Atlas Medical

Tuberculosis IgG/IgM/IgA Rapid Test Device (Serum/Plasma)

IVD For *in vitro* diagnostic and professional use only.

2 30°C Store at 2-30 °C CE

INTENDED USE

The Tuberculosis Rapid Test Cassette (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of anti-TB antibodies (Isotypes IgG, IgM and IgA) in serum or plasma specimens.

INTRODUCTION

Tuberculosis (TB) is still a serious public health problem in the world, with about 8.9 to 9.9 million new cases and 1.3 million deaths occurring worldwide annually; it has been estimated that one-third of the world's population is infected with Mycobacterium tuberculosis (MT). One of the principles of TB control is rapid and accurate diagnosis of infected patients in order to allow prompt initiation of antibiotic therapy and to prevent transmission. Microscopic examination of sputum is a rapid, technically simple, and inexpensive test available for the routine diagnosis of TB in most developing countries. However, sputum smear microscopy with Ziehl-Neelsen staining is only 60 to 70% sensitive for the diagnosis of pulmonary TB (pTB) compared with the sensitivity of sputum culture. Mycobacterial cultures are more sensitive but take at least 2 weeks or longer if solid media are used, and culture facilities are not available in many countries. On the other hand, the lack of radiological appearances specific to TB makes chest radiography a relatively subjective and error-prone practice for the diagnosis of pTB. In addition, coinfection with HIV may change the clinical presentation of TB and reduce the sensitivity of classical microbiology methods. Therefore, in developing countries, it is especially important to have an inexpensive and rapid test for TB identification so that infected individuals can be isolated and treated immediately.

The Tuberculosis Rapid Test Cassette (Serum/Plasma) is a rapid test for qualitative detection of anti-TB antibodies (Isotypes IgG, IgM and IgA) in serum or plasma specimens. The test utilizes a combination of recombinant antigens to detect elevated levels of anti-TB antibodies in serum or plasma specimens.

PRINCIPLE

The Tuberculosis Rapid Test Cassette (Serum/Plasma) is a qualitative, solid phase, two-site sandwich immunoassay for the detection of anti-TB antibodies in serum or plasma specimens. The membrane is pre-coated with TB recombinant antigen on the test line region of the Cassette. During testing, the anti-TB antibodies, if present in serum or plasma specimen react with the particles coated with TB recombinant antigen. The mixture migrates upward on the membrane chromatographically by capillary action to react with TB recombinant antigen on the membrane and generate a colored line.

The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result.

To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

MATERIALS PROVIDED

- Test devices (contains TB recombinant antigen coated particles and TB recombinant antigen coated on the membrane.
- Disposable specimen droppers.
- Package insert.

MATERIALS NEEDED BUT NOT PROVIDED

- Specimen collection containers
- Centrifuge
- Timer

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Don't 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.
- The used test should be discarded according to local regulations.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- Do not use potassium oxalate as anticoagulant to collect plasma or venous blood samples.

STORAGE AND STABILITY

- Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C).
- The test is stable through the expiration date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Do not use after the expiration date.
- Care should be taken to protect the components of the kit from contamination. Biological contamination of dispensing equipment's, containers or reagents can lead to false results.

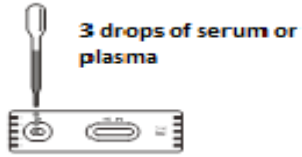
SPECIMEN COLLECTION AND PREPARATION

- The TB Tuberculosis Rapid Test Device (Serum/Plasma) can be performed using serum or plasma specimens.
- To prepare plasma Sample:
  1. Collect blood specimen into anticoagulant tubes containing EDTA, sodium heparin or sodium citrate.
  2. Separate the plasma by centrifugation.
  3. Carefully withdraw the plasma into ne pre-labelled tube.
- To prepare serum sample:
  1. Collect blood specimen into plain tube (without anticoagulants).
  2. Allow the blood to clot.
  3. Separate the serum by centrifugation.
  4. Carefully withdraw the serum into a new pre-labelled tube.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.

PROCEDURE

Allow the test device and specimen to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Place the test device on a clean and level surface.
3. Hold the dropper vertically; transfer **3 drops of serum or plasma (approximately 75 µL)** to the specimen well (S) of test device and then start the timer. See illustration below.
4. Wait for the colored line(s) to appear. The result should be read **at 10 minutes**. Do not interpret the result after **30 minutes**.



