CE
IVD

TB Antibody Rapid Test Kit (Colloidal Gold)

Instruction for Use

A rapid test for the qualitative detection of Mycobacterium Tuberculosis antibody in the specimens of human serum/plasma/whole.
For professional in vitro diagnostic use only.

PRODUCT NAME

TB Antibody Rapid Test Kit (Colloidal Gold)

SPECIFICATION

25 tests/kit, 5 tests/kit, 1 test/kit

INTENDED USE

Mycobacterium tuberculosis antibody Detection Kit is suitable for preliminary clinical screening qualitative detection of mycobacterium tuberculosis antibody in serum/plasma/whole blood sample. This reagent does not require any equipment, simple and rapid operation, and is suitable for auxiliary diagnosis of tuberculosis caused by mycobacterium tuberculosis.
For professional use only.
Tuberculosis is a chronic infectious disease caused by Mycobacterium tuberculosis, Mycobacterium bovis and Mycobacterium africanum in Mycobacterium tuberculosis complex, which can affect all organs of the body, especially pulmonary tuberculosis. The diagnosis of pulmonary tuberculosis is mainly based on bacteriological laboratory examinations, combined with chest imaging, epidemiological and clinical manifestations, necessary auxiliary examinations and differential diagnosis, and a comprehensive analysis is made. Coughing, expectoration for ≥2 weeks or hemoptysis are important clues for the detection and diagnosis of pulmonary tuberculosis. Sputum smear microscopy is the main method for finding patients infected with pulmonary tuberculosis, but requires equipment and skilled operators.

DETECTION PRINCIPLE

Mycobacterium tuberculosis antibody detection kit adopts highly specific antibody-antigen reaction and immunochromatographic analysis technology. The reagent contains tuberculosis antigen pre-immobilized in the test area (T) on the membrane and mouse anti-human IgG monoclonal antibody colloid gold conjugates as the peridium of polyester membrane. During the test, the sample is added to the reagent injection hole, and then the buffer is added dropwise to the buffer hole. The colloidal gold and buffer are then chromatographed upwardly by capillary effect. The sample reacts with the pre-peridiumed tuberculosis antigen with the buffer chromatography to the T-line position, and the colloidal gold reacts with the mixture on the membrane. If it is positive, the tuberculosis antibody in the sample first binds to the tuberculosis antigen immobilized on the membrane during the chromatography process, and then the colloidal gold binds to the conjugate on the membrane, and a purple-red band will appear in the test area (T). This band is formed by the combination of TB antigen-TB antibody-colloidal gold complexes on the membrane. If negative, there will be no purple-red band in the test area (T). The quality control line (Line C) is with peridium of sheep anti-mouse IgG polyclonal antibody.A purple-red band appears in the control area (C) regardless of whether TB antibodies are present in the specimen. The purple-red band displayed in the quality control area (C) is the standard for judging whether there are enough samples and whether the chromatography process is normal, and also serves as the internal control standard of the reagent.

MAIN COMPONENTS

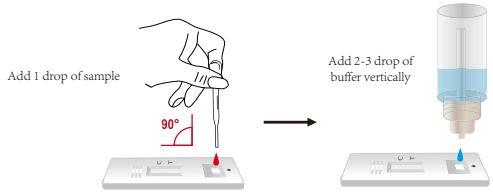
Reagent card
Buffer
Instruction manual
Items required for the test but not included in the kit: sampler, timer
Storage conditions and validity period: 4~30° C,
protected from light, valid for 24 months. Do not store
frozen.

