Proflow™ Astrovirus

(for *In Vitro* Diagnostic use only)

PRODUCT CODE PL.3012 **20 Tests**

INTENDED USE

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

SUMMARY AND EXPLANATION

Astrovirus is the most common cause of gastroenteritis in children and young people, and has also been observed in adults. This virus is transmitted through faecal-oral contact. The affected person may also have headache, fever, and abdominal cramps. In general, the symptoms begin 1-2 days following infection and may last for 3 days.

PRINCIPLE OF THE TEST

The Proflow™ Astrovirus test is a single use rapid membrane immunoassay for the qualitative detection of Astrovirus antigen in human faecal samples.

Monoclonal antibodies to Astrovirus 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 Astrovirus antigen is present in the sample. A negative test result, read at 10 minutes, will show only a green control line, indicating that Astrovirus antigen was not detectable in the sample.

MATERIALS PROVIDED

- PL.3112 Proflow™ Astrovirus Test Devices: 20 devices
- PL.3212 Proflow™ Astrovirus 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 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™ Astrovirus 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.

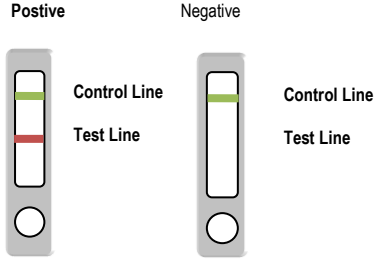
QUALITY CONTROL PROCEDURE

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).

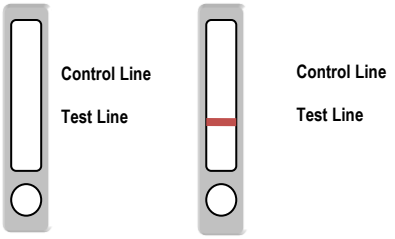
INTERPRETATION OF RESULTS

Positive
A pink/red line of any intensity appears in the test window at the test line position. This indicates a reactive result that is interpreted as positive for Astrovirus 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 Astrovirus 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.



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LIMITATIONS OF THE PROCEDURE

- Excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test..
- Samples should be taken within a week of first onset of symptoms. After a week of infection the presence of virus eliminated in faeces decreases significantly and is of a low concentration in the sample.
- This test provides a presumptive diagnosis of Astrovirus infection. Results should be confirmed by a physician, taking into account the clinical and laboratory tests.
- The test must be carried out within 2 hours of opening the sealed bag.

PERFORMANCE CHARACTERISTICS

An evaluation was conducted comparing the results obtained using the Proflow™ Astrovirus test with a commercial ELISA test.

Proflow™ Astrovirus test showed:
Specificity >99%
Sensitivity >94%

CROSS-REACTIVITY

An evaluation was performed to determine the cross reactivity of Proflow™ Astrovirus test. There is no cross-reactivity with common gastrointestinal pathogens occasionally present in feces.

- Adenovirus	- Escherichia coli O157:H7	- Salmonella
- Campylobacter	- Giardia lamblia	- Shigella
- Clostridium difficile	- Helicobacter pylori	- Staphylococcus aureus
- Cryptosporidium parvum	- Listeria monocytogenes	- Yersinia enterocolitica
- Enterovirus	- Norovirus	
- Entamoeba hystolitica	- Rotavirus	

REFERENCES

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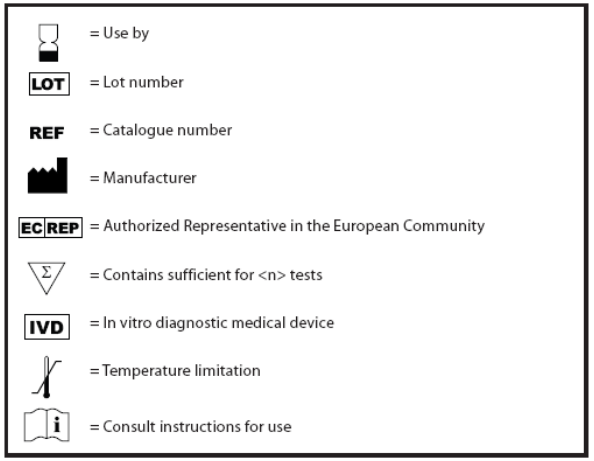
- Bon, F. et al. Prevalence of group A rotavirus, human calicivirus, astrovirus type 40 and 41 infections among children with acute gastroenteritis in Dijon, France: J. Clin. Microbiol. 1999; 37(9): 3055-8.



EC REP

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