DIALAB Produktion und Vertrieb von chemisch – technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
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„DIAQUICK“ Tuberculosis IgG/IgM Cassette

for serum and plasma samples

REF

Content

Z09460

- 25 cassettes individually packed (25 x Ref. No: Z09460B)
- 1 buffer tube – assay diluent sufficient for 25 tests
- 25 10µl capillary pipettes
- 1 package insert

For In-vitro diagnostic use only

INTENDED USE

The DIAQUICK Tuberculosis IgG/IgM Cassette is a chromatographic immunoassay for the qualitative differentiation of IgG and IgM antibodies to M. tuberculosis in human serum or plasma. This test is intended for professional use and may be useful as a complementary technique for the diagnosis of *M. tuberculosis* infection.

SUMMARY

Tuberculosis is a highly infectious disease caused by *Mycobacterium tuberculosis* and potentially fatal disease of human. Traditional laboratory test in diagnosis of TB infection includes sputum examination for the presence of M. tuberculosis, culture of sputum or other body fluid, the tuberculin skin test and radiology, which is either insensitive or time-consuming. Accuracy of both methods is limited. Therefore reliable serologic test would have considerable advantage.
Tuberculosis is entirely regulated by cell mediated immune response (CMI) of the host. When bacillary antigens are present at low levels the CMI response causes macrophages to accumulate, get activated and then destroy the bacilli. When the bacillary antigens are present at high levels the CMI response causes necrosis of tissue. Tuberculosis involves both macrophages and lymphocytes, dead organism, are broken down relatively within the granuloma, releasing large quantities of glycolipid and polysaccharides, antigen into the draining lymphnodes leads to predominately humoral immune response. TB IgG antibodies appear when an infection becomes established. This indicates a good immunological response of the patients to the infection.
TB IgM plus TB IgG measurements are analyzed together to detect reactivation cases in chronic infection or active TB infection. An IgM positive result indicates for a fresh TB infection, while an IgG positive response suggests a previous or chronic/acute infection.

TEST PRINCIPLE

The DIAQUICK Tuberculosis IgG/IgM Cassette has a letter of C (control line), M (TB IgM test line) and G (TB IgG test line) on the surface of the case.
The inner test strip is composed of
1) a conjugate pad containing recombinant TB specific antigens (38 kDa, 16kDa and 6 kDa) conjugated with colloidal gold,
2) a nitrocellulose membrane containing C (control line), M (TB IgM test line) and G (TB IgG test line). The M line is pre-coated with monoclonal anti-human IgM, the G line is pre-coated with monoclonal anti-human IgG and the C line is pre-coated with goat anti-TB.
The “Control Line” is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. During the test, TB IgG or/and TB IgM if present in the specimen, migrate through the conjugate pad where they bind to the conjugates. The antibody conjugates are then captured by anti-human IgM immobilized on M line, or the specific reagents to TB IgG immobilized on G line of the membrane, forming a colored band on the test region (M or/and G), indicating a positive result.

MATERIALS PROVIDED

The DIAQUICK Tuberculosis IgG/IgM Cassette contains the following items to perform the assay:

- Test device individually foil pouched with a desiccant
- 10µl capillary pipette
- Assay diluent
- Instructions for use

KIT STORAGE AND STABILITY

- The DIAQUICK Tuberculosis IgG/IgM Cassette should be stored at room temperature (1-30°C).
- The test device is sensitive to humidity and as well as to heat.
- Perform the test immediately after removing the test device from a foil pouch.
- Do not use it beyond the expiration.
- Do not freeze.
- Do not store the test kit in direct sunlight

WARNINGS

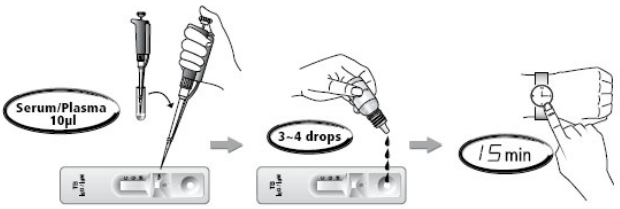
- For in vitro diagnostic use only.
- Do not eat or smoke while handling specimens.
- Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
- Clean up spills thoroughly using an appropriate disinfectant.
- Decontaminate and dispose of all specimens, reaction kits and potentially 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.

SPECIMEN COLLECTION AND PREPARATION

- The DIAQUICK Tuberculosis IgG/IgM Cassette may be performed using human serum or plasma.
- **Serum**: Collect the whole blood into the collection tube (not containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant. Carefully withdraw the serum into a new tube.
- **Plasma**: Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture. Separate the plasma by centrifugation. Carefully withdraw the plasma into a new tube.
- If serum/plasma specimens are not tested immediately, they should be refrigerated at 2-8°C. For storage period longer than 2 weeks, freezing is recommended. They should be brought to room temperature (1-30°C) prior to use.
- Specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
- Repeated freezing and thawing may give erroneous results.
- The use of hemolytic, lipemic or bacterially contaminated specimens should be avoided.

TEST PROCEDURE

- Remove the test device from the foil pouch, and place it on a flat, dry surface.
- Add 10µl of serum or plasma into the square-shaped sample well with capillary pipette.
- Add 4 drops (90-120µl) of assay diluent into the round-shaped diluent well.
- As the test begins to work, you will see purple color move across the result window in the center of the test device.
- Interpret the test results in 15 minutes after sample application.



INTERPRETATION OF THE TEST

Negative result
The presence of only control band (“C” line) within the result window indicates that no TB antibodies are detected. The result is negative.

TB IgM Positive Only
The presence of two color bands (“M” and “C” line) within the result window, no matter which band appears first, indicates presence of TB IgM. An IgM positive result indicates for a fresh TB infection.

TB IgG Positive Only
The presence of two color bands (“G” and “C” line) within the result window, no matter which band appears first, indicates presence of TB IgG. An IgG positive response suggests a previous or chronic/acute infection.

TB IgG and IgM Positive
The presence of three color bands (“G”, “M” and “C” line) within the result window, no matter which band appears first, indicates presence of both TB IgG and TB IgM. These results are analyzed together to detect reactivation cases in chronic infection or active TB infection.

Invalid result
If the control band is not visible within the result window after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen should be re-tested.

LIMITATION OF THE TEST

1) Although the DIAQUICK Tuberculosis IgG/IgM Cassette is very accurate in detecting antibodies to TB, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained.
2) The DIAQUICK Tuberculosis IgG/IgM Cassette is limited to the qualitative detection of IgG and IgM anti-*M. tuberculosis* in human serum or plasma.
3) Test also recognizes antibodies to *M.bovis* and *M. africanum*.
4) 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.

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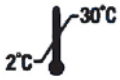

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