Proflow™ Cryptosporidium

(for *In Vitro* Diagnostic use only)

PRODUCT CODE PL.3020 **20 Tests**

INTENDED USE

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

SUMMARY AND EXPLANATION

Cryptosporidiosis is a diarrhoeal disease caused by microscopic parasites of the genus *Cryptosporidium*. Once an animal or person is infected, the parasite lives in the intestine and passes in the faeces. The parasite is protected by an outer shell that allows it to survive outside the body for long periods of time and makes it very resistant to chlorine- based disinfectants.

PRINCIPLE OF THE TEST

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

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

MATERIALS PROVIDED

- PL.3120 Proflow™ Cryptosporidium Test Devices: 20 devices
- PL.3220 Proflow™ Cryptosporidium 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).
- 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.
- Make sure that samples are not treated with solutions containing formaldehyde or its derivatives.

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, 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™ Cryptosporidium 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).

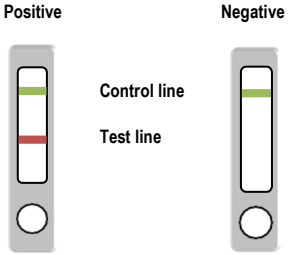
INTERPRETATION OF RESULTS

Positive

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 Cryptosporidium antigen.

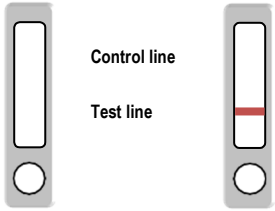
Negative

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 Cryptosporidium 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 any 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

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LIMITATIONS OF THE PROCEDURE

- The Proflow™ Cryptosporidium test will only indicate the presence of Cryptosporidium parasites in the sample (qualitative detection) and should only be used for the detection of Cryptosporidium antigens in faecal samples. Neither the quantitative value nor the rate of increase in Cryptosporidium 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.
- Do not use samples treated with solutions containing formaldehyde or its derivatives.
- 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 cryptosporidiosis.
- After one week of infection, the number of parasites in faeces falls, making the sample less reactive. Faeces samples should be collected within one week of the onset of symptoms.
- This test provides a presumptive diagnosis of cryptosporidiosis. All results must be interpreted together with other clinical information and laboratory findings available to the clinician.

PERFORMANCE CHARACTERISTICS

EXPECTED VALUES

Cryptosporidium has caused several large waterborne disease outbreaks of gastrointestinal illness, with symptoms including diarrhoea, nausea and stomach cramps. People who are severely immunocompromised are likely to have more severe and persistent symptoms than healthy individuals.

SENSITIVITY AND SPECIFICITY

An evaluation was conducted using the Proflow™ Cryptosporidium test. The samples were confirmed with microscopy technique/PCR. Proflow™ Cryptosporidium test showed:

Specificity >99%
Sensitivity >99%

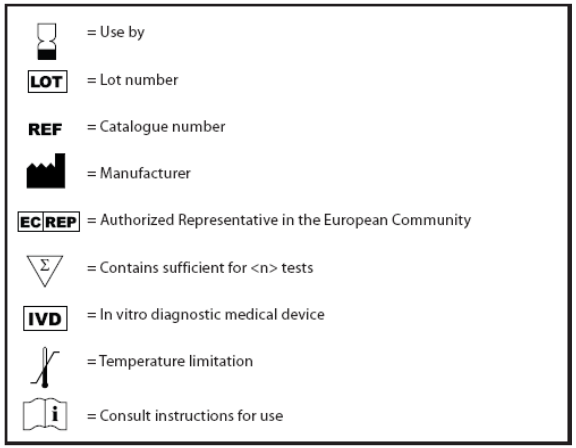
CROSS-REACTIVITY

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

- Campylobacter
- *Clostridium difficile*
- *Entamoeba histolytica*
- *Escherichia coli*
- *Giardia lamblia*
- *Helicobacter pylori*
- Listeria
- Salmonella
- Shigella
- *Staphylococcus aureus*

REFERENCES

- Copue S., Delabre K., Pouillot R. et al. Detection of Cryptosporidium, Giardia and Enterocytozoon bieneusi in surface water, including recreational areas: a one year prospective study: *FEMS Immunol Med Microbiol*. 2006; 47:351-9.
- Hill D.R. and Nash T.E. Intestinal Flagellate and Ciliate Infections. In: Guerrant R.L., Walker D.H., Weller P.F. eds. *Tropical Infectious Diseases. Principles, Pathogens & Practice*. 2nd ed. Elsevier, Philadelphia. 2006:984-8.



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