SPECIMEN COLLECTION AND HANDING

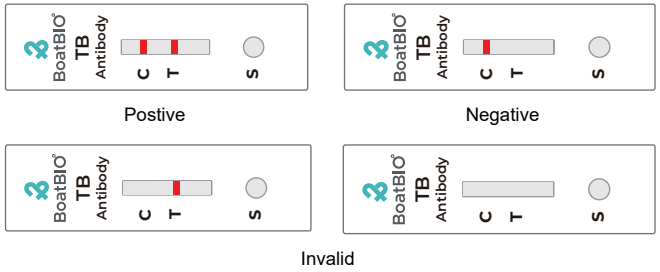
A.Whole blood sample
1. Extract the whole blood from the vein, and add the whole blood to the anticoagulant tube (EDTA. citrate and heparin, each of which can be used as an anticoagulant).
2.The whole blood sample should be detected immediately, or stored at 2~ 8°C, but no more than three days.
B.Plasma sample
1. Extract the whole blood from the vein, and add the whole blood to the anticoagulant tube (EDTA. citrate and heparin, each of which can be used as an anticoagulant);
2. Centrifugated at 3000rpm, for 5 to 10 minutes, carefully separate and remove the plasma.
3. The samples can be directly used for testing, and can be stored for 14 days from 2 to 8°C, and stored for 1 year at -20°C.
C.Serum sample
1. Extract the whole blood from the vein, and put the whole blood into the test tube (no anticoagulation), waiting for the blood to be frozen, about 30 minutes at room temperature.
2. Take the serum by centrifugal separation at 3000rpm for 5 to 10 minutes, make it carefully separated and removed serum.
3. Serum samples can be directly used for detection, and can be stored for 14 days at 2 ~ 8°C and 1 year at -20°C

TEST METHOD

1.Please read this instruction carefully before testing.
2.Take out the reagent card, test sample and etc., to restore at room temperature for use. everything is ready, tear the aluminum foil bag of the reagent card, take out the reagent card and place it on the horizontal table.
3.Add sample : Add 1 drop (about 20μl) serum/plasma or whole blood sample to the filling well through a pipette, or add 20μL sample through a quantifier, and then add 2-3 drops of buffer vertically.
4.Result judgement : Judge the result in 5 to 10 minutes after adding sample, do not read the result after 10 minutes.
5.Operation diagram is as follows:



INTERPRETATION OF TEST RESULTS



Postive: A red line appears on both the quality control line (line C) and the test line (line T) indicating the presence of hemoglobin in the sample.
Negative: There is only one red line on the quality control line (line C), while the absence of a red line on the test line (line T) which indicates that there is no hemoglobin in the sample or that the content of hemoglobin is below the minimum detection limit.
Invalid: No red line appears on the quality control line (line C), indicating invalid that may be due to incorrect operation or failure of the kit, and should be retried.

LIMITATIONS OF THE TEST METHOD

1. This kit is only used for qualitative detection of MycobacteriumTuberculosis urease antibody in human blood.
2. The positive results only show that the presence of Tuberculosis antibody which is not the only criterion for the infection of MycobacteriumTuberculosis, and the diagnosis should be combined with clinical symptoms and other diagnostic techniques.
3. The patient has been infected with MycobacteriumTuberculosis, and the antibody can also exist in the body for a long time, so the positive antibody result does not indicate that the patient is being infected with MycobacteriumTuberculosis.
4.The results of the negative results do not completely eliminate the possibility of the infection of MycobacteriumTuberculosis, which may be that the antibody of the MycobacteriumTuberculosis does not appear or the level of the antibody is too low to be detected by this kit.

PRODUCT PERFORMANCE INDEX

1. 1150 clinical samples were tested simultaneously with this reagent and Aikang reagent, the positive coincidence rate was 98.84%, the negative coincidence rate was 98.91%, and the total coincidence rate was 98.87%.
2. The common interfering substance whose concentration is less than or equal to the following values doesn't influence on the test results of this product.

Interfering substance name	Concentration
Hemoglobin	1000mg/dL
Ascorbic acid	20mg/ml
Bilirubin	60mg/dL
Oxalic acid	1000mg/dL
human serum albumin	2000mg/dL
Triglycerides	500mg/dL

3. This reagent is used to detect HIV-positive, hepatitis C-positive, mycoplasma pneumoniae, chlamydia pneumoniae, adenovirus, respiratory syncytial virus, influenza A virus, ev virus, streptococcus pneumoniae, lung cancer, pneumonia, chronic bronchitis and emphysema serum samples , resulting in no cross-reactivity.

INDEX OF SYMBOL

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
	Batch code		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		Tests per kit
	CE Mark		Biological Risks
	Authorized representative in the European Community		

BASIC INFORMATION

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