ASSURE® TB
RAPID TEST

Instructions for Use
FOR RESEARCH USE ONLY
NOT FOR USE IN DIAGNOSTIC PROCEDURES

REVISION DATE: 2015-07
MDG 0012-ENG-1

Note Changes Highlighted

REF 43502-020 (20 Tests)

TRADE NAME AND INTENDED USE

The **MP DIAGNOSTICS (MPD) ASSURE® TB Rapid Test** is an immunochromatographic test device intended for the rapid detection of antibodies to *M. tuberculosis* in human serum, plasma or whole blood.

This kit is supplied for research purposes only. It is not intended for use in the diagnosis or prognosis of disease.

INTRODUCTION

The **MP DIAGNOSTICS (MPD) ASSURE® TB Rapid Test** was developed utilizing two recombinants, one of which contains a multiple-epitope recombinant *Mycobacterium tuberculosis* antigen. The proteins are well characterized. The **MPD ASSURE® TB Rapid Test** can provide additional information to current bacteriology tests that include a smear test and bacterial culture.

CHEMICAL AND BIOLOGICAL PRINCIPLES OF THE PROCEDURE

MPD ASSURE® TB Rapid Test is an indirect solid-phase immunochromatographic assay, in which antibodies in the test sample (serum, plasma or whole blood) forms an antibody-antigen complex with immobilized TB antigens on a membrane in the test window as the test sample migrates upwards from the sample well. The bound antibody-antigen complexes are subsequently detected by a dye conjugated to anti-human IgG carried by the chase buffer migrating downward giving a pink-purplish color. The control line contains protein A which binds with the anti-human IgG-dye conjugate. The control band serves as an indication of proper sample addition and migration plus reagent (anti-human IgG dye conjugate) control.

DESCRIPTION OF SYMBOLS USED

The following are graphical symbols used in or found on MP Diagnostics products and packaging. These symbols are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the British and European Standard BS EN 980: 2003.

	Use by		Do not reuse
LOT	Batch Code *Synonym for this are:* Lot Number Batch Number	REF	Catalogue Number
	Temperature Limitation		Attention. See instructions for Use
	Manufacturer		Consult Instructions for Use
Σ	Contains sufficient for <n> tests		

KIT COMPONENTS

DEVICE	MPD ASSURE® TB Rapid Test Device. Twenty test devices packed in individual sealed aluminium pouch with dessicant. Store at 2°C - 28°C	20 devices
APPLICATOR	SAMPLE APPLICATOR Twenty plastic samples applicators, each with marks at 25µl and 35µl	20 pieces
BUFFER	CHASE BUFFER Buffer containing 0.1% sodium azide. Store at 2°C-28°C	1 bottle (5 ml)
	Instructions For Use	1 copy

HEALTH AND SAFETY INFORMATION

1. In case of an accident or contact with eyes, rinse immediately with plenty of water and seek medical advice.
2. Consult a physician immediately in the event that contaminated materials are ingested or come in contact with open lacerations, or other breaks in the skin.
3. Wipe any spills of sera, plasma or blood promptly with 1% sodium hypochlorite solution.
4. Autoclave all used and contaminated materials at 121°C,15 p.s.i. for 30 minutes before disposal. Alternatively, decontaminate materials in 5% sodium hypochlorite solution for 30-60 minutes before disposal in biohazard waste bags.
5. The Chase Buffer contains 0.1% Sodium azide, which is not considered dangerous according to European Economic Community (EEC), as it is present in low concentrations. Sodium azide can react with copper and lead used in some plumbing systems to form explosive salts. The quantities used in this kit are small, nevertheless when disposing of azide-containing materials they should be flushed away with relatively large quantities of water.

ANALYTICAL PRECAUTIONS:

1. For research use only.
2. Please refer to the product labeling for information on potentially hazardous components
3. Gloves must be worn.
4. Optimal assay performance requires **STRICT ADHERENCE** to the assay procedure described in this Instructions For Use. Deviations from the procedure may lead to aberrant results.
5. Do not interchange reagents between kit lots.
6. Do not use kit components beyond the expiration date printed on the kit box.
7. The chase buffer reagent contains sodium azide as a preservative. Handle reagent carefully to avoid spills on work surface. Clean up spills with absorbent paper and water.
8. Reagents supplied should not present a hazard to health if used in accordance to the instructions stated.
9. For best results allow all reagents and samples to reach room temperature (25°C ± 3°C) before use.

