



## Gastrointestinal



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0483

# berkeleyhealth BOWEL FOB

Self-test for the detection of occult blood in the faeces



### FOB (FAECAL OCCULT BLOOD)

Faecal Occult Blood (FOB) is the presence in the faeces of blood that is not clearly visible to the naked eye. Occult blood may be the consequence of gastro-intestinal disorders such as ulcers, polyps, colitis, diverticulitis, rhagades, haemorrhoids or cancer. The signs of these lesions are often silent in the first phases, so searching for occult blood in the stool is an important screening test, which allows to identify the presence of pathologies in the gastro-intestinal system at an early stage.

### WHO ARE THE INTENDED USERS

Everyone, especially over 45 years.

### WHY - BENEFITS

Sometimes, the presence of low quantity of blood in stools is not easily noticeable. In these cases BOWEL FOB TEST is useful to detect the presence of blood in the stools even if they look normal in order to prevent more serious diseases.

### TEST PRINCIPLE

BOWEL FOB TEST is an immunochromatographic test that detects the smallest amounts of blood in stool samples by using highly specific monoclonal antibodies. These properties mean that the BOWEL FOB TEST does not require particular dietary restrictions before being carried out.

### TECH SPECS

| CUT-OFF  | SENSITIVITY | SPECIFICITY | OVERALL ACCURACY |
|----------|-------------|-------------|------------------|
| 40 ng/mL | 78.7%       | 99%         | 92.6%            |

Performance data obtained by clinical study with 148 participants enrolled. Hb Fecale - Mascia Brunelli kit has been utilized as reference method.

### CONTENT:

1 sealed aluminium pouch containing: 1 test device and 1 desiccant bag; 1 vial with collection stick and dripper, containing the diluent; 1 small sheet for the collection of the stool sample; 1 instructions for use leaflet.

### CLINICAL EVIDENCES

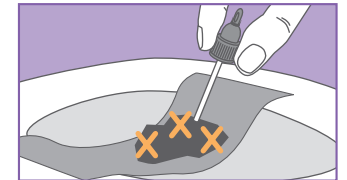
1. Van Rossum Leo G. et al.: "Random Comparison of Guaiac and Immunochemical Faecal Occult Blood Tests for Colorectal Cancer in a Screening Population" *Gastroenterology*, Volume 135, Issue 1, 82 – 90.
2. Faivre J., Dancourt V., Denis B., Dorval E., Piette C., Perrin P., Bidan J.M., Jard C., Jung S., Levillain R., Viguier J., Bretagne J.F.: "Comparison between a guaiac and three immunochemical faecal occult blood tests in screening for colorectal cancer". *European Journal of Cancer*. 2012; 48(16):2969-76.
3. Benton S.C., Seaman H.E., Halloran S.P.: "Faecal Occult Blood Testing for Colorectal Cancer Screening: the past or the Future". *Current Gastroenterology Reports*. 2015; 17(2):428
4. European Commission. *European guidelines for quality assurance in colorectal cancer screening and diagnosis*. First edition 2010

### HOW TO USE IT

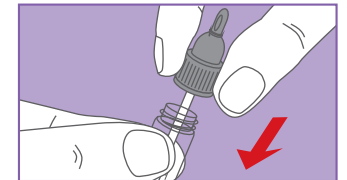
1) Attach the two adhesive surfaces of the stool-collecting sheet on the toilet seat surface.



2) Dip the stick into the faeces in three different points of the sample.



3) Screw on the cap, immersing the stick in the stool extraction liquid, and shake the vial.



4) Break the end of the cap, freeing the dropper portion. Dispense 3 drops of the diluted stool sample in the well shown on the cassette.

