Proflow™ Salmonella

(for *In Vitro* Diagnostic use only)

PRODUCT CODE PL.3017 **20 Tests**

INTENDED USE

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

SUMMARY AND EXPLANATION

Clinical syndromes in humans caused by infection with *Salmonella enterica* are divided into typhoid fever, caused by *S. enterica* serovars Typhi and Paratyphi, and a range of clinical syndromes, including diarrhoeal disease, caused by the non-typhoid salmonellae (NTS) of which there are around 2,500 serovars. Typhoid fever is a human-restricted and highly adapted invasive systemic disease of adults and children that shows little association with immunosuppression. In contrast, NTS have a broad vertebrate host range and epidemiology that often involves food animals, and it usually presents as gastroenteritis.

The Proflow™ Salmonella test provides rapid detection of Salmonella species directly from faecal samples.

PRINCIPLE OF THE TEST

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

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

MATERIALS PROVIDED

- PL.3117 Proflow™ Salmonella Test Devices: 20 devices
- PL.3217 Proflow™ Salmonella 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 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 (maximum 1 year).
- 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 faecal 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™ Salmonella 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).

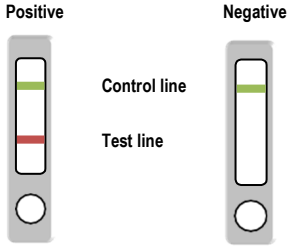
INTERPRETATION OF RESULTS

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 Salmonella antigen.

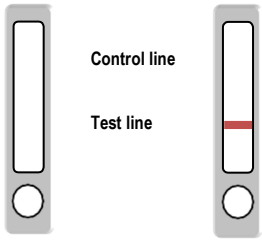
Negative

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 Salmonella 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

- Proflow™ Salmonella test will only indicate the presence of Salmonella in the sample (qualitative detection) and should be used for the detection of Salmonella antigens in faeces samples only. Neither the quantitative value nor the rate of increase in Salmonella 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 faecal 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 Salmonella infection.
- Salmonella determination should be carried out on the sample by enrichment culture.
- This test provides a presumptive diagnosis of salmonellosis. A confirmed infection diagnosis should only be made by a clinician after all clinical and laboratory findings have been evaluated and must be based on the correlation of the results with further clinical observations.

PERFORMANCE CHARACTERISTICS

EXPECTED VALUES

Typhoid fever and salmonellosis are public health problems in developing countries, where the incidence of cases per year is 200-500 per 100,000. Transmission occurs by contamination of water or food with bacteria. Animals and humans are the principal reservoirs.

LIMIT OF DETECTION

The detection limit range for different Salmonella species are as follows:

- *S. enteritidis* 3.34x107 CFU/mL
- *S. typhimurium* 6.15x106 CFU/mL
- *S. typhi* 2.26x109 CFU/mL
- *S. paratyphi* A 2.15X106 CFU/mL
- *S. paratyphi* B 3.68X104 CFU/mL

SENSITIVITY AND SPECIFICITY

An evaluation was conducted comparing the results obtained using the Proflow™ Salmonella test with another commercially available membrane immunoassay. Proflow™ Salmonella test showed:

Specificity >97%
Sensitivity >99%

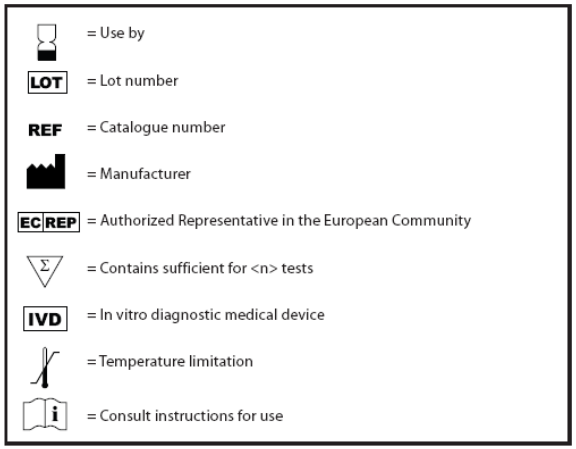
CROSS-REACTIVITY

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

- Campylobacter
- *Clostridium difficile*
- *Escherichia coli* O157:H7
- *Helicobacter pylori*
- *Listeria monocytogenes*
- Shigella
- *Staphylococcus aureus*
- *Yersinia enterocolitica*

REFERENCES

- Gordon M. et al. Invasive salmonellosis in Malawi. *J Infect Developing Countries* 2008; Vol 2, No 6: pp438-442.
- Sanchez-Jimenez M. et al. Validation of a PCR for diagnosis of typhoid fever and salmonellosis by amplification of the hilA gene in clinical simples from Colombian patients. *Journal of Medical Microbiology* 2004; Vol 53: pp875–878.



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