

INTENDED USE

The Proflow™ Adenovirus test is a single use rapid membrane immunoassay for the qualitative detection of adenovirus antigen in faeces samples to aid in the diagnosis of Adenovirus 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. Adenoviruses and astroviruses cause diarrhoea mostly in young children, but older children and adults can also be affected.

PRINCIPLE OF THE TEST

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

MATERIALS PROVIDED

- PL.3111 Proflow™ Adenovirus Test Devices: 20 devices
- PL.3211 Proflow™ Adenovirus 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 2-30°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 1-2mL for liquid samples).
- 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™ Adenovirus test from its sealed pouch.
4. Break off the top of the vial on the sample preparation device.
5. Dispense 3 drops (100 µL) 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).

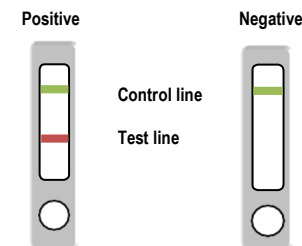
INTERPRETATION OF RESULTS

Positive

A 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 adenovirus antigen.

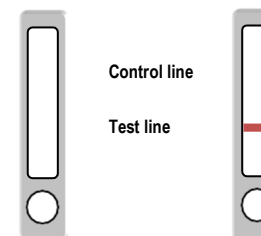
Negative

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 adenovirus 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 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.



LIMITATIONS OF THE PROCEDURE

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

PERFORMANCE CHARACTERISTICS

EXPECTED VALUES

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 was conducted comparing the results obtained using the Proflow™ Adenovirus test with PCR. The Proflow™ Adenovirus test showed:

Specificity >99%
 Sensitivity >99%

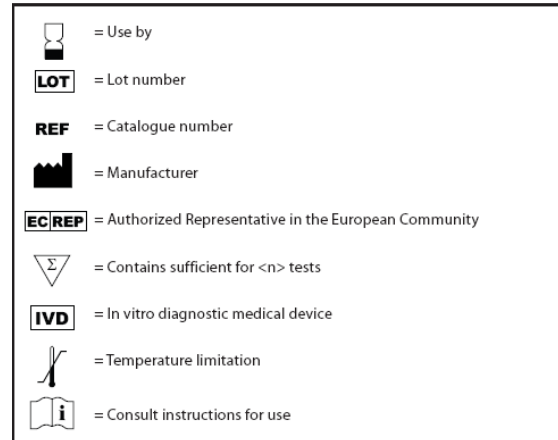
CROSS-REACTIVITY

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

- Astrovirus
- Campylobacter
- *Clostridium difficile*
- *Cryptosporidium parvum*
- *Entamoeba histolytica*
- Enterovirus
- *Escherichia coli*
- *Giardia lamblia*
- *Helicobacter pylori*
- *Listeria monocytogenes*
- Norovirus
- Rotavirus
- Salmonella
- Shigella
- *Staphylococcus aureus*
- Yersinia

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.



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