PreventID® **Haemo/HaptOccult** Manual (FOR PROFESSIONAL USE)

→REF KST40112TP
KST40112GP
KST40112BW

Intended Use

The **PreventID® Haemo/HaptOccult** is a simple one step immunochromatographic assay for the rapid detection of human occult blood in faeces.

Test Principle

The **PreventID® Haemo/HaptOccult** employs a unique combination of monoclonal and polyclonal antibodies to selectively identify human hemoglobin (Hb) and hemoglobin-haptoglobin complex (Hp-Hb) in test samples with a high degree of sensitivity. The test sensitivity is 25 ng/ml for both Hb and for Hb-Hp.

Materials

Materials Provided

- test devices, individually packed TEST
- folding boxes; each contains 1 sample collection tube (with buffer) TUBE, 1 paper stool catcher for faecal samples, 1 identification label, 1 instruction for stool sample collection
- manual

Materials Required but not Provided: timer or stop watch

Storage and Stability

The **PreventID® Haemo/HaptOccult** test should be stored at room temperature (4–30 °C). The test device is susceptible to humidity and high temperatures. Therefore, this test should be protected from extreme temperature and should be run immediately after the opening of the pouch. This test should not be run after the expiry date.

Precautions

1. For *in vitro* diagnostic use only.
2. Do not eat or smoke while handling specimen.
3. Wear protective gloves and wash hands thoroughly after performing the test.
4. Avoid splashing or aerosol formation while handling specimen and performing the test.
5. All samples and materials used should be treated as potentially infectious and disposed in a biohazard container. Clean all contaminated objects and surfaces carefully.
6. Do not use test if the pouch is torn or if the membrane of the test device is visibly damaged. Do not use the test after expiry date.
7. Read the instruction carefully before performing the test.
8. Do not mix reagents from different lots
9. If you have any questions please contact Preventis GmbH.

Specimen Preparation

1. Specimen collection should not be performed during or within three days of a menstrual period, or if the patient suffers from bleeding gums or haemorrhoids or blood in the urine. These may cause false-positive results.
2. No dietary requirements.
3. Alcohol, aspirin and some medications sometimes cause gastrointestinal irritation or bleeding. Advise your patient prior to the test to prescribe a temporary dose reduction if necessary.

Specimen Collection

1. Collect a stool sample with the paper stool catcher attached to your toilet according to the manual. The sample must not get in contact with water or urine.
2. Unscrew the cap of the sample collection tube and stick the attached sample collection stick **in one go at three different sites into the faeces.** Only the amount of stool that sticks to the grooves of the sample collection stick should be transferred to the sample collection tube (see also *Fig. 1*).
3. Now retract the sample collection stick with the adhering faecal sample and insert it **only once** into the sample collection tube containing an extraction buffer solution.
   Please note: A repeated transfer of stool into the sample collection tube compromises the test performance!
4. Screw cap on firmly and shake well. This defined stool sample solution is now ready to use for the test.
5. If the **PreventID® Haemo/HaptOccult** rapid test is not run within one day of sample collection, the sample collection tube should be stored at 2–8 °C, but no longer than 3 days.

Test Procedure

1. Remove test device from its pouch and place it on a flat dry surface. The oval sample openings at the one end of the test device should be at the right side *(Fig.1–2)*.
2. After the sample collection procedure has been completed, the sample collection tube should be shaken well.
3. Break off the tip of the sample collection tube carefully (avoid dropping; *Fig. 1*). Squeeze **3 drops** of the extracted sample into each of both sample application windows on the right side of the test device *(Fig. 2)*.
4. In a properly working test, a violet line will pass through the square result window in the middle of the test device.
5. Read the result **10 minutes** after having squeezed the 3 drops. Do not interpret later.

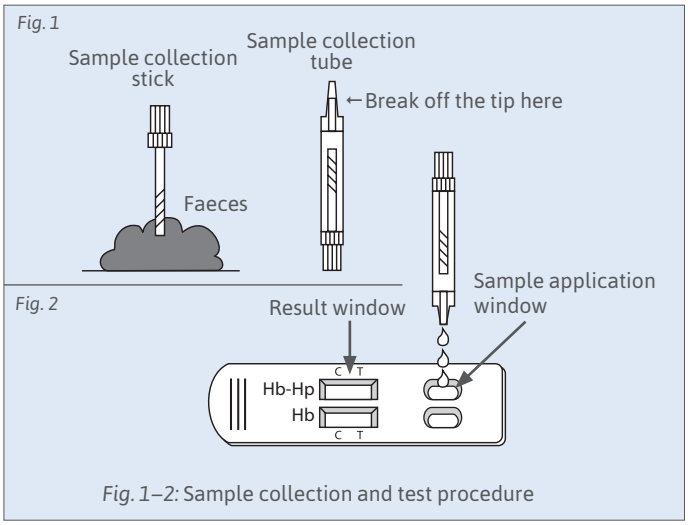

Fig. 1–2: Sample collection and test procedure

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Test Interpretation *(Fig. 3)*

The test result is indicated by the appearance or non-appearance of one or two coloured **test lines (T)** in the test areas of the result window.
A coloured **control line (C)** in the control area of the result window indicates that the test has run correctly.

