DRG® Hb/Hp Combo Rapid Test (RAP-4637)

CE

Revised 18 Nov. 2010 rm (Vers. 3.1) **RUO in the USA**

Please use only the valid version of the package insert provided with the kit.

This kit is intended for Research Use Only. Not for use in diagnostic procedures.

1 INTENDED USE

The haemoglobin - haptoglobin (stool) combo test cassette detects the protein complex haemoglobin-haptoglobin (Hb-Hp) in addition to haemoglobin (Hb) for the detection of occult blood. The haemoglobin-haptoglobin complex has a higher survival rate within the digestive tract than haemoglobin, thus the dual blood protein detection meaningfully increases the sensitivity for occult blood, including bleeding from upper digestive tract. The test sensitivity for Hb is 25 ng/ml and Hb-Hp is 25 ng/ml.

2 MATERIALS PROVIDED

The haemoglobin - haptoglobin (stool) combo test kit contains the following items to perform the test:

- haemoglobin - haptoglobin (stool) combo test cassette in foil pouch (20 per kit box)
- Instructions (1 per kit box)
- Sample collection device (20 per kit box)

3 MATERIALS REQUIRED, BUT NOT PROVIDED

- Stop watch

4 WARNINGS

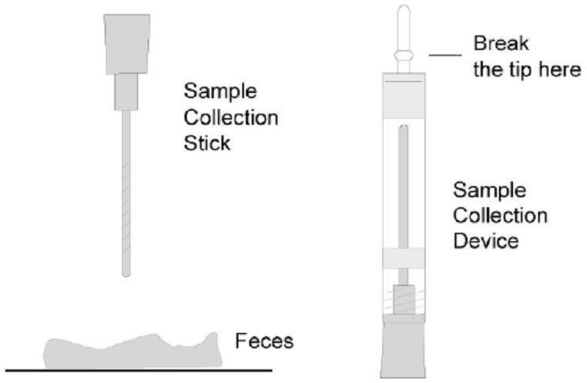
1. This kit is intended for Research Use Only. Not for use in diagnostic procedures.
2. Do not use the test kit if the pouch is damaged or the seal is broken.
3. Do not re-use the test kit.
4. Do not use it beyond the expiration date.
5. Do not eat or smoke while handling specimens.
6. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
7. Avoid splashing or aerosol formation.
8. Clean up spills thoroughly using an appropriate disinfectant.
9. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.

5 STORAGE AND STABILITY

The haemoglobin - haptoglobin test kit must be stored at 4-30°C. If test kit is refrigerated, it should be brought to room temperature before use. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration date.

6 SPECIMEN COLLECTION

1. Only faecal specimens should be used in this assay. It can be collected from toilet paper or caught in a clean container. Specimen should avoid contamination of toilet water.
2. Dietary restrictions are not required, but 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.
3. Specimen collection should not be performed during or three days before or after a menstrual period, or if the patient suffers from bleeding haemorrhoids or blood in the urine, false-positive test results may be obtained.
4. Unscrew the top of the sample collection device and use the sample collection stick to collect stool sample by dipping the stick randomly into 3 different places of the same stool sample.
   Important: Make sure you collect sufficient stool sample. To little stool sample may cause false negatives!
5. Put the sample collection stick containing the sample back into the sample collection device and screw it tightly. Shake it very well.
6. Sample collected can be stored at room temperature (below 30°C) for 7 days or refrigerated at 4 to 8°C for 14 days.



7 PROCEDURE OF THE TEST

1. Bring the extracted sample to room temperature if it is refrigerated. Then mix the extracted sample well by shaking the sample collection device a few times.
2. Remove the test cassette from the foil pouch, and place it on a flat, dry surface.
3. If the stool sample is refrigerated, then bring the sample collection device to room temperature. Then shake the device several times.
4. Hold the sample collection device so that the device tip facing up, then break off the tip of the collection device. Squeeze 3 drops of the extracted sample into each sample well.
5. As the test kit begins to work, you will see a purple coloured front move across the Result Window in the centre of the test cassette.

6. Interpret test results at 10 minutes. Do not read after more than 15 minutes.

CAUTION: The above interpretation time is based on reading the test results at room temperature of 15 to 30°C. If your room temperature is significantly lower than 15°C, then the interpretation time should be properly increased.

8 INTERPRETATION OF THE TEST

- Coloured lines will appear at the section of the result window distant from the sample well to show that the test is working properly. These lines are the control lines ("C" lines).
- The sections of the result window close to the sample wells indicate the test lines ("T" lines).

Hb + Hb-Hp positive **Hb positive** **Hb-Hp positive** **negative** **invalid**

Positive Result: The presence of two coloured lines ("C" and "T" lines) in the result window, no matter how faint the "T" line is and no matter which line appears first, indicates a positive result.

Negative Result: The presence of only one purple coloured ("C") line in the result window indicates a negative result.

Invalid Result: If after performing the test no purple coloured line is visible within the result window, the test is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.

Note: A positive result will not change once it has been established at 10 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after more than 15 minutes. Interpreting test results after 15 minutes, the sensitivity of the test will be higher.

9 LIMITATIONS OF THE TEST

1. The presence of blood in stools may be other than colorectal bleeding, such as haemorrhoids, blood in urine or stomach irritations. If a positive result is obtained, additional diagnostic procedures should be performed to determine the cause and source of the occult blood in the fecal specimen.

2. Negative results do not exclude bleeding since it can be intermittent. False negative results may occur when occult blood is not evenly distributed throughout the bowel movement and faecal formation.
3. Some colorectal polyps and colorectal cancers may bleed intermittently or not at all at early stages.

10 REFERENCES / LITERATURE

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3. Block GE, "Colon Cancer: Diagnosis and Prognosis in the Elderly," Geriatrics, 1989, 44(5):45-7, 52-3.
4. Doyle AC, "A Study in Scarlet," Philadelphia, PA: JB Lippincott Co, 1902.
5. Fleischer DE, Goldberg SB, Browning TH, et al, "Detection and Surveillance of Colorectal Cancer," JAMA, 1989, 261(4):580-5.