**INTENDED USE**
The LIODetect®TB-ST Tuberculosis Rapid Test is an in-vitro diagnostic test for the qualitative detection of IgG, IgA and IgM antibodies to Mycobacterium tuberculosis in serum or plasma within 20 minutes.

This test is intended for research use only and should not be used for diagnostic purposes.

**INTRODUCTION / FIELD OF APPLICATION**
Human tuberculosis (TB) has become a global disease with its re-emergence in the Western countries in the last decades. According to WHO, more than 30% of the world’s population is estimated to be infected with the TB bacterium, Mycobacterium tuberculosis. TB is predominantly a disease of the respiratory tract, but can also affect other organs. People who are suffering from active pulmonary tuberculosis are highly infectious. The spread of TB takes place by coughing and sneezing. TB kills yearly about 2 million people. Although, the TB bacterium was identified more than 100 years ago, the diagnostic methods, which are currently available, suffer from high price, poor sensitivity and specificity and are mostly time consuming. The diagnosis of TB is usually made based on a combination of several laboratory tests. The LIODetect®TB-ST Tuberculosis Rapid Test is suitable for the qualitative detection of human IgG, IgA and IgM antibodies to M. tuberculosis within 20 minutes.

**PRINCIPLE OF THE TEST**
The LIODetect®TB-ST Tuberculosis Rapid Test is a membrane based test for the qualitative detection of IgG, IgA and IgM antibodies to Mycobacterium tuberculosis in serum or plasma.

The test consists of one test strip, which is integrated in a test cassette. This test strip consists of the following components:

1. A special antibody-binding protein, coupled to colloidal gold particles (conjugate).
2. A membrane with two test lines and one control line.

One test line contains a unique combination of TB antigens, the other one consists of a single cell wall antigen. The control line consists of an antibody-binding protein.

After the sample (serum or plasma) is pipetted followed by the LIODetect®TB-ST Diluent into the sample well (S), the diluted sample passes through the gold-labelled antibody-binding protein (conjugate). The immunoglobulins in the sample bind to the conjugate. The antibody-conjugate complex migrates due to the capillary action to the site of the membrane where the TB antigens / cell wall antigen are immobilized (test lines). If antibodies against tuberculosis are present in the sample, these bind to the test line / S.

In the result window of the test device, one or two pink / purple lines appear in the test zone ("T"). The remaining complex migrates further across the membrane to the control zone ("C"). Again a pink / purple line appears, indicating that the test was performed correctly.

**SUPPLIED MATERIALS**

**Packaging sizes:**

**REF: 3010 (10 Tests):**
- 10 test cassettes and 1 dropper bottle containing 3.5 mL LIODetect®TB-ST Diluent.

**REF: 3020 (20 Tests):**
- 20 test cassettes and 2 dropper bottle containing 3.5 mL LIODetect®TB-ST Diluent.

**REF: 3050 (50 Tests):**
- 50 test cassettes and 5 dropper bottle containing 3.5 mL LIODetect®TB-ST Diluent.

**TEST COMPONENTS**

- LIODetect®TB-ST Diluent: dropper bottle containing dilution buffer - 3.5 mL
- Test cassette: individually sealed in an aluminum bag with a single use pipet.
- 1 Instructions for use

**NOTE:** Pictures may differ from the original.

**MATERIALS NEEDED BUT NOT SUPPLIED**

- Stop watch.
- Containers for sample collection. We recommend using standard containers for blood collection.

**PREPARATION OF REAGENTS**

All reagents are ready-to-use. No further preparation of reagents is necessary.

**STABILITY AND STORAGE CONDITIONS**

Store the test at 2 - 30°C. Unopened kit components (aluminum bags and LIODetect®TB-ST Diluent) are stable until the expiry date. The expiry date is printed on the labels of the aluminum pouch, the LIODetect®TB-ST Diluent and the outer packaging. Do not use if the aluminum bag is damaged. DO NOT FREEZE or expose to temperatures above 30°C.

Aluminum pouch with test cassette: Keep the test in unopened aluminum bag at 2 - 30°C.

Opened aluminum bag: Use test cassette within one day!

LIODetect®TB-ST Diluent (dilution buffer): Store the diluent at 2 - 30°C. Unopened diluent is stable until the expiry date. After first opening the diluent is stable until the expiry date, if the bottle is tightly closed after every usage.

