

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

For professional use only.

### ***INTENDED USE***

The Occult Detect Test is a simple, direct binding immunoassay for the rapid detection of human haemoglobin in faeces. This test is used to obtain a visual result and is intended for professional research use only.

### ***PRINCIPLE***

The test principle is an immunochromatographic sandwich method, which employs two specific monoclonal antibodies to selectively identify haemoglobin in test samples. The results are very specific, and easier to interpret than those of guaiac-based tests. The sensitivity is very high with the ability to detect 40 ng/ml of human haemoglobin in faeces.

### ***SPECIMEN COLLECTION AND PREPARATION***

Collect stool sample by using the special sample collection device provided. First, unscrew the top of the sample collection device, take out the sample collection stick, and collect the sample by dipping the stick into 3 different places of the stool sample. Then, put the sample collection stick back in the sample collection device and screw together tightly. The stool specimen is to be collected with the stool collection unit. You will find the corresponding instructions of use on the stool collection unit.

**Important:** The stool specimen should not get in contact with water from the toilet or urine. This could adversely affect the test result.

The stool sample dissolved in the buffer solution can be stored at ambient temperature for 14 days and for up to one month at 2-8°C. Stir and bring the specimen to room temperature before testing.

### ***MATERIALS PROVIDED***

- 20 Test cassettes
- 20 stool collection tubes, content 1.5 ml Phosphat buffer solution, pH 7,4) in clip bag
- 20 stool sample collection units
- 20 short instructions for stool sample collection
- 1 package insert

### ***Materials Required But Not Provided***

- Timer

### ***TEST PROCEDURE***

Allow test card and collected specimen to equilibrate to room temperature. Remove the test cassette from its foil pouch by tearing along the notch.

Use the test kit as soon as possible.

Shake the sample collection device vigorously several times.

**Revised 31 Aug. 2010 rm (Vers. 4.1)****USA: RUO****Leave the white cap tightly closed!**

Hold the sample collection tube so that the tip of the blue cap faces up, and then break off the tip of the blue cap.

Squeeze 3 drops of the extracted sample into the sample well (S).

Interpret results after 5-10 minutes.

Do not interpret after more than 10 minutes.

***QUALITY CONTROL***

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

External controls may also be used to assure that the reagents are working properly and that the assay procedure is followed correctly. It is recommended that a control be tested at regular intervals as good laboratory testing process.

Users should follow the appropriate local guidelines concerning the running of external quality controls.

***LIMITATIONS***

1. The Occult Detect Test is intended only for the detection of haemoglobin in faeces.
2. Donors with haemorrhoids or menstrual bleeding should not be considered for testing, however they may be tested after such bleeding ceases.
3. Urine and excessive dilution of samples from water from the toilet bowl may cause erroneous results.
4. The Occult Detect Test is not for use in testing urine, gastric specimens or other body fluids.

***PRECAUTIONS***

- Do not use test kit beyond expiry date.
- Do not use if pouch is damaged.
- The test device must not be reused.
- Keep out of the reach of children.
- Donor specimens may contain infectious agents and should be handled as though capable of transmitting disease. Wear disposable gloves throughout the specimen collection and assay procedures.

***STORAGE AND STABILITY***

The test kit can be stored at temperatures between 2 to 30°C in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

***References***

1. Gorzynski TJ, Krco CJ, David CS., An idiotope expressed on a monoclonal antibody specific for human haemoglobin beta chain and naturally occurring immunoglobulin(s).  
J Immunogenet. 1985 Dec;12 (6):281-91.
2. Gorzynski TJ, Krco CJ, David CS., The Hb-2d cross-reactive idiotype. A common idiotype expressed by monoclonal and polyclonal antibodies to human haemoglobin.  
J Immunogenet. 1985 Dec;12(6):267-79.