Tell Me Fast Mycobacterium Tuberculosis – IgG/IgM Test Device (Serum/Plasma) Instructions for Use Catalog Number: B900C

For the rapid detection of IgG and IgM antibodies of Mycobacterium tuberculosis infection in serum or plasma samples.

Intended Use

The TELL ME FAST Mycobacterium Tuberculosis IgG/IgM Test Device (Serum/Plasma) is a qualitative immunochromatographic screening assay for the detection of Mycobacterium tuberculosis antibodies (IgG and IgM) infection in serum or plasma.

Principle

TELL ME FAST Mycobacterium Tuberculosis IgG/IgM Test Device (Serum/Plasma) is a qualitative test for the detection of IgG and IgM antibodies to M. Tuberculosis (TB) in human serum or plasma. The test provides a differential detection of anti-TB-IgG and anti-TB-IgM antibodies and can be used for the presumptive distinction between a primary and secondary TB infection. Serum or plasma samples may be used with this test. First a specimen is dispensed with sample buffer, the Gold antigen conjugate will bind to anti-TB IgG and IgM antibodies in the specimen sample which in turn will bind with Anti-Human IgG and Anti-Human IgM coated on the membrane as two separate lines in the test region as the reagent move across the membrane. The anti-Human antibodies on the membrane will bind the IgG or IgM antigen complex at the relevant IgG and or IgM test lines causing pale or dark colored lines to form at the IgG or IgM region of the test membrane. The intensity of the lines will vary depending upon the amount of antibody present in the sample. The appearance of colored line in a specific test region (IgG or IgM) should be considered as positive for that particular antibody type (IgG or IgM).

Precautions

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.

Storage & Stability

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

Materials

Materials Provided:
1. Test Device
2. TB Buffer in dispenser vial
3. Package Insert

Materials required but not provided:
1. Timer
2. Pipette

Specimen Collection & Preparation

1. Use fresh specimens. Make sure test cassettes and TB Test Buffer are at room temperature before using.
2. Handle and dispose of specimens as if they were infectious and capable of transmitting infection. Avoid contact with skin, inhalation or ingestion.

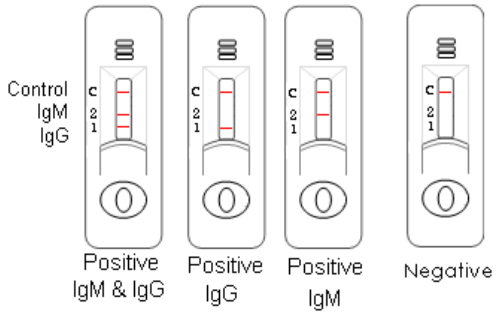
Directions for Use:

1. Bring the pouched test device and buffer to room temperature (15-30°C) before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Pipette 5 µL of serum or plasma into the sample well.
3. Add 2 drops (80 µl) of test buffer to sample well.
4. Wait for the colored line(s) to appear. The test result should be read at between 15 and 20 minutes. Result may be read up to 30 minutes.

Note: Do not interpret the result after 60 minutes.

Interpretation of Results:

(Please refer to the illustration)



IgM POSITIVE: Two distinct lines appear. The control line (C) and IgM (M) line are visible on the test cassette. The test is positive for IgM antibodies.

IgG POSITIVE: Two distinct lines appear. The

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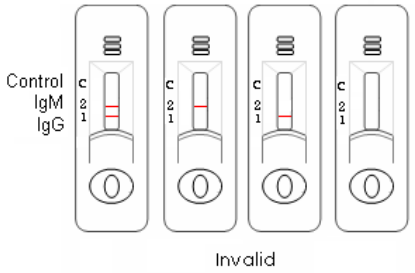
control line (C) and IgG (G) line are visible on the test cassette. The test is positive for IgG antibodies.

IgM and IgG POSITIVE: Three distinct lines appear. The control line (C), IgM (M) and IgG (G) lines are visible on the test cassette. The test is positive for IgM and IgG antibodies.

NEGATIVE: One distinct line appears. The control line (C) is the only line visible on the test cassette. No IgG or IgM antibodies were detected.

INVALID: Control line fails to appear. The test results are INVALID, if no control line (C) is visible, regardless of the presence or absence of lines in the IgG (G) or IgM (M) region of the cassette. Repeat the test using a new cassette.



NOTE: The intensity of the lines in the test regions (G) and (M) will vary depending on the concentration of IgG and IgM present in the specimen. However, neither the quantitative value nor the rate of increase in IgG or IgM can be determined by this qualitative test.

Quality Control

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Bibliography

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4. Kaustova J, Serological IgG, IgM and IgA diagnosis and prognosis of mycobacterial diseases in routine practice. *Eur J Med Res.* 1996 May 24;1(8):393-403

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