries, Campylobacter infections in children under the age of two 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 AND SPECIFICITY

An evaluation was conducted comparing the results obtained using the Proflow™ Campylobacter test vs a commercial qPCR kit (VIASURE Campylobacter Real Time PCR Detection Kit, CerTest Biotec). The specimens were obtained from patients with the same as Campylobacter infection symptoms. The results were as follows:

		qPCR: VIASURE Campylobacter Real Time PCR Detection Kit		
		+	-	Total
IC test: Proflow™ Campylobacter Device	+	59	1	60
	-	4	49	53
	Total	63	50	113

		Campylobacter device vs VIASURE Campylobacter Real Time PCR Detection Kit
		95% CI (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%

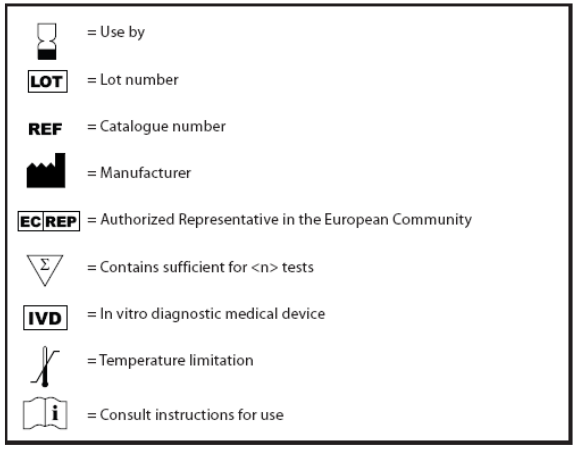
CROSS-REACTIVITY

An evaluation was performed to determine the cross-reactivity of the Proflow™ Campylobacter test. There was no cross-reactivity with common intestinal pathogens or other organisms and substances occasionally present in faeces:

- Adenovirus
- Astrovirus
- *Clostridium difficile* Ag GDH
- *Clostridium perfringens*
- Cryptosporidium
- *Entamoeba dispar / histolytica*
- *Escherichia coli* O:111 / O149 / O157:H7
- Giardia
- *Helicobacter pylori*
- Legionella
- *Listeria monocytogenes*
- Norovirus GI / GII
- Rotavirus
- *Salmonella enteritidis / paratyphi A / paratyphi B / typhi / typhimurium*
- *Shigella boydii / dysenteriae / flexneri / sonnei*
- *Staphylococcus aureus*
- *Streptococcus pneumoniae / pyogenes*
- *Yersinia enterocolitica* O:3 / O:9

REFERENCES

- Fernández H. and Farace M.I. Manual de Procedimientos Campylobacter. *INEI*. 2003.
- 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; 46:No. 4: pp 1226-1231.



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