DRG® Occult Detect Advanced Rapid Test (RAP-4723)

As of 10 Jan. 2008 **RUO in the USA**

A rapid, one step test for the qualitative detection of human occult blood in faeces.

SUMMARY

Many times gastro-intestinal diseases are not recognized. In Europe colon cancer is one of the most common cancer types (Lieberman, 1994; MMWP 1995). Colon cancer can be diagnosed by continuous preventive examinations at an early stage and in most cases it can be healed. By an early and reliable detection of occult blood in stool, colon cancer can be recognized early and reduce the mortality rate of patients suffering from colon cancer (Dam et al., 1955; Miller, 1995; and Lang, 1996). Colon cancer develops over years and the early stages usually do not cause any afflictions. Polyps, colitis, diverticulitis, fissures and colon cancer have fine and very sensitive blood vessels – that sensitive that they can be damaged by the passing stool and release small quantities of blood to the stool that cannot be recognized visually. The Occult Detect Test detects by specific antibodies even smallest amounts of occult blood and provides for more exact and more reliable results than chemical occult blood tests (guaiac tests). The Occult Detect Test cannot lead to false results due to certain nourishment such as meat, vitamins and others. There are no necessary dietary restrictions to observed prior to taking the test.

The detection level is at 40 ng/mL hemoglobin or 2 µg hemoglobin/g feces.

PRINCIPLE

The new immunologic Occult Detect Test is a rapid, chromatographic immunoassay that detects exclusively human hemoglobin by a specific antibody reaction. The hemoglobin that is contained in the stool sample reacts with specific mono- and polyclonal antibodies, that are attached to colloidal particles. This complex disperses on the membrane and reaches the test line (T) that contains anti-hemoglobin. On a positive result the hemoglobin molecules from the stool sample that are loaded with colloidal antibodies are attached to the test line (T) and become visible by a red colouration. On a negative result there are no hemoglobin molecules that can attach to the test line (T) and therefore there will not be any colouration of the test line (T). The control line (C) ensures by a red colouration that the sample application and membrane wicking has occurred correctly and that the test result is valid.

MATERIALS

Materials Provided	Materials Required But Not Provided
– 12 single pouched test cards – 12 stool collection tubes (each tube contains extraction buffer of 2 mL 0,1M TBS with BSA and 0.02% sodium acid). – 12 patient information for stool sample collection – Package insert	– Timer

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use.

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- Do not freeze.
- Do not use after expiration date.

PRECAUTIONS

- For professional **in vitro** use only. This kit is intended for Research Use Only in the United States.
- Do not use if pouch is torn or damaged.
- The test device should remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled. Use disposable gloves and wash and disinfect your hands after taking the test.
- All stool samples should be handled as if they contain infectious agents.
- Do not moisten membrane with liquids. Humidity and temperature can adversely affect results.
- Observe established precautions against microbiological hazards throughout the testing and follow the standard procedures for proper disposal of specimens.

SPECIMEN COLLECTION AND PATIENT PREPARATION

- Specimen should not be collected during or within three days of a menstrual period, on occlusion related bleedings, or if the patient suffers from bleeding hemmorhoids or on medications with rectal application. This may cause false positive results.
- Alcohol and certain medications such as aspirin, corticosteroids and non-steroid anti-inflammatory medication may cause gastrointestinal irritation resulting in occult bleeding and result in false positive results. Such substances should be discontinued at least 48 hours prior to testing.
- Dietary restrictions are not necessary.

1.1 SPECIMEN COLLECTION AND PREPARATION

The specimen is stool. It may be collected from the toilet paper or caught in a clean cup. You can also use special stool collecting devices.

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

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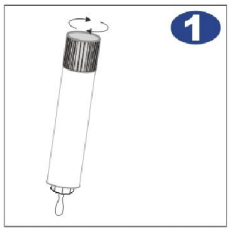
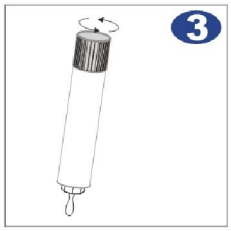


Take the stool collection tube from the stool collection set and twist off the cap.
The spiralled tip of the cap is to be used for the stool specimen collection.

