

# Directions for Use and Safety Data Sheet for Doctor and Specialist Staff

## INFORMATION ABOUT THE TEST:

### Intended Use:

HEMDETECT® is a guaiac-based in vitro test for the qualitative detection of occult blood in stool for evaluation in a laboratory or medical practice. The test serves for the detection of haemorrhage caused by intestinal diseases such as diverticulitis, colitis, polyps and colorectal carcinoma.

Tests for occult blood in stool are recommended for preventive medical examinations by the doctor, routine tests in hospital and screening tests for gastrointestinal haemorrhage associated with any condition, including colorectal carcinoma.

### Principle:

The use of guaiac resin for the detection of blood is based on the method of Irons et al.<sup>1</sup> and involves the formation of a blue colour as a result of colourless phenols present in guaiac resin being oxidised to coloured quinones. If blood is present in the stool sample, the haematin in the haemoglobin molecule catalyses the release of oxygen from the hydrogen peroxide and this oxygen leads in turn to oxidation of the phenolic components of the guaiac resin. If the sample material does contain blood, the indicator paper in the HEMDETECT® slide turns blue as soon as it is impregnated with the hydrogen peroxide developer solution. If the test field does not change colour, there is no occult blood in the sample.

### Summary and Explanation:

The HEMDETECT® Test is based on a modified guaiac method for detecting occult blood. If developer solution (stabilized hydrogen peroxide  $\leq 4\%$  in denatured ethanol  $> 60\%$ ) is applied to the test field of the HEMDETECT® Test, a blue colour indicates the presence of haemoglobin. If the result is positive, further tests are necessary in order to determine the cause of the haemorrhage. The HEMDETECT® guaiac test is a conventional, reasonably priced and aesthetic method for taking, storing and transporting stool samples to be tested for occult blood.

Guaiac tests cannot provide definitive proof either for the presence or for the absence of gastrointestinal haemorrhage or pathological processes. False positives or false negatives can occur as a result of failing to keep to the diet or of taking medication (see *PREPARING OF THE PATIENT*).

This test is conceived as a preventive medical examination and not as a replacement for other diagnostic methods such as sigmoidoscopy, barium enema or X-ray methods.

### Reagents and Materials Supplied:

HEMDETECT® 50x3 – Ref. no. D 596090 (standard pack) contains:

- 50 envelopes each with 3 HEMDETECT® test slides (3x3 test fields), 9 spatulas for taking the stool samples and instructions for the patient.
- HEMDETECT® developer solution (2x20 ml)
- Directions for use and safety data sheet for the doctor and specialist staff

HEMDETECT® Single Slides – Ref. no. D 596092 contains:

- 102 HEMDETECT® Single Slides (1x3 test fields),
- 102 spatulas for taking the stool samples,
- Instructions for the patient.
- HEMDETECT® developer solution (2x20 ml)

- Directions for use and safety data sheet for the doctor and specialist staff

Also necessary but not included in the pack: stopwatch or stopclock for 30 seconds  $\pm 2$  seconds.

### Storage and Stability:

Slides and reagents are stable if stored in the original packaging at a controlled room temperature between 15 and 30°C. Protect from heat, direct sunlight, ultra-violet light, irradiation, moisture and volatile chemicals and their vapours. Do not store cooled or deep frozen. The developer solution must be kept tightly closed to avoid evaporation during storage. Do not use the test beyond the given expiration date.

## PREPARATION OF THE PATIENT:

### Nutrition:

If possible the patient should follow a special diet, starting two days before and continuing during the test period. The patient should avoid eating the following foods: raw or half-cooked meat, horseradish and raw fruit or raw vegetables such as broccoli, cauliflower, red radishes, swede or other kinds of vegetable with a high peroxidase content that could lead to false positive results. An appropriate diet contains cooked fruit and vegetables such as spinach and should also include grains and salad, plums, grapes and apple. Cereal and well-cooked fowl or fish are also allowed<sup>2</sup>. A diet of this kind increases the intake of fibrous materials during the test period. The patient should inform the doctor if any of the recommended foods are known to cause problems.

### Medicines and Supplementary Foods:

Certain medicines such as aspirin, indomethacin, phenylbutazone, reserpine, corticosteroids and NSAIDs may cause gastrointestinal haemorrhage and lead to positive test results. Under medical supervision, taking these drugs can be temporarily discontinued, starting seven days before the test period and finishing at the end of the test period<sup>3</sup>. If the patient takes in more than 250 mg vitamin C per day, this may lead to false negative results<sup>4</sup>. Rectal medication can interfere with

the test and should therefore be discontinued. The effect of different iron compounds on tests for occult blood in stool is the subject of controversy. Although it has been reported that iron compounds can influence the results and give rise to false positives, other reports claim that this is not the case. In any case, caution should be exercised in evaluating test results from patients being administered iron preparations therapeutically. Medication of this kind should be discontinued from the second day before, and during the test period<sup>5</sup>.