Positive: If the control line (C) is visible along with either or both test lines (T) of the Hb and the Hb-Hp sections (no matter which line appears first), the test result is positive *(Fig. 3 a-c)*. Please note: This result does not automatically indicate the presence of colon cancer!

Negative: If only the control line (C) is visible within the result windows in both the Hb and the Hb-Hp sections, the test result is negative *(Fig. 3d)*.

Invalid: If no control lines are visible within the result window, even if test lines appear, the test is considered invalid (Fig. 3e-f). The instructions may not have been followed correctly or the test may have deteriorated. It is recommended to re-test the specimen with another test device.

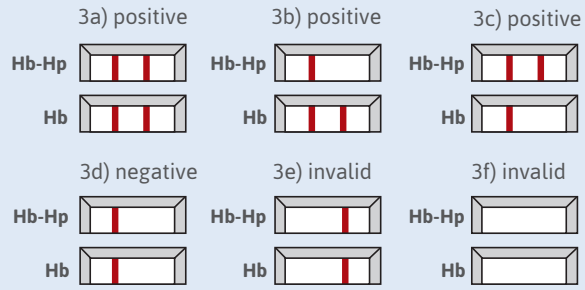

Fig. 3: Test Interpretation

Test Characteristics

Analytical Sensitivity and Specificity

Absolute Sensitivity of **PreventID® Haemo/HaptOccult** test to hemoglobin and hemoglobin-haptoglobin complex is 25 ng/ml of hemoglobin or hb-hp-complex. This was shown in spiking experiments with samples with 5 ng/ml, 10 ng/ml, 25 ng/ml, 50 ng/ml of hemoglobin and samples with 5 ng/ml, 10 ng/ml, 25 ng/ml, 50 ng/mlhb-hp-complex. The test shows positive results with hb or hb-hp-complex ≥ 25 ng/ml.

Analytical Specificity: the test showed no interference with spiking with the following substances: Acetamiophen, 20 mg/dl, Acetyl salicylic Acid, 20 mg/dl, Ascorbic Acid, 20 mg/dl, Atropine, 20 mg/dl, Bilirubin, 60 mg/dl, Caffeine, 20 mg/dl, Creatinine, 20 mg/dl, Gentesic Acid, 20 mg/dl, Glucose, 2000 mg/dl, Ketones, 40 mg/dl, Mestranol, 3 mg/dl, Nitrite, 20 mg/dl, Penicillin, 40,000 U/dl, Sodium Heparin, 3 mg/dl, Lithium Heparin, 3 mg/dl.

Clinical Sensitivity and Specifity

Relative Sensitivity/Specificity of the iFOBT with Gold-Standard Colonoscopy (n = 334), **PreventID® Haemo/HaptOccult** is considered to be Occult Blood Positive when either hemoglobin or hemoglobin-haptoglobin-complex is positive. A true positive result is defined as colorectal cancer (CRC) or adenomas > 1 cm diagnosed by colonoscopy.
61 out of 68 true positives were detected, meaning a sensitivity of 89.7 %. 264 out of 266 true negatives were detected, meaning a specificity of 99.2 %.

Test Limitations

Faecal blood may origin not only from colorectal cancer but also from haemorrhoids, blood in urine or gastric irritations.
Negative results do not rule out colorectal cancer because some polyps or adenomas bleed intermittently and blood may not be distributed homogeneously within the faecal sample and may thus be missed during sample collection.
Colorectal polyps may not bleed during very early stages. Other clinical tests are indicated in the case of unspecific results.
As with other diagnostic tests, a definitive clinical diagnosis should not be based on a single test result, but should be made by a qualified professional after evaluation of all clinical and laboratory findings.

References

1. Lüthgens K et al. (1998) Hemoglobin-Haptoglobin-Complex: a highly sensitive assay for the detection of fecal occult blood. Clin Lab 44: 543-551
2. Schirrmacher S et al. (2003) Faecal Hemoglobin-haptoglobin Complex Tests and Faecal Occult Blood Tests in Diagnosis of Inflammatory Bowel Disease, Colorectal Cancer and Adenoma. Abstract P4.54 of EUREGIO Congress of Clinical Chemistry and Laboratory Medicine, 08.-10.10.2003, Aachen
3. Sieg A et al. (1999) Detection of colorectial neoplasms by the highly sensitive hemoglobin-haptoglobin complex in feces.Int J Colorectal Dis 14: 267-271

Short instruction PreventID® Haemo/HaptOccult

1. Collect the faecal sample using the sample collection tube and the sample collection stick as described in the instruction.
2. Shake the solution in the sample collection tube very thoroughly.
3. Unpack the test device.
4. Break off the tip of the sample collection tube carefully. Squeeze **3 drops** of the extracted sample into each of both sample application windows.
5. Read the result at **10 minutes**.

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Status: 2018-11-20

US: all products: Research Use Only. Not for use in diagnostic procedures.

Temperature limitation	Manufacturer
In vitro diagnostic device	Lot number
Catalogue number	Expiry date
To be used with	Do not reuse
Read user instructions	Contains sufficient for <n> tests
Keep away from sunlight	

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