CE
IVD

TB IgG/IgM Rapid Test Kit (Colloidal Gold) Instruction for Use

Read this instruction carefully before use

A rapid test for the qualitative detection of Human TB IgG/IgM in human serum, plasma or whole blood.For professional medical institutions use only,Not for self testing.

PRODUCT NAME

TB IgG/IgM Rapid Test Kit (Colloidal Gold)

SPECIFICATION

25 tests/kit; 5 tests/kit; 1 test/kit

INTENDED USE

The TB IgG/IgM Rapid Test Kit is a 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, plasma or whole blood. 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 Kit must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION THE TEST

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.

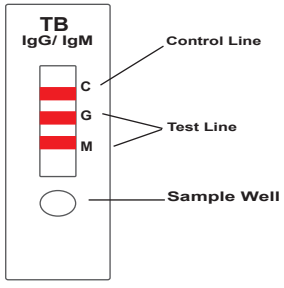
The risk of TB infection has exponentially declined in the 20th century. However, the recent emergence of drug-resistant strains1, particularly among patients with AIDS2, has rekindled interest in TB. The incidence of infection was reported around 8 million cases per year with a death rate of 3 million 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 TB5,6. 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 Combo Rapid Test is developed to alleviate these obstacles. The test detects IgM and IgG anti-M.TB in serum, plasm, or whole blood in 15 minutes . An IgM positive result indicates for a fresh M.TB infection, while an IgG positive response suggests a previous or chronic 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

The TB IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy 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 bands (M and G bands) and a control band (C band). The M band is pre-coated with monoclonal anti-human IgM for the detection of IgM anti- M.TB, the G band is pre-coated with reagents for the detection of IgG anti-M.TB, and the C band 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 cassette. 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 M band, 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 G band, indicating a M.TB IgG positive test result.

Absence of any test bands (M and G) suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the T bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

Components	25tests/kit	5tests/kit	1test/kit
Cassettes	25 cassettes with dependent sealed foil pouch	5 cassettes with dependent sealed foil pouch	1 cassette with dependent sealed foil pouch
Sample Diluent Solution with dropper	5 ml/bottle	1 ml/bottle	300ul/tube
Transfer tube	25 pcs	5 pcs	1 pcs
Package insert	1	1	1

MATERIALIS REQUIRED BUT NOT PROVIDED

Clock or Timer

WARNINGS AND PRECAUTIONS

For in Vitro Diagnostic Use

1.This package insert 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 reagents to room temperature (15°C-30°C) before use.
5.Do not use the components in any other type of test kit as a substitute for the components in this kit.
6.Do not use hemolized blood specimen for testing.
7.Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8.Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9.Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10.Dispose of all specimens and materials used to perform the test as biohazardous waste.
11.Handle the Negative and Positive Control in the same manner as patient specimens.
12.The testing results should be read within 25 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 25 minutes may give erroneous results.
13.Do not perform the test in a room with strong air flow, ie. electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. The positive and negative controls should be kept at 2°C-8°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety 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.
5.Test specimens as soon as possible after collecting. Store specimens at 2°C to 8°C if not tested immediately.
6.Store specimens at 2°C to 8°C up to 5 days. The specimens should be frozen at -20°C for longer storage

Blood

Drops of whole blood can be obtained by either finger tip puncture or veinpuncture. Do not use any hemolized blood for testing.

Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.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.

ASSAY PROCEDURE

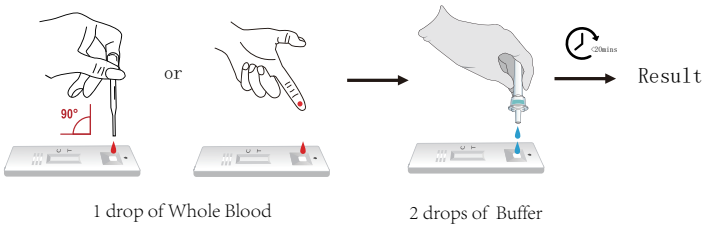
Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once thawed, mix the specimen well prior to assay.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with specimen's ID number.

Step 4: For whole blood test

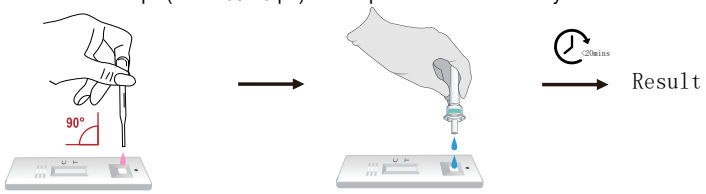
- Apply 1 drop of whole blood (about 30-35uL) into the sample well.
- Then add 2 drops (about 60-70 μL) of Sample Diluent immediately.