### Taking Samples:

Stool samples can be taken from the toilet bowl or from toilet paper, or caught in a clean container. (Doctors can use the stool which has adhered to a greased rubber glove after a rectal examination.) Small quantities of stool are taken from three different parts of the stool. (Samples from the outside of the stool very probably reflect the condition of the lower part of the large intestine whereas samples from inside the stool tend to indicate the upper intestinal tract.) Since haemorrhage can occur periodically, it is necessary to take samples from three, preferably consecutive, bowel movements (see also *Instructions for Patients*).

### Interfering Influences:

Stool samples should be taken neither during menstruation, nor if haemorrhage occurs as a result of constipation, in case of bleeding haemorrhoids or if rectal medication is being used. Hands, utensils and test surfaces must not come into contact with blood in order to prevent false positives.

### Handling and Storing Samples:

Patients must be instructed to send the HEMDETECT® slide to the doctor or the laboratory as soon as possible. No more than 12 days should elapse between taking the first sample of a series and the development of the test. The name of the patient and the date must be entered on every test card. The test fields must be dry before they are developed; re-dampening the slide is not advisable. The HEMDETECT® slides with the samples must be protected from heat, direct sunlight, fluorescent light, volatile chemicals and moisture.

## PERFORMANCE OF THE TEST AND THE CONTROL:

### Performing the Test:

Open the perforated flap at the back of the slide.

Apply two (2) drops of developer solution to each of the three test fields. Read the results at room temperature (16–32°C) after 30 seconds and before 2 minutes have elapsed. Even the slightest blue coloration of the test field indicates a positive result for occult blood. If there is no blue colour, there is no indication of occult blood. Record the test result within 2 minutes (the coloration can disappear after 2 minutes).

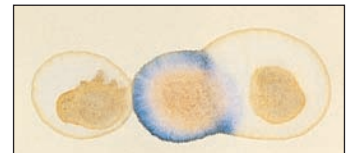
### Interpretation of the Test Results:

The results must be read from the back of the slide. Every trace of blue colour on a test field within a time of 30 seconds to 2 minutes corresponds to a **positive** result for occult blood. If no signs of a blue coloration are detectable, the test result is **negative**. The test results must not be interpreted by persons who are colour blind.



Example: negative test result

**NOTE:** A positive result for occult blood in stool is not an indicator for cancer or any other specific disease. Nutrition or medication can lead to false positive results. In order to determine the exact cause and origin of occult blood in stool, further tests must be performed; all patients with positive test results should be subjected to further examinations.



Example: positive test result

False positive results may be expected with a frequency of 1–2%, depending on the diet or other parameters specific to the patient<sup>6</sup>. Patients with diagnosed colorectal carcinoma deliver positive test results in 50–87% of cases<sup>7</sup>.

### Test Control:

One positive and one negative control field are incorporated in the HEMDETECT® test to enable the functioning of the test to be checked. If the slide is opened at the back the two control points are visible at the bottom. Note that only the doctor or control laboratory may open the back.

### Performing the Control:

Apply two drops of HEMDETECT® developer solution to each control point. Start the stopwatch. Read off the results after 30 seconds.

- The negative control (right) must not display any blue coloration
- The positive control (left) must have become blue.

If the results of the control are different to those described above, discard the test and repeat the entire test with a new slide.

## WARNINGS, DAFETY PRECAUTIONS, EXPLANATION OF SYMBOLS AND REFERENCES:

### Warnings and safety precautions for handling the developer solution:



Xi

Irritant



F

Highly flammable

R: 11,36/38

S: 2,7,15,16,24/25,26,28

Please note that this is an **in vitro test**. The developer solution is an **irritant**.  
R11 Highly flammable, R36/38 Irritating to eyes and skin.

S2 Keep out of the reach of children, S7 Keep container tightly closed, S15 Keep away from heat, S16 Keep away from sources of ignition, S24/25 Avoid contact with eyes and skin, S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice, S28 After contact with skin, wash immediately with plenty of water.

Reagents from test kits with different batch numbers must not be exchanged and must not be replaced by articles from other manufacturers. Stool samples and objects that have come into contact with these must be handled as potentially infectious materials. Dispose of test components and used samples in an appropriate and safe manner.

### Explanation of Symbols:



Single-use-only



Observe directions for use



Use by



Store at



Batch No.



