Proflow™ *E. coli*

(for *In Vitro* Diagnostic use only)

PRODUCT CODE PL.3015 **20 Tests**

INTENDED USE

The Proflow™ *E. coli* test is a single use rapid membrane immunoassay for the qualitative detection of *E. coli* O157 antigen in faeces samples to aid in the diagnosis of *E. coli* O157 infection. For *In Vitro* Diagnostic Use.

SUMMARY AND EXPLANATION

E. coli O157:H7 is one of hundreds of strains of the bacterium *Escherichia coli*. Although most strains are harmless, this strain produces a powerful toxin that can cause severe illness. *E. coli* O157:H7 has been found in the intestines of healthy cattle, deer, goats and sheep.

E. coli O157:H7 was first recognised as a cause of illness in 1982 during an outbreak of severe bloody diarrhoea; the outbreak was traced to contaminated hamburgers. Since then, more infections worldwide have been caused by eating undercooked ground beef than by any other food.

PRINCIPLE OF THE TEST

The Proflow™ *E. coli* test is a single use rapid membrane immunoassay for the qualitative detection of *E. coli* O157 antigen in human faeces samples.

Monoclonal antibodies to *E. coli* O157 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 *E. coli* O157 antigen is present in the sample. A negative test result, read at 10 minutes, will show only a green control line, indicating that *E. coli* O157 antigen was not detectable in the sample.

MATERIALS PROVIDED

- PL.3115 Proflow™ *E. coli* Test Devices: 20 devices
- PL.3215 Proflow™ *E. coli* Sample Preparation Devices: 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, 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™ *E. coli* 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).

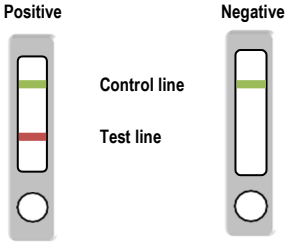
INTERPRETATION OF RESULTS

Positive

A pink/red line of any intensity appears in the test window at the test line position; a green line will appear at the control line position. This indicates a reactive result that is interpreted as positive for *E. coli* O157 antigen.

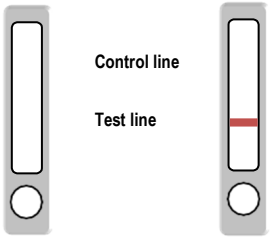
Negative

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 *E. coli* O157 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

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LIMITATIONS OF THE PROCEDURE

- The Proflow™ *E. coli* test will only indicate the presence of *E. coli* O157 in the sample (qualitative detection) and should be used for the detection of *E. coli* O157 antigens in faeces samples only. Neither the quantitative value nor the rate of increase in *E. coli* 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 *E. coli* O157 infection.
- This test provides a presumptive diagnosis of *E. coli* O157. All results must be interpreted together with other clinical information and laboratory findings available to the clinician.

PERFORMANCE CHARACTERISTICS

EXPECTED VALUES

Escherichia coli O157:H7 is a leading cause of foodborne illness. Based on a 1999 estimate, 73,000 cases of infection and 61 deaths occur in the US every year.

SENSITIVITY AND SPECIFICITY

An evaluation was conducted using the Proflow™ *E. coli* test, confirmed by culture. Proflow™ *E. coli* test showed:

Specificity >85%
Sensitivity >99%

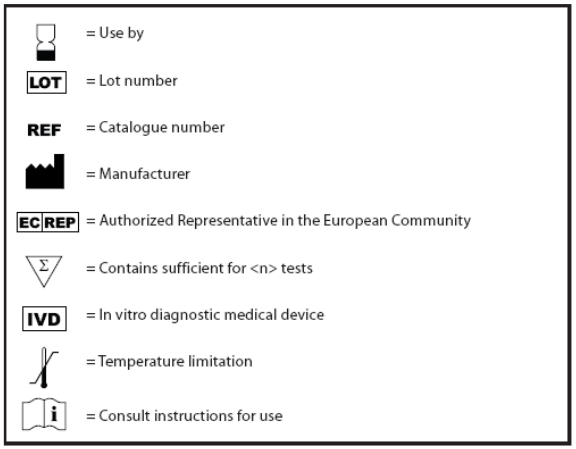
CROSS-REACTIVITY

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

- Campylobacter
- *Citrobacter freundii*
- *Clostridium difficile*
- *Escherichia coli*
- *Helicobacter pylori*
- *Klebsiella pneumoniae*
- *Listeria monocytogenes*
- *Morganella morganii*
- *Proteus mirabilis*
- Salmonella
- Shigella
- *Staphylococcus aureus*
- *Yersinia enterocolitica*

REFERENCES

- Rangel J.M., Sparling P.H., Crowe C., Griffin P.M. and Swerdlow D.L. Epidemiology of Escherichia coli O157:H7 outbreaks, United States, 1982–2002. *Emerg. Infect. Dis.* 2005; 11: pp603–609.
- Griffin P.M. The Epidemiology of infections caused by Escherichia coli O157:H7, other enterohemorrhagic E. coli, and the associated hemolytic uremic syndrome. *Epidemiol. Rev,* 1991; 13: pp60-98.



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