Tuberculosis IgM/IgG Rapid Test

Cat. No.:DTS514
Pkg.Size:50 Tests

Intended use

The TB IgG/IgM Rapid Test is a sandwich lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of IgM anti-Mycobacterium Tuberculosis (M.TB) and IgG anti- M.TB in human serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with M. TB. Any reactive specimen with the TB IgG/IgM Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

General Description

Tuberculosis is a chronic, communicable disease caused principally by M. TB hominis (Koch's bacillus), occasionally by M. TB bovis. The lungs are the primary target, but any organ may be infected.
The risk of TB-infection has exponentially declined in the 20th century. However, the recent emergence of drug-resistant strains, particularly among patients with AIDS, has rekindled interest in TB. The incidence of infection was reported around 8 million cases per year with a death rate of 3 million per year. The mortality exceeded 50% in some African countries with high HIV rates.
The initial clinical suspicion and radiographic findings, with subsequent laboratory confirmation by sputum examination and culture are the traditional method(s) in the diagnosis of active TB. However, these methods either lack sensitivity or are time consuming, in particularly are not suitable for patients who are unable to produce adequate sputum, smear-negative, or suspected to have extra-pulmonary TB.
The TB IgG/IgM Rapid Test is developed to alleviate these obstacles. The test detects IgM and IgG anti-M.TB in serum or plasma in 10 minutes. An IgM positive result indicates for a fresh M.TB infection, while an IgG positive response suggests a previous or latent infection. Utilizing M.TB specific antigens, it also detects IgM anti-M.TB in patients vaccinated with BCG. In addition, the test can be performed by untrained or minimal skilled personnel without cumbersome laboratory equipment.

Principle Of The Test

The TB IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a colored conjugate pad containing M.TB antigens conjugated with colloid gold (M.TB conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing two test lines (T1- and T2-line) and a control line (C-line). The T1-line is pre-coated with monoclonal anti-human IgM for the detection of IgM anti- M.TB, the T2-line is pre-coated with reagents for the detection of IgG anti-M.TB, and the C-line is pre-coated with goat anti-rabbit IgG.
When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the membrane. IgM anti-M.TB if present in the specimen will bind to the M.TB conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody, forming a burgundy colored T1-line, indicating a M.TB IgM positive test result.
IgG anti- M.TB, if present in the specimen, will bind to the M.TB conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a burgundy colored T2-line, indicating a M.TB IgG positive test result.
Absence of any T lines (T1 and T2) suggests a negative result. The test contains an internal control (C-line) which should exhibit a burgundy colored line of the immunocomplex of goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the T-lines. Otherwise, the test result is invalid and the specimen must be retested with another device.

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Reagents And Materials Provided

1. Single wrapped test devices, each sealed in a foil pouch with three items inside:
a. 50 cassette devices.
b. Plastic dropper.
c. Desiccant.
2. Package insert (instruction for use).

Materials Required But Not Supplied

1. Clock or timer

Storage

1. Store the unused and unopened test kit at room temperature (2-30ºC).
2. Each device may be used until the expiration date printed on the label if it remains sealed in the foil pouch containing desiccant.
3. Do not freeze the kit and or expose the kit to the temperature over 30ºC.

Specimen Collection And Preparation

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.
Plasma
1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma into new pre-labeled tube.
Serum
1. Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube.
Test specimens as soon as possible after collecting. Store specimens at 2°C-8°C if not tested immediately. Store specimens at 2°C- 8°C up to 5 days. The specimens should be frozen at -20°C for longer storage.
Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently.
Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

Assay Procedure

1. Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.
2. When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
3. Be sure to label the device with specimen’s ID number.
4. Fill the plastic dropper with the specimen. Holding the dropper vertically, dispense 2-3 drops (about 60-90 µl) of specimen into the sample well making sure that there are no air bubbles.
Note: Add 1 drop of Saline or Phosphate-Saline buffer (common buffers used in clinic not provided in the kit) into the sample well if flow migration is not observed within 30 seconds in the result window, which could occur with a highly viscous specimen.

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5. Set up timer.
6. Results can be read in 10 minutes. Positive results can be visible in as short as 1 minute.
Don’t read result after 10 minutes. To avoid confusion, discard the test device after interpreting the result.

Interpretation of Results

1. NEGATIVE RESULT: If only the C-line is present, the absence of any burgundy color in the both T-lines (T1 and T2) indicates that no anti- M.TB antibodies are detected. The result is negative.