In vitro diagnostic



Reference number



This product conforms to the requirements of EU Directive 98/79/EC for in vitro diagnostic

### Literatur:

- 1 Irons G.V. Jr. and Kirsner; Routine chemical tests for occult blood in the feces. Am. J. of Med. Sci. 1965; 249:247–260.
- 2 Calipore, P. et al. Peroxidase levels in food; Relevance to colorectal cancer screening. Am J Clin Nutit 1982; 35:1487–9.
- 3 Grossman et al.; Fecal blood loss produced by oral and intravenous administration of various salicylates. Gastroenterology 1961; 40:383–88.
- 4 Jaffe R.M. et al.; False negative stool occult blood tests caused by ingestion of ascorbic acid (Vitamin C). Ann Int Med 1975; 83:824–6.
- 5 Lifton L.J., and Kreiser, J.; False-positive stool occult blood tests caused by iron preparations. A controlled study and review of the literature. Gastroenterology 1982; 83:860–3.
- 6 Hofbauer et al. 1991; Wiener Klin Wochenschr. 103; 10:288–295.
- 7 Crowley, M.L. et al. 1983; Sensitivity of guaiac impregnated cards for the detection of colorectal neoplasias. J. Clin. Gastroenterology; 5:127–130.

## SAFETY DATA SHEET FOR CHEMICAL SUBSTANCES AND PREPARATIONS

COMMERCIAL NAME: HEMDETECT DEVELOPER SOLUTION

Article No.: D 596080, D 596080H, D 596090, D 596192, D 596193,

Issue date: 2003-10-01

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1 CHEMICAL COMPOSITION AND INFORMATION ON SAFETY RELEVANT INGREDIENTS:

Ethanol C<sub>2</sub>H<sub>5</sub>OH > 60% Hydrogen peroxide H<sub>2</sub>O<sub>2</sub> ≤ 4% Toluene C<sub>7</sub>H<sub>8</sub> ≤ 4%

1.1 FORM: liquid 1.2 COLOUR: colourless 1.3 ODOUR: ethanol

2 PHYSICAL PROPERTIES AND SAFETY RELEVANT TECHNICAL INFORMATION:

2.1 CHANGES OF STATE: MELTING POINT –117°C\*

BOILING POINT 78.4°C\*

2.2 RELATIVE DENSITY: (20/4°C) 0.85–0.87g/cm<sup>3</sup>

BULK DENSITY: kg/m<sup>3</sup>

2.3 VAPOUR DENSITY: 20°C 77 mbar\*

( °C) mbar

2.4 VISCOSITY: DYNAMIC ( °C) mpA.s

KINEMATIC ( °C) m<sup>2</sup>/s

2.5 SOLUBILITY IN WATER: miscible with water g/l

( °C)

2.6 pH:

2.7 FLASH POINT: 12°C

2.8 AUTOFLAMMABILITY: 425°C

2.9 EXPLOSIVE LIMITS: LOWER: 3.4 vol.% UPPER: 15 vol.%

2.10 THERMAL DECOMPOSITION: –

2.11 DANGEROUS DECOMPOSITION PRODUCTS: –

2.12 DANGEROUS REACTIONS: –

2.13 OTHER INFORMATION: This information is based on the safety data for pure ethanol

3 TRANSPORT: RID/ADR

Other information: no number

4 REGULATIONS: Danger symbols Xi Irritant

F Highly flammable

R phrases: 11 Highly flammable; 36/38 Irritating to eyes and skin

S phrases: 2 Keep out of reach of children; 7 Keep container tightly closed; 15 Keep away from heat; 16 Keep away from sources of ignition; 24/25 Avoid contact with eyes and skin; 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice; 28 After contact with skin, wash immediately with plenty of water.

5 SAFETY MEASURES, STORAGE AND HANDLING

5.1 Technical safety measures:

5.2 Personal protective equipment:

5.3 Working hygiene: While working with the reagent do not eat, drink or smoke. Avoid contact with skin and eyes. After finishing work wash the hands thoroughly with soap and water. Wear work clothing and protective eyewear.

5.4 Fire and explosion prevention: Keep away from electrical devices, open flames, sources of heat and sparks. Smoking is strictly forbidden in the workroom. Do not leave containers open.

5.5 Disposal according to ÖNORM S 21010 Code 59305

6 MEASURES IN CASE OF ABNORMAL OCCURRENCE, ACCIDENT OR FIRE:

6.1 After spills flush away with large volumes of water.

6.2 Extinguishing agents: suitable use CO<sub>2</sub>, powder extinguisher or a stream of water.

6.3 First aid: Thoroughly wash skin and mucous membranes of affected person with water, possibly with soap. Remove contaminated clothing. After contact with eyes, rinse with plenty of water for several minutes with the eyelids open. After swallowing, plenty of water should be drunk immediately and repeatedly. Seek medical advice.

6.4 Further information:

7 TOXICOLOGICAL INFORMATION: –

8 ECOLOGICAL INFORMATION: –

9 OTHER INFORMATION:

The informaton is based on the current state of our knowledge. It is intended to describe the product in respect of safety requirements and therefore does not constitute any guarantee of specific properties.