INTERPRETATION OF RESULTS

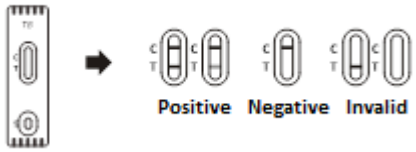
(Please refer to the illustration below)

POSITIVE:* Two distinct colored lines appear. One line should be in the control region (C) and another line should be in the test region (T).

*NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of anti-TB antibodies present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test Cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



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.
- 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. Some preservatives may interfere with the operation of the test. External controls should be validated before use to ensure valid results.

LIMITATIONS

- The Tuberculosis Rapid Test Cassette (Serum/Plasma) is for in vitro diagnostic use only. The test should be used for the detection of anti-TB antibodies in serum or plasma specimens. Neither the quantitative value nor the rate of increase in anti-TB antibodies concentration can be determined by this qualitative test.
- The Tuberculosis Rapid Test Cassette (Serum/Plasma) will only indicate the presence of anti-TB antibodies in the specimen and should not be used as the sole criteria for the diagnosis of active tuberculosis diagnosis.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

1. Clinical Sensitivity, Specificity and Accuracy:

The Tuberculosis Rapid Test Cassette (Serum/Plasma) has been calibrated against specimens that have been collected from individuals found to be either smear positive/negative or culture positive/negative. The results show that the relative sensitivity of the Tuberculosis Rapid Test Cassette (Serum/Plasma) is 83.8%, the relative specificity is 98.8 % and the relative accuracy is 95.7%.

Tuberculosis Rapid Test Cassette vs. Smear/Culture

Method		Serum/Culture		Total Results
Tuberculosis Rapid Test Cassette	Results	Positive	Negative	
	Positive	88	5	93
	Negative	17	405	422
Total Results		105	410	515

Relative Sensitivity: 88/105=83.8% (95%CI*: 75.3%~90.3%);
Relative Specificity: 405/410=98.8% (95%CI*: 97.2%~99.6%);
Relative Accuracy: (88+405)/(88+17+5+405)=493/515=95.7% (95%CI*: 93.6%~97.3%).
*Confidence Intervals

2. Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of two specimens: a negative and a high positive. The negative and positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 5 independent assays on the same two specimens: The negative and positive values. Three different lots of the Tuberculosis Rapid Test Cassette (Serum/Plasma) have been tested using negative and positive specimens. The specimens were correctly identified >99% of the time.

3. Cross-Reactivity

has been tested with specimens positive for: HBsAg , HBsAb , HBeAb , HBeAg, HBeAb, HBcAb, HCV , HAMA, HIV, H.pylori, MONO ,RF ,CMV, Rubella , TOXO and specimens from children below 15 years,, who have been administered BCG vaccine. No cross-reactivity was observed, indicating that the performance of the Tuberculosis Rapid Test Cassette (Serum/Plasma) is stable in presence of these factors.

4. Interfering Substances

The Tuberculosis Rapid Test Cassette (Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens, as well as serum specimens containing high bilirubin levels. Results indicate that no interference was observed in specimens containing up to 500 mg/dL hemoglobin; up to 30 mg/dL bilirubin; and up to 2,000 mg/dL human serum albumin.

REFERENCES

- Global tuberculosis control (2003). WHO Report 2003: 1-40.
- Raviglione M.C., Snider, Jr., D.E., and Kochi, A. Global epidemiology of tuberculosis. JAMA (1995), 273: 220-225.
- Laszlo A. Tuberculosis: laboratory aspects of diagnosis. CMAJ (1999), 160: 1725-1729.
- Bothamley G.H. Serological diagnosis of tuberculosis. Eur. Resp. J. (1995), 8: 676s-688s.
- Lyashchenko K., Colangeli R., Houde M., Jahdali H.A., Menzies D., and Gennaro M.L. Heterogenous antibody responses in tuberculosis. Infect. Immun. (1998), 66: 3936-3940.
- Lyashchenko K.P., Singh M., Colangeli R., and Gennaro M.L. A multi-antigen print immunoassay for the serological diagnosis of infectious diseases. J. Immunol. Methods (2000), 242: 91-100.

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry