# Proflow™ Rotavirus

(for *In Vitro* Diagnostic use only)

**PRODUCT CODE PL.3009** **20 Tests**

## INTENDED USE

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

## SUMMARY AND EXPLANATION

Viral gastroenteritis is an infection caused by a variety of viruses which results in vomiting and/or diarrhoea. Many different viruses can cause gastroenteritis, including rotaviruses, noroviruses, adenoviruses, sapoviruses, and astroviruses.

The main symptoms of viral gastroenteritis are watery diarrhoea and vomiting. The affected person may also have headache, fever, and abdominal cramps. In general, the symptoms begin 1-2 days following infection with a virus that causes gastroenteritis and may last for 1-10 days, depending on which virus causes the illness. Some research studies have shown that the duration of the symptoms is approximately 3-4 days. Rotavirus is the more frequent cause of acute diarrhoea in children under two years of age.

## PRINCIPLE OF THE TEST

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

## MATERIALS PROVIDED

- PL.3901 Proflow™ Rotavirus Test Device: 20 devices
- PL.3902 Proflow™ Rotavirus Sample Prep 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.

## SAMPLE STORAGE AND COLLECTION

- Collect sufficient quantity of faeces (1-2g or 1-2mL for liquid samples)
- Faeces 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 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™ Rotavirus 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).

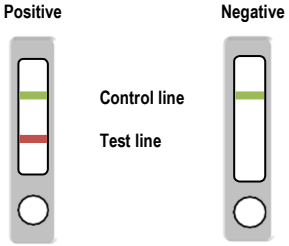
## INTERPRETATION OF RESULTS

**Positive**

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 rotavirus antigen.

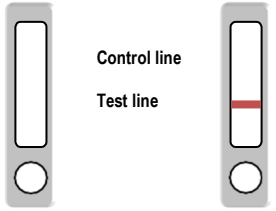
**Negative**

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 rotavirus 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 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™ Rotavirus test will only indicate the presence of rotavirus in the sample (qualitative detection) and should be used for the detection of rotavirus antigens in faecal samples only.
- 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.
- 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 rotavirus infection.
- This test provides a presumptive diagnosis of rotavirus infections. All results must be interpreted together with other clinical information and laboratory findings available to the clinician.

## PERFORMANCE CHARACTERISTICS

EXPECTED VALUES

Each year in the US, rotavirus infection results in the hospitalisation of an estimated 70,000 children, 160,000 emergency room visits in children younger than five, and half a million visits to doctor's offices. It is estimated that 100 children die each year in the US from complications of the infection. Rotavirus affects populations in all socioeconomic groups, and is equally prevalent in industrialised and developing countries, so differences in sanitation practises or water supply are not likely to affect the incidence of infection.

Rotavirus infections usually peak in the autumn months in the southwest of the US, and spread to the northeast by spring, meaning infections are most common during the winter months. However, infection can occur at any time of the year.

SENSITIVITY AND SPECIFICITY

An evaluation was conducted comparing the results obtained using the Proflow™ Rotavirus with a commercially available rotavirus assay. The Proflow™ Rotavirus test showed:

Specificity >98%
Sensitivity >99%

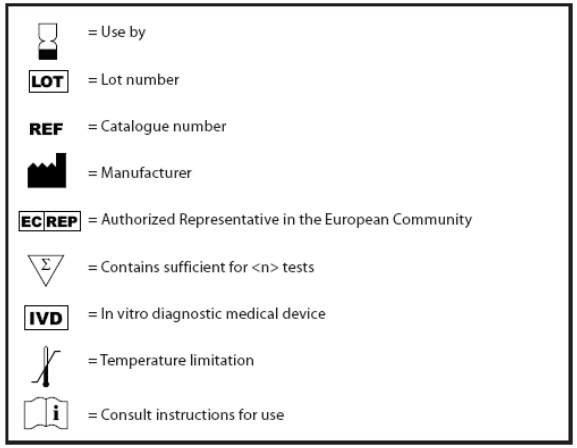
CROSS-REACTIVITY

An evaluation was performed to determine the cross-reactivity of the Proflow™ Rotavirus 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*
- *Entamoeba histolytica*
- Enterovirus
- *Escherichia coli*
- *Giardia lamblia*
- *Helicobacter pylori*
- *Listeria monocytogenes*
- Norovirus
- Salmonella
- Shigella
- *Staphylococcus aureus*
- Yersinia

## REFERENCES


- Silva De Oliveira C. and Linhares A.C. Rotavirus: clinical features and prevention. *Jornal de Pediatria*. 1999, vol. 75, suppl.1.


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