INTENDED USE
The Proflow™ Faecal Occult Blood (FOB) test is a single use rapid membrane immunomassay for the qualitative detection of human haemoglobin in faecal samples. It may also 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. Blood in faeces may be the only symptom of colorectal cancer, but not all blood in faeces is caused by cancer. Other causes of diarrhoea include: Crohn’s disease, peptic ulcers and ulcerative colitis. Celiac 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 appear at the control line position. If both test and control lines are present, the test result is negative.

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

MATERIALS PROVIDED
• PL3127 Proflow™ FOB Test Devices: 20 devices
• PL3127 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 2-30°C.
• 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.

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 two or three times into the faecal sample to pick up the sample. Shake the sample preparation device to ensure good sample dispersion.
2. Remove the Proflow™ FOB test from its sealed pouch.
3. Break off the top of the vial on the sample preparation device.
4. Dispense 4 drops into the sample well on the test (S).
5. 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 that 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 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.

LIMITATIONS OF THE PROCEDURE
(for In Vitro Diagnostic use only)

Do not interchange reagents between kits with different lot numbers.
Reagents are provided at the necessary working strength. Do not dilute.
Tests are for single use only. Do not reuse.
For professional use only.
For In Vitro Diagnostic Use only.
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)
• 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.

PL.3127 Proflow™ FOB Test Devices: 20 devices
Proflow™ Faecal Occult Blood (FOB)
INTENDED USE
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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. 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: Crohn’s disease, anal fissures, colon polyps, peptic ulcers and ulcerative colitis, gastrointestinal 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 appear at the control line position. If both test and control lines are present, the test result is negative.

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

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• Store all components at 2-30°C.
• 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.

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 two or three times into the faecal sample 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 4 drops 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 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.

LIMITATIONS OF THE PROCEDURE
(for In Vitro Diagnostic use only)

Do not interchange reagents between kits with different lot numbers.
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PL.3127 Proflow™ FOB Test Devices: 20 devices
Proflow™ Faecal Occult Blood (FOB)
PERFORMANCE CHARACTERISTICS

SENSITIVITY AND SPECIFICITY
An evaluation was conducted comparing the results obtained using the Proflow™ FOB test with a commercially available guaiac assay and other commercial membrane immunoassay tests.

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 or other organisms occasionally present in faeces:
- Rotavirus
- Adenovirus
- Astrovirus
- E. coli
- Campylobacter
- Giardia lamblia.

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

REFERENCES