Proflow™ Rotavirus-Adenovirus Dual Test

(for *In Vitro* Diagnostic use only)

PRODUCT CODE PL.3033 **20 Tests**

INTENDED USE

The Proflow™ Rotavirus-Adenovirus Dual Test is a coloured chromatographic immunoassay for the simultaneous qualitative detection of rotavirus and adenovirus in human faecal samples to aid in the diagnosis of rotavirus and adenovirus infection. For *In Vitro* Diagnostic Use.

SUMMARY AND EXPLANATION

Rotavirus, adenovirus and astrovirus are most common and major causes of severe gastroenteritis in infants and young children. Pattern also observed in adults. They are transmitted by faecal-oral contact. The main symptoms of viral gastroenteritis are watery diarrhoea and vomiting. The affected person may also have headache, fever and abdominal cramps ("stomach ache"). 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 is causing the illness (rotavirus 3 days, adenovirus 5-8 days and astrovirus 3 days).

PRINCIPLE OF THE TEST

The Proflow™ Rotavirus-Adenovirus Dual Test is a single use rapid membrane immunoassay for the qualitative detection of rotavirus and adenovirus antigens in human faeces.

Strip A is pre-coated with mouse monoclonal antibodies against rotavirus on the test line. This strip is then sprayed with mouse monoclonal antibodies anti-rotavirus conjugated to red polystyrene latex particles. Strip B is pre-coated with mouse monoclonal antibodies against adenovirus on the test line. This strip is then sprayed with mouse monoclonal antibodies anti-adenovirus conjugated to red polystyrene latex particles. Both strips also have a control line, onto which rabbit polyclonal antibodies against a specific protein are coated. Finally, both strips are sprayed with specific binding protein conjugated to green polystyrene latex particles.

During testing the sample migrates along the membranes by capillary action and is allowed to react with the conjugates on the test strips.

If the sample is rotavirus positive, the antigens in the sample react with the red-coloured conjugate complex in strip A; if the sample is adenovirus positive, the antigens in the sample react with the red-coloured conjugate complex in strip B. The conjugate complexes continue to migrate upwards on the membranes. The anti-rotavirus antibodies at the test line of strip A, and the anti-adenovirus antibodies on the test line of strip B, capture the coloured conjugates, and the red lines become visible, indicating a positive result.

On both strips, the green coloured conjugate complexes on the strips will capture the anti-specific protein antibodies. The conjugate mixture will continue to migrate up the membranes to the immobilised specific antibodies placed in the control lines. These antibodies will capture the green conjugate complex and both control lines will always appear. Green lines 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 either 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 regions at 10 minutes or less depending on the concentrations of the antigens present. A positive rotavirus result will show a pink/red test line on strip A and green control lines on both strips, indicating that rotavirus antigen is present in the sample. A positive adenovirus result will show a pink/red test line on strip B and green control lines on both strips, indicating that adenovirus antigen is present in the sample. A negative test result, read at 10 minutes, will show only green control lines on both strips, indicating that neither rotavirus nor adenovirus antigens were detectable in the sample.

MATERIALS PROVIDED

- PL.3340 Proflow™ Rotavirus-Adenovirus Dual Test Devices: 20 devices
- PL.3350 Proflow™ Rotavirus-Adenovirus Dual 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 2-30°C.
- 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 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-Adenovirus 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 lines (C) are 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 Rotavirus

One pink/red line will appear at the left test line; a green line will appear at the control line on both strips of the test. This indicates a reactive result that is interpreted as positive for rotavirus antigen.

Positive Adenovirus

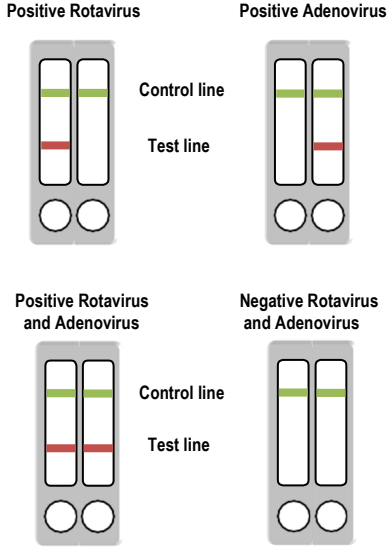
One pink/red line will appear at the right test line; a green line will appear at the control line on both strips of the test. This indicates a reactive result that is interpreted as positive for adenovirus antigen.

Positive Rotavirus and Adenovirus

A pink/red line will appear on the test line on both strips of the test; a green line will appear at the control line on both strips of the test. This indicates a reactive result that is interpreted as positive for both rotavirus and adenovirus antigens.