STORAGE

1. Store entire kit at 2°C-28°C. Test devices should be kept sealed until use.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Lancet
2. Alcohol swabs

SAFETY PRECAUTIONS

1. Autoclave all used and contaminated materials at 121°C, 15 p.s.i. for 30 minutes before disposal. Alternatively, decontaminate materials in 5% sodium hypochlorite solution for 30-60 minutes before disposal in biohazard waste bags.
2. Wipe any spills of sera, plasma or blood promptly with 1% sodium hypochlorite solution.

SPECIMEN COLLECTION

Whole blood can be collected in anti-coagulant containing tubes and used as outlined in the assay procedure immediately or stored at 2°C to 8°C for not more than 48 hours before use.
Serum / plasma samples should be stored at 2°C to 8°C if the test is to be run within 7 days of collection or frozen at -20 °C or colder if the test is to be delayed for more than 7 days. Clear, non-hemolyzed samples are preferred.
Lipemic, icteric or contaminated (particulate or bacterial) samples should be filtered (0.45 µ m) or centrifuged before testing.

Samples can be inactivated but this is not a requirement for optimal test performance.
Inactivate as follows:

1. Loosen cap of sample container.
2. Heat-inactivate sample at 56°C for 30 minutes in a water bath.
3. Allow sample to cool down before retightening cap.
4. Sample can be stored frozen until analysis. Repeated freeze-thawing of sample is not recommended.

ASSAY PROCEDURE

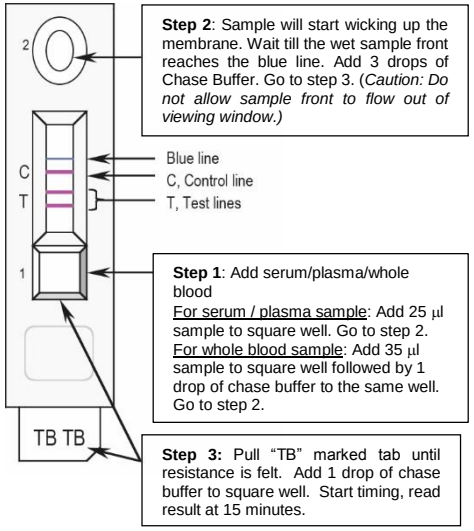
IMPORTANT: Strict adherence to the assay procedure will ensure optimal assay performance. Deviations from the procedure may lead to aberrant results.

Note :

- Allow the kit to warm to room temperature before running the assay.
- Chase buffer with crystallization may affect test results.
- In order to prevent crystallization in chase buffer, it is highly recommended that the kit to be stored at 18°C - 28°C.
- Check the chase buffer carefully. If crystals are present in the chase buffer, make sure that they are fully dissolved before use. Warming at 37°C helps to expedite the dissolving process.

1. Open the pouch by cutting the sealed side of the pouch.
2. Label the test device with the sample name.
3. Proceed with the assay procedures as shown in the diagram below.

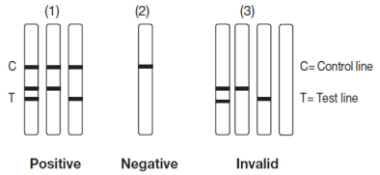
Diagrammatic Representation of Assay Procedure



QUALITY CONTROL

1. Positive and negative controls are not included and are optional.
2. Blue line contains a blue dye which is the only line visible before running the assay. If the control line at position C does not become visible, the test is invalid. Positive samples will have additional colored band(s) at position T.

INTERPRETATION OF RESULTS



1. **Positive** for TB antibodies if colored bands appear at the Test line(s) (T) and Control line (C). Any intensity of band should be considered as a positive.
2. **Negative** for TB antibodies if only the Control line (C) is visible through the viewing window.
3. **Invalid** if the Control line (C) is absent. If this occurs, the assay should be repeated using a new device.

LIMITATIONS OF THE PROCEDURE

Optimal assay performance requires strict adherence to the assay procedure described. Deviation from the procedure may lead to aberrant results.

BIBLIOGRAPHY

Houghton RL et al. Use of multiepitope polyproteins in serodiagnosis of active tuberculosis. Clin Diag Lab Imm. 2002; 9(4):883-891.

LIMITED EXPRESSED WARRANTY DISCLAIMER

The manufacturer makes no expressed warranty other than that the test kit will function as as an RUO (for research use only) assay within the specifications and limitations described in the Instructions for Use when used in accordance with the instructions contained therein. The manufacturer disclaims any warranty expressed or implied, including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any other purposes. The manufacturer's liability is limited.

TECHNICAL PROBLEMS / COMPLAINTS

Should there be any technical problem / complaint, please do the following:
1. Note the kit lot number and the expiry date.
2. Retain the kits and the results that were obtained.
3. Contact the nearest MP Biomedicals office or your local distributor.

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* US Patent No. 6,316,205 ; 6,617,116