Proflow™ Faecal Occult Blood (FOB)

(for *In Vitro* Diagnostic use only)

PRODUCT CODE PL.3027 **20 Tests**

INTENDED USE

The Proflow™ Faecal Occult Blood (FOB) test is a single use rapid membrane immunoassay for the qualitative detection of human haemoglobin in human faecal samples. It may be used to screen for gastrointestinal bleeding, which may be an indicator of colorectal cancer, gastric cancer or peptic ulcers. For *In Vitro* Diagnostic Use.

SUMMARY AND EXPLANATION

Colorectal cancer is cancer that occurs in the colon or rectum, and affects both men and women of all racial and ethnic groups. It is most often found in people aged 50 years or older. For men, colorectal cancer is the third most common cancer after prostate and lung cancers. For women, colorectal cancer is the third most common cancer after breast and lung cancers.

Blood in faeces may be the only symptom of colorectal cancer, but not all blood in faeces is caused by cancer. Other conditions that can cause blood in faeces include: haemorrhoids, anal fissures, colon polyps, peptic ulcers and ulcerative colitis, gastro-oesophageal reflux disease (GORD), Crohn's disease, use of aspirin or nonsteroidal anti-inflammatory drugs (NSAIDs).

PRINCIPLE OF THE TEST

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

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

MATERIALS PROVIDED

- PL.3127 Proflow™ FOB Test Devices: 20 devices
- PL.3227 Proflow™ FOB 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.
- 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. 15 mg, and put back into the sample preparation device with buffer. For liquid faecal samples, aspirate with a dropper and add 15 µL into the sample preparation device.
2. Shake the sample preparation device to ensure good sample dispersion.
3. Remove the Proflow™ FOB 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).

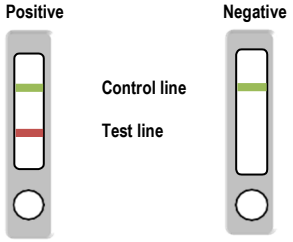
INTERPRETATION OF RESULTS

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 human haemoglobin.

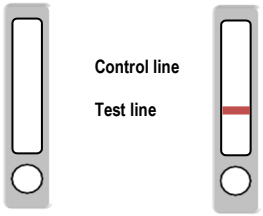
Negative

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 human haemoglobin.



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

- Proflow™ FOB test will only indicate the presence of human haemoglobin in the sample (qualitative detection) and should be used for the detection of haemoglobin in faecal samples only. Neither the quantitative value nor the rate of increase in haemoglobin 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.
- Patients should not collect samples during their menstrual period, if they have bleeding haemorrhoids, blood in urine, or if they have strained during bowel movement.
- This test may be less sensitive for detecting upper gastrointestinal bleeding because blood degrades as it passes through the gastrointestinal tract.
- Negative results do not exclude bleeding since some polyps and colorectal cancers may bleed intermittently or not at all during certain stages of the disease. Additionally, blood may not be uniformly distributed in faecal samples.
- Positive results confirm the presence of haemoglobin in faecal samples. Nevertheless, it can be due to several causes besides colorectal bleeding, such as haemorrhoids, anal fissures, colon polyps, peptic ulcers, ulcerative colitis, gastro-oesophageal reflux disease (GORD) or Crohn's disease. All positive results should be followed up with additional testing by a clinician to determine the exact cause and source of the blood in the faeces.

PERFORMANCE CHARACTERISTICS

EXPECTED VALUES

Colorectal cancer affects both men and women of all racial and ethnic groups, and is most often found in people aged 50 or older. For men, colorectal cancer is the third most common cancer after prostate and lung cancers. For women, colorectal cancer is the third most common cancer after breast and lung cancers.

CUT-OFF VALUE

The cut-off value for the Proflow™ FOB test is 50 ng/ml (5.1µg hHb/g faeces) for human haemoglobin.

SENSITIVITY AND SPECIFICITY

An evaluation was conducted comparing the results obtained using the Proflow™ FOB test with a commercially available test. Proflow™ FOB test showed:

Specificity >99%
Sensitivity >99%

CROSS-REACTIVITY

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

- Calprotectin (human)
- Haemoglobin (bovine / pig)
- Lactoferrin (human / bovine)
- Transferrin (human / bovine / pig)

No special diet is recommended prior to testing. There are no interferences with any foods (vitamin C, broccoli, carrots…) or supplements (iron).

REFERENCES

- Walker C.W. Fecal occult blood tests reduce colorectal cancer mortality:, *Am Fam Physician*. Jun 2007;75 (11):1652-3.

= Use by
LOT = Lot number
REF = Catalogue number
= Manufacturer
EC REP = Authorized Representative in the European Community
= Contains sufficient for <n> tests
IVD = In vitro diagnostic medical device
= Temperature limitation
= Consult instructions for use

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