Proflow™ Norovirus

(for *In Vitro* Diagnostic use only)

PRODUCT CODE PL.3008

10 Tests

INTENDED USE

The Proflow™ Norovirus test is a single use rapid membrane immunoassay for the qualitative detection of norovirus GI and GII antigens in human faecal samples to aid in the diagnosis of norovirus infection. For *In Vitro* Diagnostic Use.

SUMMARY AND EXPLANATION

Noroviruses, members of the *Caliciviridae* family, are a group of more than 40 extremely heterogeneous viruses. Infection is typically characterised by self-limited vomiting and diarrhoea, with symptoms prevailing for 12–60 hours.

Noroviruses are divided into five distinguishable genogroups (GI–GV) based on genome sequence similarity; however, only virus strains from genogroups I–II are known to widely infect humans. Additional strains in the newly identified genogroup IV have also been detected in human faeces. Noroviruses within a genogroup can differ by up to 40% in capsid amino acid sequence and >50% between genogroups.

PRINCIPLE OF THE TEST

The Proflow™ Norovirus test is a single use rapid membrane immunoassay for the qualitative detection of norovirus GI and GII antigens in human faeces.

Specific antibodies to norovirus GI and GII antigens 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 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 antigens present.

A positive result will show a pink/red test line and a green control line, indicating that norovirus GI and/or GII antigens are present in the sample. A negative test result, read at 10 minutes, will show only a green control line, indicating that norovirus GI and GII antigens were not detectable in the sample.

MATERIALS PROVIDED

- PL.3801 Proflow™ Norovirus Devices: 10 devices
- PL.3802 Proflow™ Norovirus Sample Prep Device: 10 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.

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 faecal sample 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 samples, 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™ Norovirus 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).

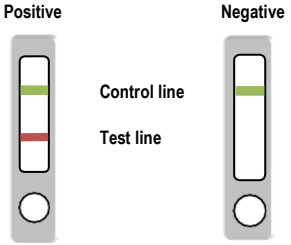
INTERPRETATION OF RESULTS

Positive

One pink/red line of any intensity will appear 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 norovirus GI and/or GII antigens.

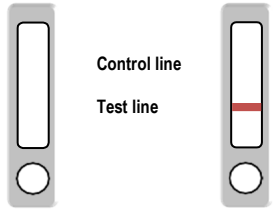
Negative

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 norovirus GI and GII antigens.



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 coloured 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

Revision: 2022 08

LIMITATIONS OF THE PROCEDURE

- The Proflow™ Norovirus GI+GII device will only indicate the presence of norovirus GI and/or norovirus GII in the sample (qualitative detection) and should be used for the detection of norovirus GI and GII in faecal samples only. Neither the quantitative value nor the rate of increase in 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 bands.
- The test must be carried out within 2 hours of opening the sealed bag.
- 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 infection caused by norovirus.
- This test provides a presumptive diagnosis of infection caused by norovirus. All results must be interpreted together with other clinical information and laboratory findings available to the clinician and should be followed up with additional laboratory techniques.
- After one week of infection, the viral load in faeces falls, making the sample less reactive. Faeces samples should be collected within one week of the onset of symptoms.

PERFORMANCE CHARACTERISTICS

EXPECTED VALUES

Noroviruses are recognised as the most common cause of viral gastroenteritis among adults in the US. It is estimated that more than 40% of foodborne outbreaks of gastroenteritis are attributable to noroviruses. These highly contagious viruses can be transmitted by contaminated food, water, or direct person-to-person contact. Outbreaks have been documented on cruise ships, at day-care centres and schools, and among members of the military. Severe illness is rare, but unusual complications can occur in the elderly, young, and immunocompromised individuals.

SENSITIVITY AND SPECIFICITY

An evaluation was conducted comparing the results obtained using the Proflow™ Norovirus test to a commercially available norovirus immunochromatographic membrane assay. The Proflow™ Norovirus test showed:

Sensitivity >99%
Specificity >99%

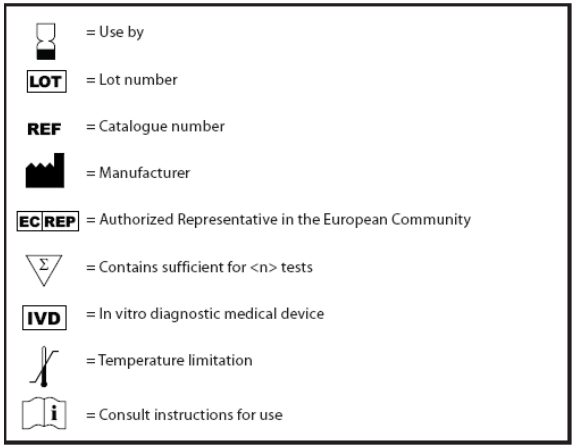
CROSS-REACTIVITY

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

- Adenovirus
- Astrovirus
- Campylobacter
- *Clostridium difficile*
- *Cryptosporidium parvum*
- Enterovirus
- *Escherichia coli*
- *Giardia lamblia*
- *Helicobacter pylori*
- Hepatitis A
- *Listeria monocytogenes*
- Rotavirus
- RSV
- Salmonella
- Shigella
- *Staphylococcus aureus*
- *Yersinia enterocolitica*

REFERENCES

- Kissmann J. et al. Physical stabilization of Norwalk Virus-like Particles. *Journal of Pharmaceutical Sciences* Oct 2008; 97 (10): 4208-18.
- Lobuea A. et al. Multivalent norovirus vaccines induce strong mucosal and systemic blocking antibodies against multiple strains. *Vaccine* 2006; 24: 5220– 5234.



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