Proflow™ *H. pylori*

(for *In Vitro* Diagnostic use only)

PRODUCT CODE PL.3006 **20 Tests**

INTENDED USE

The Proflow™ *H. pylori* test is a single use rapid membrane immunoassay for the qualitative detection of *Helicobacter pylori* antigen in human faecal samples to aid in the diagnosis of *H. pylori* infection. For *In Vitro* Diagnostic Use.

SUMMARY AND EXPLANATION

H. pylori is a small, spiral-shaped bacterium that is found in the surface of the stomach (epithelial lining) and duodenum (mucous layer). *H. pylori* causes duodenal ulcers and gastric ulcers.
The importance of *H. pylori* testing has increased greatly since the discovery of the strong correlation between its presence and confirmed gastrointestinal diseases like gastritis, peptic ulcer disease and gastric carcinoma. Invasive and non-invasive methods are used to diagnose *H. pylori* infection in patients with symptoms of gastrointestinal disease.

PRINCIPLE OF THE TEST

The Proflow™ *H. pylori* test is a single use rapid membrane immunoassay for the qualitative detection of *H. pylori* antigen in human faeces.
Monoclonal antibodies to *H. pylori* 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 *H. pylori* antigen is present in the sample. A negative test result, read at 10 minutes, will show only a green control line, indicating that *H. pylori* antigen was not detectable in the sample.

MATERIALS PROVIDED

- PL.3601 Proflow™ *H. pylori* Test Devices: 20 devices
- PL.3602 Proflow™ *H. pylori* Sample Preparation Device: 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 the sample 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™ *H. pylori* 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.

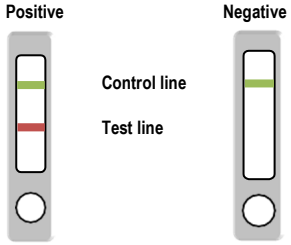
QUALITY CONTROL PROCEDURE

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 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).

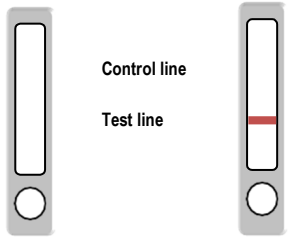
INTERPRETATION OF RESULTS

Positive
A pink/red line of any intensity appears in the test window at the test line position; a green line will appear at the control line position. This indicates a reactive result that is interpreted as positive for *H. pylori* 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 *H. pylori* 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.



UK: Tel +44 (0)151 353 1613
3 Bassendale Road, Bromborough, Wirral, CH62 3QL
www.pro-lab.co.uk

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LIMITATIONS OF THE PROCEDURE

- Proflow™ *H. pylori* test will only indicate the presence of *H. pylori* in the sample (qualitative detection) and should be used for the detection of *H. pylori* antigens in faeces samples only. Neither the quantitative value nor the rate of increase in *H. pylori* antigens 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 *H. pylori* infection.
- This test provides a presumptive diagnosis of *H. pylori* infections. All results must be interpreted together with other clinical information and laboratory findings available to the clinician.

PERFORMANCE CHARACTERISTICS

EXPECTED VALUES

Studies have found that more than 90% of patients with duodenal ulcer, and 80% of patients with gastric ulcer, are infected with *H. pylori.* The Proflow™ *H. pylori* device has been compared with different methods, including cultures, Urea Breath Test and Urease Test, demonstrating an overall accuracy of over 92%.

LIMIT OF DETECTION

The detection limit range for the Proflow™ *H. pylori* device is 0.78-0.09 ng/ml of recombinant outer membrane protein.

SENSITIVITY AND SPECIFICITY

An evaluation was performed using the Proflow™ *H. pylori* Device vs a commercial qPCR kit (VIASURE *Helicobacter pylori* Real Time Detection Kit, CerTest Biotec). The results were as follows:

		qPCR test: VIASURE *Helicobacter pylori* Real Time Detection kit		
		Positive	**Negative**	**Total**
IC test: Proflow™ *H. pylori* Device	**Positive**	54	1	55
	Negative	1	60	61
	Total	55	61	116

		***H. pylori* Device vs. VIASURE kit**
		95% CI (Confidence Interval)
Sensitivity	98.2%	90.3%-100.0%
Specificity	98.4%	91.2%-100.0%
PPV	98.2%	91.2%-100.0%
NPV	98.4%	90.3%-100.0%

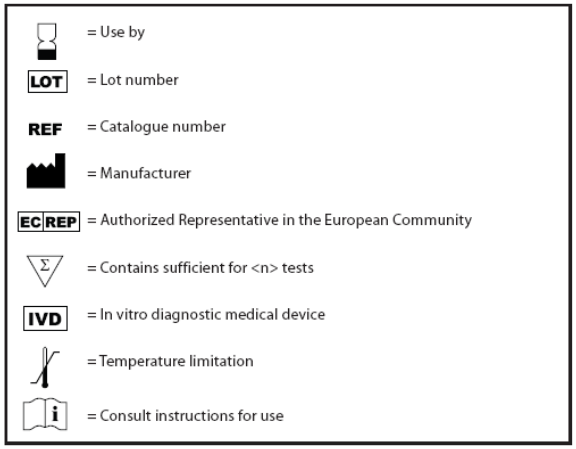
CROSS-REACTIVITY

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

- *Campylobacter coli / jejuni*
- *Clostridium difficile*
- *Escherichia coli* O157:H7
- *Listeria monocytogenes*
- *Salmonella enteritidis / paratyphi / typhi / typhimurium*
- *Shigella boydii / dysenteriae / flexneri / sonnei*
- *Staphylococcus aureus*
- *Yersinia enterocolitica*

REFERENCES

- Blaser M.J. Helicobacter pylori and gastric diseases. *BMJ* 1998; 316: 1507-1510.
- Cutler A.F. Testing for Helicobacter pylori in clinical practice. *Am J. Med.* 1996; 100:35S-41S.
- Soll A.H. Pathogenesis of peptic ulcer and implications for therapy. *New England J. Med.* 1990, 322: 909-16.



EC REP Advena Ltd. Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013, Malta.