PRODUCT INFORMATION

HEMDETECT IMMO

Immunological One Step Rapid Test
for the qualitative detection
of human occult blood in feces

REF D596091 25 x 1 test kits

IVD

INTENDED USE

The HEMDETECT IMMO - FOB Test is a rapid chromatographic immunoassay for the qualitative detection of human occult blood in feces.

SUMMARY

Most of diseases can cause hidden blood in the stool. In the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood. Traditional guaiac-based method lacks sensitivity and specificity, and has diet-restriction prior to the testing.

The HEMDETECT IMMO - FOB Test is a rapid test to qualitatively detect lower levels of fecal occult blood in feces. The test uses double antibody sandwich assay to selectively detect above 50 ng/ml occult blood in specimen. In addition, unlike the guaiac assays, the accuracy of the test is not affected by the diet of the patients.

PRINCIPLE

The HEMDETECT IMMO - FOB Test is a qualitative, lateral flow immunoassay for the detection of human occult blood in feces. The membrane is pre-coated with anti-hemoglobin antibody on the test line region of the device. During testing, the specimen reacts with the particle coated with anti-hemoglobin antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-hemoglobin antibody on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occured.

REAGENTS

The test device contains anti-hemoglobin antibody particles and anti-hemoglobin antibody coated on the membrane.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.

PATIENT PREPARATION

- Specimen should not be collected during or within three days of a menstrual period, or if the patient suffers from bleeding hemmorhoids or blood in the urine.
- Alcohol, aspirin and other medications taken in excess may cause gastrointestinal irritation resulting in occult bleeding. Such substances should be discontinued at least 48 hours prior to testing.
- Dietary restrictions are not necessary.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2–30° C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The HEMDETECT IMMO - FOB Test can be performed only using stool.
- SAMPLE COLLECTION: randomly collect feces in a clean, dry receptacle. Unscrew the cap of the collection tube. Randomly insert the stick of the cap into the fecal specimen on at least 3 different sites. Screw on and tighten the cap to the collection tube. Shake the tube vigorously to mix the specimen and the extraction buffer.
- Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2–8°C if not tested within 6 hours.

MATERIALS

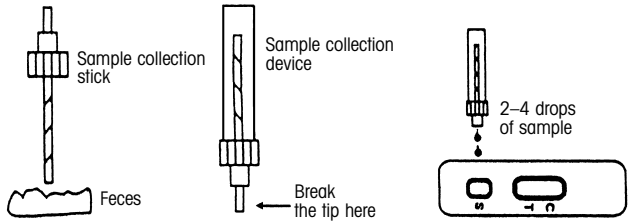
Materials provided: Test device, Specimen collection container with extraction buffer, Package insert.

Materials required but not provided: Timer.

DIRECTIONS FOR USE

Allow test device, stool specimen, extraction buffer to equilibrate to room temperature (15–30° C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. After collecting stool samples, place the test device on a clean and level surface, break off the tip of the collection tube and transfer 2–4 full drops of the extracted sample (approx. 90 μl) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the red line(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

* NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of hemoglobin present in the specimen. So any shade in the test region indicates positive result.

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATION

1. The HEMDETECT IMMO - FOB Test is for in vitro diagnostic use only.
2. The HEMDETECT IMMO - FOB Test will only indicate the presence of human hemoglobin in the specimen and the presence of blood in stool may be other than colorectal bleeding.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. Other clinically available tests are required if questionable results are obtained.

EXPECTED VALUES

The HEMDETECT IMMO - FOB Test has been compared with another leading commercial fast tests. The correlation between these two systems is 98%.

PERFORMANCE CHARACTERISTICS

Sensitivity: The HEMDETECT IMMO - FOB Test can detect the levels of human occult blood as low as 50 ng/ml hemoglobin or 6 μg hemoglobin/g feces.

Spezificity: The HEMDETECT IMMO - FOB Test is specific to human hemoglobin. Samples containing the following substances were tested on both positive and negative controls with no effect on the results:

Substances	Concentrations (Dilute by the extraction buffer)
Bovine hemoglobin	1 mg/ml
Chicken hemoglobin	1 mg/ml
Pork hemoglobin	1 mg/ml
Goat hemoglobin	1 mg/ml
Horse hemoglobin	1 mg/ml
Rabbit hemoglobin	1 mg/ml
Turkey hemoglobin	1 mg/ml

BIBLIOGRAPHY

1 Simon J.B. Occult Blood Screening for Colorectal Carcinoma: A Critical Review; Gastroenterology, Vol. 1985;88:820

2 Blebea J. and Nepherson RA, False-Positive Guaiac Testing With Iodine, Arch Pathol Lab Med, 1985;109:437-40

596091infoE1
01-06-2005

CE

Explanation of Symbols					
	Read instructions for use	2° 30	Store at 2–30°C	CE	IVD Directive 98/97/EC
IVD	In vitro diagnostic	REF	Reference/ Product Number		Used by
RGT	Reagent		Use only once	LOT	Lot Number
					Manufacturer acc. to IVD-Directive 98/79/EC

DIPRO med Handels GmbH
Boschanstrasse 3, A-2484 Weigelsdorf, Austria
Tel.: +43/2254/72072 – Fax: +43/2254/72072-20
e-mail: dipro@dipro.co.at – www.dipro.co.at