Negative

A green line of any intensity appears in both test windows at the control line positions. There are no lines at either test line position. This indicates a non-reactive result that is interpreted as negative for both rotavirus and adenovirus antigens.



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

Revision: 2022 08

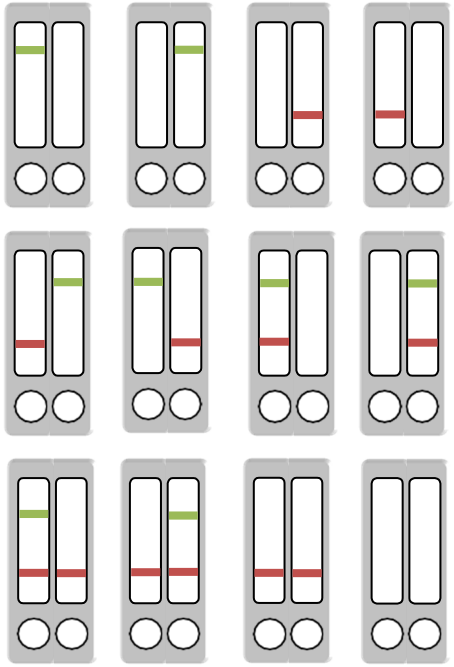
Proflow™ Rotavirus-Adenovirus Dual Test

(for *In Vitro* Diagnostic use only)

PRODUCT CODE PL.3033 **20 Tests**

Invalid

No line appears in the test window at the control line positions. These are invalid results and cannot be interpreted. This is irrespective of whether or not a coloured line appears at the test line positions. If any of the conditions below occur, the test should be repeated with a new test.



LIMITATIONS OF THE PROCEDURE

- The Proflow™ Rotavirus-Adenovirus test will only indicate the presence of rotavirus and adenovirus in the sample (qualitative detection) and should be used for the detection of rotavirus and adenovirus antigens 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 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.
- 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 and adenovirus infection.
- This test provides a presumptive diagnosis of rotavirus and adenovirus 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.

Adenoviruses cause diarrhoea mostly in young children, but older children and adults can also be affected. Adenovirus infections occur throughout the year.

SENSITIVITY AND SPECIFICITY

An evaluation with faecal samples was performed using an immunochromatographic test (Proflow™ Rotavirus-Adenovirus Dual Test). These results were compared with a commercially available test (Ridascreen® Rotavirus ELISA test, r-Biopharm) for strip A, and the results for strip B were confirmed using PCR. The results were as follows:

		Ridascreen® Rotavirus ELISA test		
		+	-	Total
Proflow™ Rotavirus-Adenovirus Dual test (Rotavirus)	+	18	1	19
	-	0	43	43
	Total	18	44	62

Proflow™ Rotavirus-Adenovirus Dual Test (Rotavirus)

Sensitivity	Specificity	PPV	NPV
>99%	98%	>94%	>99%

		PCR		
		+	-	Total
Proflow™ Rotavirus-Adenovirus Dual test (Adenovirus)	+	7	0	7
	-	0	52	52
	Total	7	52	59

Proflow™ Rotavirus-Adenovirus Dual Test (Rotavirus)

Sensitivity	Specificity	PPV	NPV
>99%	>99%	>99%	>99%

The results showed a high sensitivity and specificity to detect rotavirus and adenovirus using the Proflow™ Rotavirus-Adenovirus Dual Test.

CROSS-REACTIVITY

An evaluation was performed to determine the cross-reactivity of the Proflow™ Rotavirus-Adenovirus Dual Test; no cross-reactivity was found against gastrointestinal pathogens occasionally present in faeces:

- Adenovirus (strip A)
- Astrovirus
- Campylobacter
- *Clostridium difficile*
- *Cryptosporidium parvum*
- Enterovirus
- *Entamoeba histolytica*
- *Escherichia coli*
- *Giardia lamblia*
- *Helicobacter pylori*
- *Listeria monocytogenes*
- Norovirus
- Rotavirus (strip B)
- Salmonella
- Shigella
- *Staphylococcus aureus*
- *Yersinia enterocolitica*

REFERENCES

- Guillermo B., Luque W. et al. Fisiopatología de las Infecciones por Adenovirus. *Paediatrica Asociación de Médicos Residentes del Instituto de Salud del Niño* Oct. 2001 - Mar. 2002; vol. 4 (2):41-47.
- Silva De Oliveira C. and Linhares A.C. Rotavirus: clinical features and prevention. *Jornal de Pediatria*. 1999, vol. 75, suppl.1.

= Use by

LOT = Lot number

REF = Catalogue number

= Manufacturer

EC REP = Authorized Representative in the European Community

= Contains sufficient for <n> tests

IVD = In vitro diagnostic medical device

= Temperature limitation

= Consult instructions for use

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

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

Revision: 2022 08