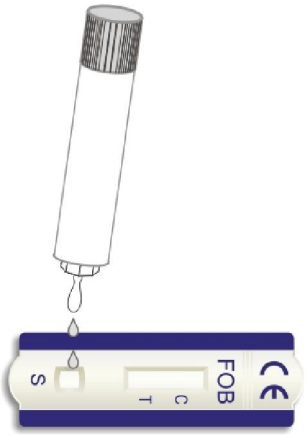
Stick the spiralled tip in 3 different sites of the stool specimen.
Enough stool will accumulate in the grooves; the result will not become more secure by collecting greater amounts of specimen.



Insert the spiralled tip back into the collection tube and close the cap tightly.
Mark the collection tube or the envelope of the collection set.

NOTE: The stool collection tube contains a buffer solution in which the collected sample be store up 3-4 days at a temperature between 2-8°C.

TEST PROCEDURE



Allow test card and collected specimen to equilibrate to room temperature. Remove the test card out of the sealed pouch only shortly before performing the test. Make sure that the test card has reached room temperature in order to avoid humidity on the membrane. Put the test card on a plain surface.

If performing several tests simultaneously, we recommend to mark the test cards with the patients' name and / or number.

When required the stool collection tube should also reach room temperature.

Shake the collection tube thoroughly in order to release the stool specimen from the spiralled tip to the extraction buffer.

Take a paper towel or a swab (in order to avoid spilling) to break off the tip of the collection tube.

Hold the collection tube vertically in order to avoid a spillage of the buffer solution. Add 3 full drops of this solution to the specimen well (S) of the test card.

Interpret the results after 8 minutes. After more than 10 minutes do not interpret any results. The test is valid if you obtain a red colouration of the control line (C).

INTERPRETATION OF RESULTS

If you obtain a **positive result** both the control line (C) and the test line (T) show a red colouration. Positive result means that in the stool specimen human hemoglobin was detected.
These bleedings are not always caused by benign or malign polyps. The presence of blood in stool may frequently other causes. Therefore, a positive result always should be checked with other clinical test methods and have a physician consider the disease pattern.

If only the control line (C) shows a red colouration, the result indicates that the test worked and confirms a **negative result** (no colouration of the test line (T)). This mean that no human hemoglobin could be detected in the stool specimen. Negative results do not completely eliminate the possibility of bleedings, as due to the usual heterogenal dispersion of possible traces of blood in stool can be missed during collection. Negative results do not completely eliminate the presence of polyps and colon cancer as colorectal polyps in the early stage oftentimes do not bleed.

An **invalid result** may have various causes. The testing procedure can be wrong (e. g. specimen solution has not run properly), or the test reagents were not operative. The test should be repeated with a new test card if there is a colouration only at the test line (T) and none at the control line (C), or if there no colouration at all.

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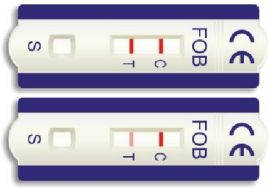
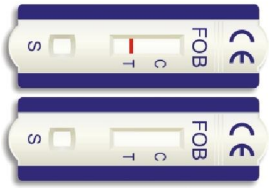


Positive:

Both the control line (C) and the test line (T) show a red colouration. With this the presence of human blood in the stool sample has been detected.

Negative:

Only the control line (C) show a colouration. This means there is no blood in the stool specimen.



Invalid

If after performing the test the control line (C) does not appear, even if the test line does appear.

Also if no colouration of any of the both lines has taken place, this means that test procedure or test card have not worked properly. In those cases please repeat the test with a new test card.

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QUALITY CONTROL

Internal 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.