**WARNINGS AND PRECAUTIONS**

- In accordance with Good Laboratory Practice (GLP) or ISO9001, all laboratory devices employed should be regularly checked for the accuracy and precision.
- Use reagents within the expiry period (printed on the labels).
- Do not use reagents from different kit lots or batch codes and avoid mixing of reagents of different kit lots or batch codes.
- Before use bring all reagents to room temperature (preferably 15 - 30°C).
- Only for serum, plasma or whole blood. Do not use the test with other body fluids.
- Avoid contamination of the reagents. Do not use the same container for several samples! Use separate single-use pipets for each sample (included in the kit).
- Lipemic, haemolytic or bacterially contaminated samples should not be used.
- Avoid the use of turbid samples which may be contaminated with bacteria.
- Avoid repeated freezing and thawing of the samples because it could lead to denaturation of the antibodies.
- For research use only! Do not ingest or swallow! Do not eat, drink and smoke in the laboratory! Do not work without wearing protective clothing (gloves, safety glasses and lab coat)! Avoid the contact of kit reagents with skin, eye or mucosa.
- All kit components should be considered as infectious agents. Decontaminate and dispose of residues of kit reagents (test cassettes and LIODetect®TB-ST Diluent) and samples in accordance to local regulations, e.g. by autoclaving or using a disinfesting solution.
- Avoid touching of the membrane in the result window of the test device with your fingers (danger of contamination).
- Do not pipette samples and LIODetect®TB-ST Diluent directly onto the membrane in the result window of the test device.
- For single-use only. The test is sensitive to moisture. Do not use if the outer packaging (aluminum bag) is damaged. After opening the aluminum bag, it must be used within one day.

**SAMPLE COLLECTION AND PREPARATION**
The LIODetect®TB-ST Tuberculosis Rapid Test is suitable for the detection of IgG, IgA and IgM antibodies in serum, plasma or whole blood. The test works best with fresh samples.

**Collection of whole blood from the vein:**
Take the sample under standard laboratory conditions (aseptically, avoid haemolysis).

**Collection of whole blood from the fingertip:**
- Disinfect your hands.
- Ask the patient to sit or to lay down.
- Use disposable gloves.
- Disinfect a puncture site with a skin disinfectant.
- Wait for exposure and drying time of the disinfectant.
- Puncture the skin with a sterile lancet.
- Massage the hand towards the fingertip (Caution! Do not touch the puncture site! Avoid strong pressure!)
- Discard the first drop and gently massage the hand from wrist to fingers to cause the formation of a drop of blood.
- Keep the puncture site downward (horizontal or slightly inclined) and take the drop of blood with the single use capillary. Try to touch only the leaked blood and avoid air bubbles.

Serum or plasma: Separate as soon as possible from the red blood cells (e.g. by centrifugation).

If the test cannot be performed immediately after the sampling, the samples can be stored for up to 3 days at 2 - 8°C. For longer storage, the whole blood must be centrifuged (separate serum or plasma from red blood cells). Serum and plasma can be stored at temperatures below -20°C. Frozen samples must be thawed prior to testing and well mixed. Avoid repeated freezing and thawing of samples!

**TEST PROCEDURE**

Test procedure time is 20 minutes:

1. Take the required number of test cassettes from the packaging kit. Remove the aluminum pouch and place the cassette / s on a clean, non-absorbent flat surface.
2. Pipette one drop of the sample into the sample well (S) on the cassette. Use the single-use pipet contained in the aluminum bag or alternatively a microliter pipet (sample volume 20 µL).
3. Add 3 drops of LIODetect®TB-ST Diluent into the sample well (S).
4. Start stop watch after addition of LIODetect®TB-ST Diluent and read the results after 20 minutes.
LIMITATIONS

Follow the instructions of the test procedure and interpretation.

The LIODetect®TB-ST Tuberculosis Rapid Test has been developed to detect IgG, IgA and IgM antibodies to M. tuberculosis in serum, plasma or whole blood. It is intended for professional in vitro diagnostic use only. For the measurements of other body fluids, this test has not been validated and results may be incorrect.

The test is specific for active tuberculosis (TB). The test is not suitable for the detection of so-called latent TB (LTB) or for contact screening of populations. Infections with other pathogenic mycobacteria can be detected with this test.

The test must not be used for diagnostic purposes. If a patient sample was tested as positive, more confirmatory tests should be performed (e.g. microscopy, culture results, serology, PCR, clinical symptoms, IGRA-cytokine detection). For a final diagnosis, include all information available for a patient.

Likewise, a negative test result does not exclude a possible TB infection or disease.

Note that doubtful results need further confirmation. If the result is not clear it is recommended to perform an interferon gamma release assay (IGRA) with the patient to confirm or exclude a possible infection.

NOTE: If precipitates appear in the LIODetect®TB-ST Dilluent, this will not affect the test results!

Interfering substances:

An excessive amount of lipids in a sample may cause due to homogenous physicochemical interferences. In addition, high concentration of lipids can potentially change the binding behavior of antibodies and thus falsify the results. Therefore, lipemic samples may not be used.

Haemolysed samples should not be used because certain components of red blood cells pass into plasma or serum and might have potentially affects on test results.

Recent or ongoing treatment for TB may lead to faulty results. Antibody levels in the blood may diminish rapidly after treatments with anti-TB antibiotics. Sometimes antibody levels can be so low in patient’s blood samples, that antibodies cannot even be detected at all in blood, plasma or serum — even if an infection or disease is present.

LITERATURE


Baumert R, Kämpfer S, Chogos NN, Nane MF, Oehling M, Wink D, Latour PT, van Helden PD, Singh M, Wink D. A subgroup of Latently Mycobacterium tuberculosis infected individuals is characterized by consistent elevated IgG responses to several Mycobacterial Antigens. Mediators of Inflamm. 2015; pii:3-10.5p.


