Proflow™ FOB-Transferrin

(for *In Vitro* Diagnostic use only)

PRODUCT CODE PL.3028 **20 Tests**

INTENDED USE

The Proflow™ FOB-Transferrin test is a single use rapid membrane immunoassay for the qualitative detection of human haemoglobin (faecal occult blood) and transferrin in human faecal samples to aid in the diagnosis of bleeding gastrointestinal disorders. 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, and 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.

Faecal occult blood (FOB) should be an important indicator in the diagnostic evaluation of patients with suspected gastrointestinal bleeding of any aetiology, not just as an indication of colorectal cancer. The presence of human haemoglobin in faeces is inadequate as a screening test for stomach cancer (upper gastrointestinal disorders), because human haemoglobin derived from the upper digestive tract is broken down in the intestinal tract (the antigenicity is lost). Detection of faecal transferrin, which is more stable in faeces than haemoglobin, provides an alternative way of diagnosing the disease in the upper digestive tract.

Blood in faeces may be the only symptom of 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, ulcerative colitis, gastro-oesophageal reflux disease (GERD), Crohn's disease, and use of non-steroidal anti-inflammatory drugs (NSAIDs).

PRINCIPLE OF THE TEST

The Proflow™ FOB-Transferrin test is a single use rapid membrane immunoassay for the qualitative detection of human haemoglobin and human transferrin in human faeces.

Specific antibodies to human haemoglobin and human transferrin 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 transferrin result will show a pink/red test line and a green control line, indicating that transferrin is present in the sample. A positive haemoglobin result will show a red test line and a green control line, indicating that haemoglobin is present in the sample. A negative test result, read at 10 minutes, will show only a green control line, indicating that neither human haemoglobin nor human transferrin were detectable in the sample.

MATERIALS PROVIDED

- PL.3128 Proflow™ FOB-Transferrin Test Devices: 20 devices
- PL.3228 Proflow™ FOB-Transferrin 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 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 faeces 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-Transferrin 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 Transferrin

One pink/red line of any intensity will appear at the test line; a green line will appear at the control line. This indicates a reactive result that is interpreted as positive for transferrin.

Positive Haemoglobin

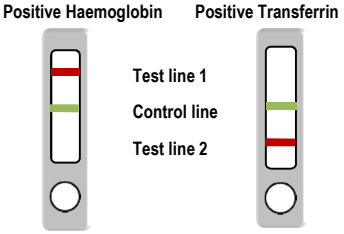
One red line of any intensity will appear at the test line; a green line will appear at the control line. This indicates a reactive result that is interpreted as positive for human haemoglobin.

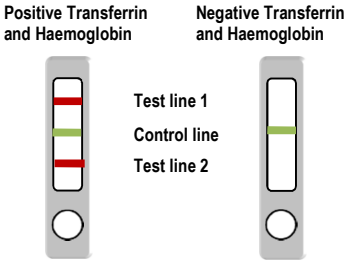
Positive Transferrin-Haemoglobin

One pink/red line and one red line of any intensity will appear at the test line positions; a green line will appear at the control line. This indicates a reactive result that is interpreted as positive for transferrin and human haemoglobin.

Negative

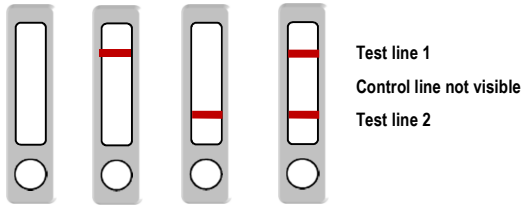
A single green line of any intensity appears in the test window at the control line position. There is no line at the test line position. This indicates a non-reactive result that is interpreted as negative for both transferrin and human haemoglobin.





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 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 Fax +44 (0)151 353 1614
3 Bassendale Road, Bromborough, Wirral, CH62 3QL

Revision: 2021 10

LIMITATIONS OF THE PROCEDURE

- The Proflow™ FOB-Transferrin test will only indicate the presence of human haemoglobin or/and transferrin in the sample (qualitative detection) and should be used for the detection of human haemoglobin and transferrin in faecal samples only. Neither the quantitative value nor the rate of increase in haemoglobin or transferrin 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.
- 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 occult blood 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) and 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. Endoscopy is the method of choice in diagnosing the cause of upper and lower gastrointestinal bleeding.

PERFORMANCE CHARACTERISTICS

EXPECTED VALUES

Common causes of upper GI bleeding include duodenal ulcer (20-30%), gastric or duodenal erosions (20-30%), varices (15-20%), gastric ulcer (10-20%), erosive esophagitis (5-10%), angioma (5-10%), arteriovenous malformation (<5%), and gastrointestinal stromal tumours.
Common causes of lower GI bleeding (percentages vary with the age group sampled) include anal fissures, angiodysplasia (vascular ectasia), colitis (radiation / ischemic / infectious), colonic carcinoma, colonic polyps, diverticular disease, inflammatory bowel disease (ulcerative / proctitis / colitis), Crohn's disease, and internal haemorrhoids.

CUT-OFF VALUE

The cut-off value for the Proflow™ FOB-Transferrin test is 50 ng/ml (5.1µg hHb/g faeces) for human haemoglobin, and 4 ng/ml (0.4µg hTf/g faeces) for human transferrin.

SENSITIVITY AND SPECIFICITY

An evaluation was conducted comparing the results obtained by the Proflow™ FOB- Transferrin test with other commercially available immunoassay tests. The Proflow™ FOB-Transferrin test showed:

Specificity	>99% for Transferrin
	>99% for human Haemoglobin
Sensitivity	>99% for Transferrin
	>99% for human Haemoglobin

CROSS-REACTIVITY

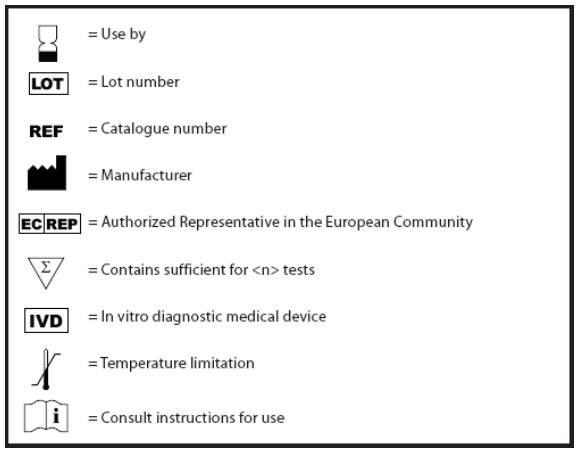
An evaluation was performed to determine the cross-reactivity of the Proflow™ FOB- Transferrin test. There was no cross-reactivity with common gastrointestinal pathogens, other organisms and substances occasionally present in faeces:

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

- Chiang C-H et al. A comparative study of three fecal occult blood tests in upper gastointestinal bleeding; *Kaohsiung J. Med. Sci*. May 2006, 22(5): 223-8.
- Miyoshi H et al. Accuracy of Detection of Colorectal Neoplasia using an Immunochemical Occult Blood Test in Symptomatic Referred Patients: Comparison of Retrospective and Prospective Studies. *Internal Medicine* Sept. 2000; 39 (9): 701-6.
- Walker C.W. Fecal occult blood tests reduce colorectal cancer mortality: *Am Fam Physician*. Jun 2007; 75(11):1652-3.



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