External Quality Control

In addition to the standard laboratory practice on quality control procedure it is recommended to perform at least one positive and one negative external control per test kit through each person who will operate this Occult Detect Test kit. This is to verify proper test and reagent performance and that all operators are in a position to perform properly the test procedure.

LIMITATIONS

The Occult Detect Test is for in vitro use only. The Occult Detect Test is only to indicate the presence of occult blood in stool specimens. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

Other clinically available tests are required if questionable results are obtained.

PERFORMANCE CHARACTERISTICS

The Occult Detect Test is specific to human hemoglobin and can detect the levels of human occult blood as low as 40 ng/mL hemoglobin or 2 µg hemoglobin/g feces. The Occult Detect Test does neither show any cross reactivity with animal hemoglobin nor with Bilirubin, Vitamin C and other antioxidants or horseradish peroxidase.

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SYMBOLS USED WITH DRG ASSAY´S

Symbol	English	Deutsch	Francais	Español	Italiano
	Consult instructions for use	Gebrauchsanweisung beachten	Consulter les instructions d'utilisation	Consulte las instrucciones de uso	Consultare le istruzioni per l'uso
CE	European Conformity	CE-Konfirmitäts-kennzeichnung	Conformité aux normes européennes	Conformidad europea	Conformità europea
IVD	In vitro diagnostic device	In-vitro-Diagnostikum	Ussage Diagnostic in vitro	Para uso Diagnóstico in vitro	Per uso Diagnostica in vitro
RUO	For research use only	Nur für Forschungszwecke	Seulement dans le cadre de recherches	Sólo para uso en investigación	Solo a scopo di ricerca
REF	Catalogue number	Katalog-Nr.	Numéro de catalogue	Número de catálogo	Numero di Catalogo
LOT	Lot. No. / Batch code	Chargen-Nr.	Numéro de lot	Número de lote	Numero di lotto
	Contains sufficient for <n> tests/	Ausreichend für "n" Ansätze	Contenu suffisant pour "n" tests	Contenido suficiente para <n> ensayos	Contenuto sufficiente per "n" saggi
	Storage Temperature	Lagerungstemperatur	Temperature de conservation	Temperatura de conservación	Temperatura di conservazione
	Expiration Date	Mindesthaltbarkeits-datum	Date limite d'utilisation	Fecha de caducidad	Data di scadenza
	Legal Manufacturer	Hersteller	Fabricant	Fabricante	Fabbricante
Distributed by	Distributor	Distributeur	Distributeur	Distribuidor	Distributtore
Content	Content	Inhalt	Conditionnement	Contenido	Contenuto
Volume/No.	Volume / No.	Volumen/Anzahl	Volume/Quantité	Volumen/Número	Volume/Quantità

Symbol	Portugues	Dansk	Svenska	Ελληνικά
	Consulte as instruções de utilização	Se brugsanvisning	Se bruksanvisningen	Εγχειρίδιο χρήστη
CE	Conformidade com as normas europeias	Europaeisk overensstemmelse	Europeisk överensstämmelse	Ευρωπαϊκή Συμμόρφωση
IVD	Diagnóstico in vitro	In vitro diagnostik	Diagnostik in vitro	in vitro διαγνωστικό
REF	Catálogo n.º	Katalognummer	Katalog nummer	Αριθμός καταλόγου
LOT	No do lote	Lot nummer	Batch-nummer	Αριθμός Παρτίδος
		Indeholder tilstrækkeligt til "n" test	Innehåller tillräckligt till "n" tester	Περιεχόμενο επαρκές για «n» εξετάσεις
	Temperatura de conservação	Opbevarings-temperatur	Förvaringstempratur	Θερμοκρασία αποθήκευσης
	Prazo de validade	Udløbsdato	Bäst före datum	Ημερομηνία λήξης
	Fabricante	Producent	Tillverkare	Κατασκευαστής
Distributed by				
Content	Conteúdo	Indhold	Innehåll	Περιεχόμενο
Volume/No.	Volume/Número	Volumen/antal	Volym/antal	Ογκος/αριθ..