Proflow™ Enterovirus

(for *In Vitro* Diagnostic use only)

PRODUCT CODE PL.3013 **20 Tests**

INTENDED USE

The Proflow™ Enterovirus test is a single use rapid membrane immunoassay for the qualitative detection of enterovirus antigen (VP1 peptide) in faeces samples to aid in the diagnosis of enterovirus infection. For *In Vitro* Diagnostic Use.

SUMMARY AND EXPLANATION

Enteroviruses consist of poliovirus, coxsackievirus, echovirus, and numbered enteroviruses. Enteroviruses are single-stranded RNA viruses and can cause a wide spectrum of diseases in humans. All enteroviruses are transmitted by the faecal-oral route but clinical outcomes may go beyond gastroenteritis as some viruses travel from the intestinal tract to other organs. Poliovirus usually infects its host by attacking the central nervous system and causing paralysis in victims (poliomyelitis). Coxsackievirus has been associated with not only respiratory system infections and gastroenteritis but also insulin-dependent diabetes and heart diseases such as myocarditis and pericarditis. Echovirus is generally less infectious than other enteroviruses and is usually associated with the common cold and respiratory diseases. The numbered enteroviruses (enterovirus types 68 to 71) have not been studied extensively but have been isolated from patients with bronchiolitis, conjunctivitis, meningitis, and paralysis resembling poliomyelitis.

PRINCIPLE OF THE TEST

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

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

MATERIALS PROVIDED

- PL.3113 Proflow™ Enterovirus Test Devices: 20 devices
- PL.3213 Proflow™ Enterovirus 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 2-30ºC.
- 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).
- 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, faecal 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, aspirate the sample 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™ Enterovirus 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).

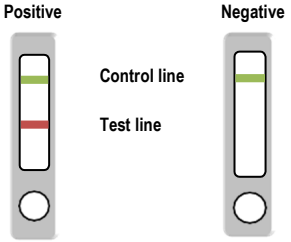
INTERPRETATION OF RESULTS

Positive

A pink/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 enterovirus antigen.

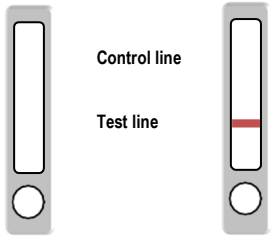
Negative

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 enterovirus 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.



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

- Proflow™ Enterovirus test will only indicate the presence of enterovirus antigens in the sample (qualitative detection) and should be used for the detection of enterovirus antigens in faeces samples only. Neither the quantitative value nor the rate of increase in enterovirus antigen concentration can be determined by this test.
- An excess of faecal sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
- 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 enterovirus infection.
- After one month of infection, the viral load in faeces falls, making the sample less reactive. Faecal samples may be collected prior to the onset of symptoms or 24-48 hours after the onset of symptoms.
- If the patient has been recently vaccinated (for example against poliovirus), it could appear as a positive result.
- This test provides a presumptive diagnosis for enterovirus group infections. Results should be confirmed by a physician, taking into account the clinical and laboratory tests.

PERFORMANCE CHARACTERISTICS

EXPECTED VALUES

Enteroviral infections are more prevalent in children than in adults. Infections are reported to peak in summer and early autumn, which also coincides with increased water recreational activities and human contact with water.

SENSITIVITY AND SPECIFICITY

An evaluation was conducted comparing the results obtained using the Proflow™ Enterovirus test with 2 other commercial assays. The antibodies used in this evaluation recognise enterovirus epitopes found in faecal samples. The Proflow™ Enterovirus test showed:

Specificity >99%
Sensitivity >99%

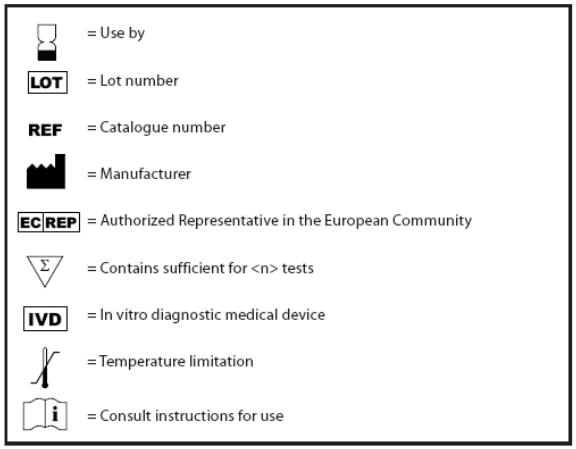
CROSS-REACTIVITY

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

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

REFERENCES

- Fong, T. et al. Enteric Viruses of Humans and Animals in Aquatic Environments: Health Risks, Detection, and Potential Water Quality Assessment Tools. *Microbiology and Molecular Biology Reviews*, June 2005;69, (2): 357-371.
- Afffi, S. et al. Isolation and Identification of Non-Polio Enteroviruses from Children in Different Egyptian Governorates. *Australian Journal of Basic and Applied Sciences*, 2009; 3, (4): 3230-3238.



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