1 drop of Whole Blood 2 drops of Buffer

For serum or plasma test

- Fill the pipette dropper with the specimen.
- Holding the dropper vertically, dispense 1 drop (about 30-35uL) of specimen into the sample well making sure that there are no air bubbles.
- Then add 2 drops (about 60-70 μL) of Sample Diluent immediately.



1 drop of serum/plasma 2 drops of Buffer

Step 5: Set up timer.

Step 6: Results can be read in 20 minutes. Positive results can be visible in as short as 1 minute.

Don't read results after 30 minutes.To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

Internal Control: This test contains a built-in control feature, the C band. The C line develops after adding specimen and sample diluent. Otherwise, review the whole procedure and repeat test with a new device.

External Control: Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performing of the assay, in particularly, under the following circumstances:
a. New operator uses the kit, prior to performing testing of specimens.
b.A new lot of test kit is used.
c.A new shipment of kits is used.
d.The temperature used during storage of the kit fall outside of 2°C -30°C.
e.The temperature of the test area falls outside of 15°C -30°C.

TEST LIMITATIONS

Negative Control

If only the C band is present, the absence of any burgundy color in the both test bands (M and G) indicates that no anti- M.TB antibodies are detected. The result is negative.

Positive Control

IgG Positive: In addition to the presence of C band, if only G band is developed, the test indicates for the presence of IgG anti- M.TB. The result is positive.

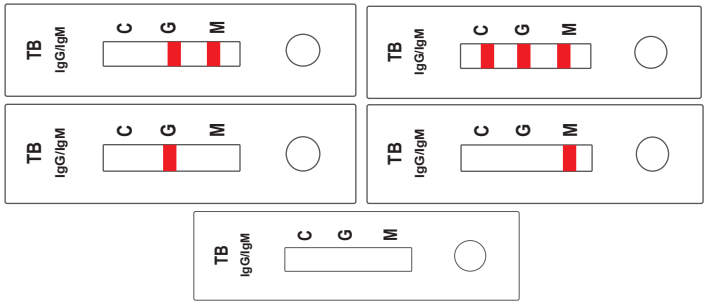
IgM Positive: In addition to the presence of C band, if only M band is developed, indicates for the presence of IgM anti- M.TB. The result is positive.

IgG/IgM Positive: In addition to the presence of C band, both M and G bands are developed, indicates for the presence of IgG and IgM anti- M.TB . The result is also positive.

Samples with positive or reactive results should be confirmed with alternative testing method(s) such as ELISA or PCR and clinical findings before a diagnostic decision is made.

INVALID:

If no C band is developed, the assay is invalid regardless of any burgundy color in the test bands(G and M) as indicated below. Repeat the assay with a new device.



PERFORMANCE CHARACTERISTICS

1. Clinical Performance For IgM Test

A total of 200 specimens from non-TB patients and 35 specimens from patients under anti TB treatment were tested by the TB IgG/IgM Combo Rapid Test and a commercial TB IgM ELISA kit. Comparison for all subjects is showed in the following table.

	TB IgG/IgM Rapid Test		
IgM ELISA Test	Positive	Negative	Total
Positive	30	5	35
Negative	7	193	200
Total	37	198	235

Relative Sensitivity: 85.7%, Relative Specificity: 96.5%, Overall Agreement: 94.9%

2. Clinical Performance For IgG Test

A total of 200 specimens from the non-TB patients and 35 specimens from the patients under anti TB treatment were tested by the TB IgG/IgM Combo Rapid Test and a commercial TB IgG ELISA kit. Comparison for all subjects is showed in the following table.

	TB IgG/IgM Rapid Test		
IgG ELISA Test	Positive	Negative	Total
Positive	31	4	35
Negative	7	193	200
Total	38	197	235

Relative Sensitivity: 88.6%, Relative Specificity: 96.5%, Overall Agreement: 95.3%

LMITATIONS OF TEST

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 band does not have linear correlation with the antibody titer in 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 limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
7 .Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
8.The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
LOT	Batch code	IVD	In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don't use the product when the package is damaged		Keep dry
	Date of manufacture	Σ	Tests per kit
CE	CE Mark		Biological Risks
EC REP	Authorized representative in the European Community		

BASIC INFORMATION

Ningbo BESTest Bio-technology Co.,Ltd.
Address: No.80 building, No.777, Qing Feng Road, Cicheng Town,Jiangbei District, Ning Bo, Zhejiang, China 315033
Tel: 0086 571 2799 8736

EC REP **SUNGO Europe B.V.**
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands.