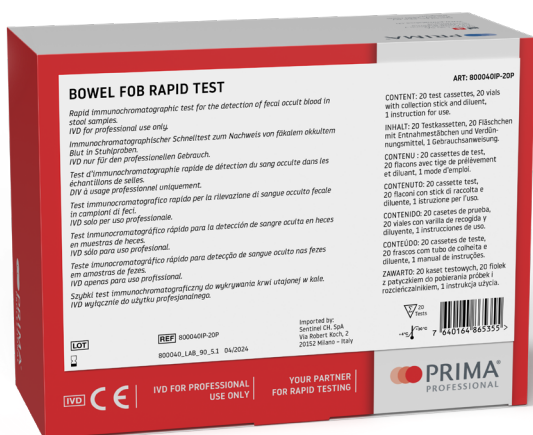




## BOWEL FOB RAPID TEST

Rapid immunochromatographic test for the detection  
of fecal occult blood in stool samples



### FOB (FAECAL OCCULT BLOOD)

Faecal Occult Blood (FOB) is the presence in the faeces of blood which is not clearly visible to the naked eye. FOB may be the consequence of gastrointestinal disorders, such as ulcers, polyps, colitis, diverticulitis, rhagades, haemorrhoids or even colorectal cancer (CRC). CRC is the second most frequent malignant disease in Europe: more than 400.000 people are diagnosed with this condition every year.

The signs of these lesions and disorders are often silent in the first phases, then searching for occult blood in the stool is an important early screening test.

### WHO ARE THE INTENDED USERS

Healthcare professionals with patients who present symptoms related to gastrointestinal disorders. The test is also recommended as check-up screening test from 45 years of age.

### TEST PRINCIPLE

BOWEL FOB RAPID TEST is a rapid immunochromatographic lateral flow assay for the detection of the smallest amounts of blood in faeces samples, thanks to special gold conjugate antibodies embedded to a test strip.

### TECH SPECS

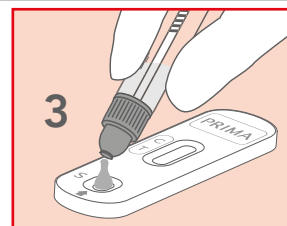
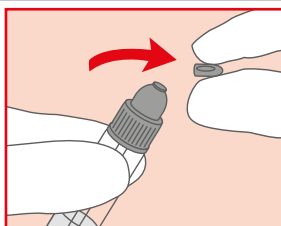
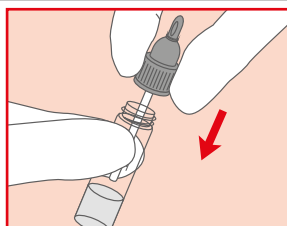
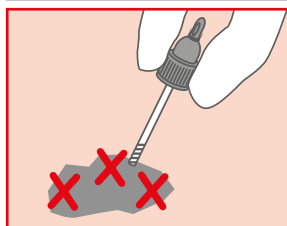
| CUT-OFF  | SENSITIVITY | SPECIFICITY | OVERALL ACCURACY |
|----------|-------------|-------------|------------------|
| 40 ng/mL | 78,70%      | 99,00%      | 92,60%           |

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

### CLINICAL EVIDENCES

1. Van Rossum Leo G. et al.: "Random Comparison of Guaiac and Immunochemical Fecal 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., Viguiere 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



**CONTENT:** 20 test cassettes; 20 vials with collection stick and diluent; 1 instructions for use leaflet.

| REF          | DESCRIPTION          | NUMBER OF TESTS | SHELF LIFE |
|--------------|----------------------|-----------------|------------|
| 800040IP-20P | BOWEL FOB RAPID TEST | 20 TESTS        | 30 MONTHS  |