2. POSITIVE RESULT:
2.1. In addition to the presence of C-line, if only T1-line is developed, indicates for the presence of IgM anti- M.TB. The result is positive.
2.2. In addition to the presence of C-line, if only T2-line is developed, the test indicates for the presence of IgG anti- M.TB. The result is positive.
2.3. In addition to the presence of C-line, both T1- and T2-lines are developed, indicates for the presence of IgG and IgM anti-M.TB. The result is also positive.
Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

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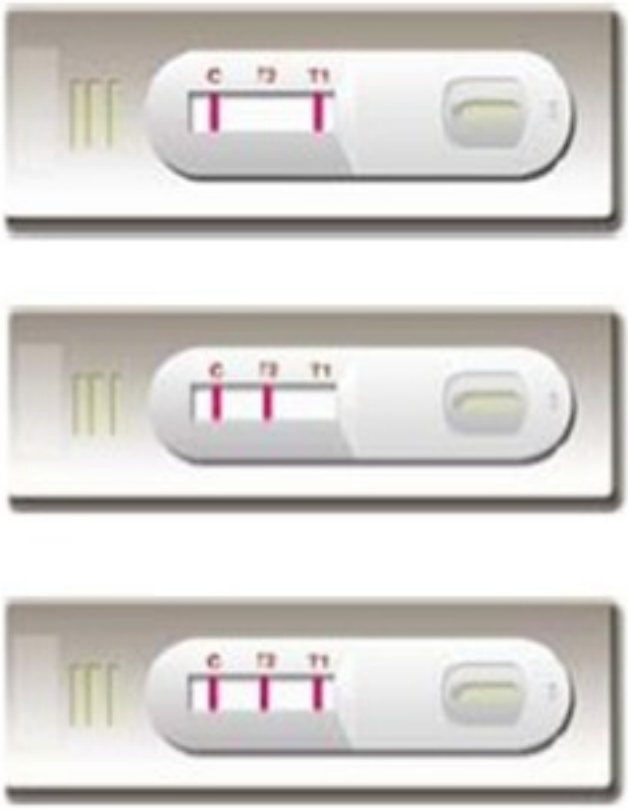

3. INVALID RESULT: If no C-line is developed, the assay is invalid regardless of any burgundy color in the T-lines as indicated below. Repeat the assay with a new device.

Performance Characteristics

1. Clinical Performance for IgM Test

A total of 300 specimens from non-TB patients and 75 specimens from patients under anti TB treatment were tested by the TB IgG/IgM Rapid Test and a commercial TB IgM ELISA kit. Comparison for all subjects is showed below.

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Relative Sensitivity: 93.3%, Relative Specificity: 97%, Overall Agreement: 96.5%

2. Clinical Performance for IgG Test

A total of 300 specimens from the non-TB patients and 75 specimens from the patients under anti TB treatment were tested by the TB IgG/IgM Rapid Test and a commercial TB IgG ELISA kit. Comparison for all subjects is showed below.

Relative Sensitivity: 94.6%, Relative Specificity: 97.6%, Overall Agreement: 97.3%

Precautions

1. Instructions must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all components (cassette, controls) to room temperature (15°C-30°C) before use.
5. Do not use hemolized blood specimen for testing.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
8. All patient samples should be treated as if capable of transmitting diseases. Dispose all of the specimens and used assay materials in a proper biohazardous container.
9. Handle the negative and positive control in the same manner as patient specimens.
10. The testing results should be read within 10 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 10 minutes may give erroneous results.
11. Do not perform the test in a room with strong air flow, ie. an electric fan or strong airconditioning

Limitations

1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of antibodies to M.TB in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The TB IgG/IgM Rapid Test is limited to the qualitative detection of IgG and IgM anti-M.TB in human serum or plasma. The intensity of the test line does not correlate with antibody titer of the specimen.
3. The test also recognizes antibodies to M. bovis and M. africanum.
4. An IgG positive response may be detected in BCG vaccinated personnel.
5. A negative result for an individual subject indicates absence of detectable antibodies to M.TB. However, a negative test result does not preclude the possibility of exposure to or infection with M.TB.
6. A negative result can occur if the quantity of the antibodies to M.TB present in the specimen is below the detection limit of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
7. Immunocompromised condition such as HIV infection may reduce the test sensitivity.
8. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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