DRG® Occult Detect Eco-Pro Rapid Test (RAP-4721)

As of 10 Jan. 2008

RUO in the USA

INTENDED USE

The DRG Occult Detect Rapid test strip is a simple, direct binding immunoassay for the rapid and qualitative detection of human haemoglobin in faeces. This test is used to obtain a visual, qualitative result and is intended for professional in vitro use only. In the United States, this kit is intended for Research Use Only.

SUMMARY

The presence of faecal occult blood (FOB) in the stool is associated with gastrointestinal disorders that may lead to colorectal cancer if not treated. Early diagnosis by FOB screening has been shown to significantly reduce mortality in colorectal cancer. The assay is designed to detect lower levels of colorectal bleeding than other biochemical detection methods. In addition, the accuracy of the test is not affected by interfering substances, and dietary restriction is not necessary.

PRINCIPLE

The test principle is an immunochromatographic sandwich method, which employs two specific monoclonal antibodies to selectively identify haemoglobin in test samples. The result is very specific, and easier to interpret than those of guaiac-based test. The sensitivity is very high with the ability to detect 50 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.

If the sample cannot be tested on the day of collection, store the stool sample at 4°C. Stir and bring the specimen to room temperature before testing.

MATERIALS PROVIDED

- 25 Test strips in round vial with desiccant
- 25 stool collection tubes, content 1.5 ml, in clip bag
- 25 short instructions for stool sample collection in clip bag
- 75 stool sample collection units (3 pieces per clip bag)
- 1 Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

Timer

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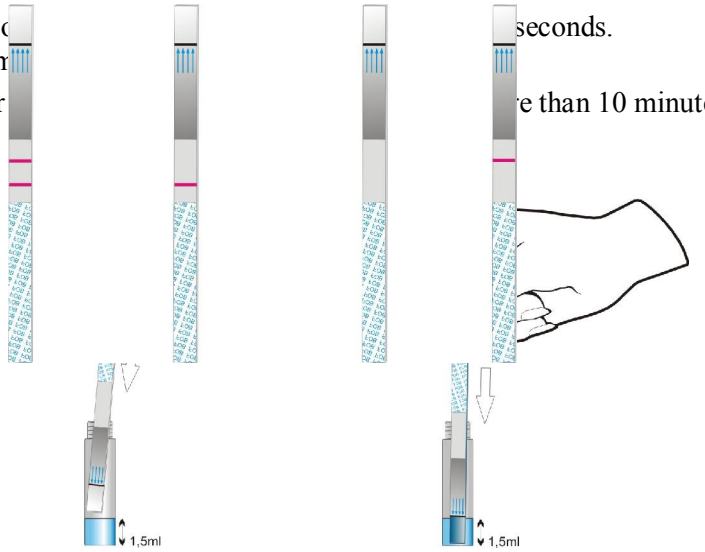
TEST PROCEDURE

1. Remove the test strip from its foil pouch by tearing along the notch.
   Use the test kit as soon as possible.
2. Shake the sample collection device vigorously several times.
3. Unscrew the cap.
4. Immerse the test strip int[illegible] seconds.
   Do not surpass the maxim[illegible]
5. Read the test results after[illegible] e than 10 minutes.



INTERPRETATION OF RESULTS

Negative: Only one coloured line appears on the control zone. No apparent line on the test zone.

Positive: In addition to a pink coloured control line, a distinct pink coloured line will also appear in the test zone. The intensity of colouration is not important. Even faint pink test lines mean a positive result.

Invalid: total absence of colour in both regions or no coloured line appears on the control (C) region is an indication of procedure error and/or test reagent deterioration.

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CONTROL LINE (C)	C
TEST LINE (T)	T

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positive **negative** **invalid**

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. As with all diagnostic tests, all results must be considered with other clinical information available to the physician. A definite clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated.
2. The Occult Detect Rapid Test is intended only for the detection of haemoglobin in faeces.
3. Patients with haemorrhoids or menstrual bleeding should not be considered for testing, however they may be tested after such bleeding ceases.
4. Urine and excessive dilution of samples from water from the toilet bowl may cause erroneous results.
5. The Occult Detect Rapid Test is not for use in testing urine, gastric specimens or other body fluids.

PRECAUTIONS

- For in vitro use only. In the United States, this kit is intended for Research Use Only.
- 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.
- Patient 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.

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STORAGE AND STABILITY

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

EXPECTED VALUES

The Occult Detect Rapid Test will detect haemoglobin in faeces at levels as low as 50 ng/ml.

PERFORMANCE CHARACTERISTICS

1.1 Sensitivity

This test is sensitive for 50 ng/ml human haemoglobin in stool sample. 100 spiked stool samples with concentrations of 0 ng, 25 ng, 50 ng, 75 ng, 100 ng per millilitre of human haemoglobin were tested. In the presence of human haemoglobin greater than the cut-off concentration, a positive result was shown by two lines (control and test line appeared). A sample with human haemoglobin levels lower than the cut-off concentration caused a negative result whereby only one line (control) appeared. Moreover, two types of abnormal blood (Thalassemia and Sickle Cell) were tested and no false negative issues were raised as results were as expected.

INTERFERENCE TESTING / CROSS REACTIVITY

A performance study was completed to investigate the cross reactivity of other species of haemoglobin and tissue extracts on the Occult Detect Rapid Test.

The haemoglobin species of bovine, equine, pig, rabbit, sheep, fish, chicken, and goat origin were added to the test device and the results as expected. Haemoglobin of the species was added to normal stool extracts at both 0 and 50 ng/ml human haemoglobin and the results were negative and positive respectively.

In addition, the study was repeated with tissue extracts of beef, pig, rabbit, sheep, fish, chicken and goat and no cross reactivity was evident.

Lastly, toilet water with the presence of various cleaners (enzymatic to chlorax based) was added to test device and results were as expected following the same protocol as above.

DIETARY TESTING

A performance study was completed to investigate the interference of dietary substances on the Occult Detect Rapid test. Aqueous extracts of raw broccoli, cauliflower, cantaloupe, horseradish, red radish, parsnip, and turnip were added to test device. Also included were dietary iron, vitamin C and horseradish peroxidase. The dietary substance extracts were added to normal stool extracts at both 0 and 50 ng/ml human haemoglobin and the results were as expected. All of the 0 ng/ml haemoglobin samples spiked with interfering substances were negative, while all of the 50 ng/ml haemoglobin spiked samples were positive.

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COMPARISON TESTING

To establish the sensitivity and specificity of the Occult Detect Rapid Test kit relative to other qualitative FOB tests, 648 clinical samples were studied.
Another commercially available qualitative test kit was used to compare with the Occult Detect Rapid Test kit for relative sensitivity and specificity in these stool samples.
Only 2 samples were discordant, the agreement was 99.67%.

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.

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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
RUO				
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	Όγκος/αριθ..