DRG® Tuberculosis Rapid Test (RAP-4758)

As of 18 Jan. 2008

RUO in the USA

BACKGROUND

Tuberculosis (TB) is spread primarily via airborne transmission of aerosolized droplets developed by coughing, sneezing and talking.

Mycobacterium tuberculosis is the common causative organism in human tuberculosis, a chronic infectious disease characterised by formation of tubercles (small rounded nodules) and tissue necrosis (destruction), usually occurring in the lung.

INTENDED USE

The TB test is a chromatographic immunoassay for the qualitative detection of human anti-TB (M. tuberculosis, M. bovis and M. africanum) antibodies (all isotypes: IgG, IgM, IgA, etc.). This test is intended for use as an aid in the diagnosis of TB. *For professional use only.* In the United States, this kit is intended for Research Use Only.

MATERIALS PROVIDED

- TB test cassette with pipette in foil pouch (25 per kit box)
- Instructions for use (1 per kit box)

MATERIALS REQUIRED, BUT NOT PROVIDED

- Stop watch
- Utensils for sample collection

PRECAUTIONS

The TB Test must be stored at 4 °C to-30 °C.

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.

SPECIMEN COLLECTION AND STORAGE

Whole Blood specimen collection:

Collect an anti-coagulated blood sample (sodium heparin or lithium heparin). Whole blood samples must be tested within 24 hours of drawing.

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Plasma/Serum specimen collection:

Centrifuge whole blood to get plasma/serum specimen.

If specimens are not immediately tested they should be refrigerated at 2 °C to 8 °C. For storage periods greater than three days, freezing is recommended.

Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

WARNINGS

- For in vitro diagnostic use only. In the United States, this kit is intended for Research Use Only.
- Do not eat or smoke while handling specimens.
- Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
- Avoid splashing or aerosol formation.
- Clean up spills thoroughly using an appropriate disinfectant.
- Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
- Do not use the test kit if the pouch is damaged or the seal is broken.

PROCEDURE OF THE TEST

- Remove the test cassette from the foil pouch, and place it on a flat, dry and clean surface.
- Holding the sample dropper above the test cassette and add 1 hanging drop into the Sample Well.
  After the drop is absorbed into the Sample Well, add another hanging drop, repeat the procedure until a total of 3 hanging drops have been added to the Sample Well.
  If specimen drops are added too quickly, specially for blood specimen, it may cause clogging of the Sample Well.
- As the test begins to work, you will see a purple coloured front move across the Result Window in the centre of the test cassette.
- Interpret test results at 15 minutes. Do not interpret test result after more than 20 minutes.

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

DRG International Inc., USA

Fax: (908) 233-0758 • E-mail: corp@drg-international.com • **Web:** www.drg-international.com

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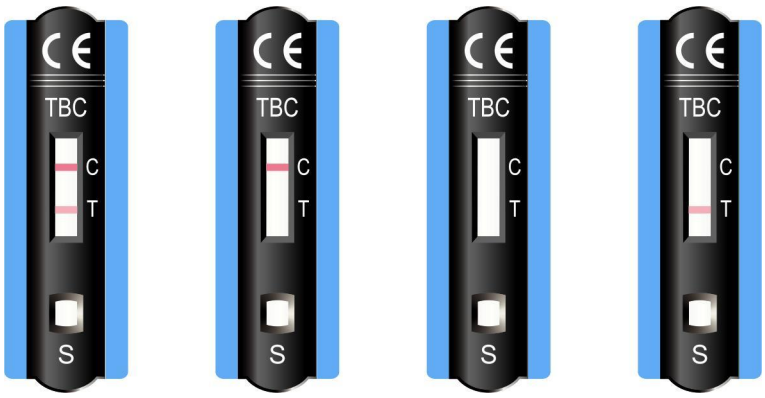

positive **negative** **invalid** **invalid**

INTERPRETATION OF RESULTS

- A coloured line will appear in the section of the Result Window marked with "C" to show that the test is working properly. This is the Control Line.
- The section of the Result Window marked with "T" indicates the test results. If another coloured line appears in the T section of the Result Window, this is the Test Line.

Positive result: The presence of two coloured lines ("T" and "C" line) in the result window regardless of which line appears first indicates a positive result (Figure 1). **Note:** Generally, the higher the analyte level in the specimen, the darker the "T" line colour will be. When the analyte level is close to but still within the sensitivity limit of the test, the colour of the "T" line will be very faint.

Negative result: The presence of only one "C-line" within the Result Window indicates a negative result (Figure 2).

Invalid result: If after performing the test no line or only a "T"-line is visible in the Result Window, the result is considered invalid (Figure 3, 4). 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 15 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after more than 15 minutes.

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LIMITATIONS OF THE TEST

A negative result does not preclude the possibility of infection with TB. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

SPECIFICITY STUDY

An in-house study is conducted with 3 separated lots of the TB Test to determine the specificity of the test. Compounds tested include: Serum with triglyceride concentrations up to 500 mg/ml, Serum with Bilirubin concentrations up to 10 mg/100 ml, haemolysed specimens with haemoglobin concentrations up to 10 mg/ml, Prostatic acid phosphatase with concentrations up to 1000 mIU/ml and Albumin with concentrations up to 20 mg/ml.

All of the above were analysed and did not show interference or cross reactivity with the test.

REFERENCES

1. Dixon RE: Symposium on nosocomial infections (Parts I,II and III). Am J Med 70:379-473, 631-744, 899-986, 1981.
2. Green GM, Daniel TM, and Ball WC: Koch Centennial Memorial. Am Rev Resp Dis 125:1-31 (Suppl), 1982.
3. Pennington JE: Respiratory Infections: Diagnosis and management. New York, Raven Press, 1983.

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SYMBOLS USED WITH DRG ASSAYS

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
Σ	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
Σ		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
Content	Conteúdo	Indhold	Innehåll	Περιεχόμενο
Volume/No.	Volume/Número	Volumen/antal	Volym/antal	Όγκος/αριθ..