NEWSCEN
NEWSCEN COAST BIO-PHARMACEUTICAL CO., LTD.
NO. 65 Sixth Ave, TEDA Tianjin, 300457, P. R. China
Web(EN): www.newscenbiotech.com
E-mail: export@newscen.com

CE IVD

M. Tuberculosis (TB) Antibody Rapid Test

【For the qualitative detection of TB antibodies in serum and plasma】

(Single use test cassette)

The instruction must be read carefully and completely prior to the use of TB Antibody Rapid Test. Instruction must be followed carefully. If directions are not followed exactly, inaccurate test result may occur. Before performing testing, all operators must read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, Hepatitis C Virus and Other Blood-Borne Pathogens in Health-Care Settings.

INTENDED USE

The kit is a single use, rapid immunoassay for qualitative detection of antibodies to M. Tuberculosis (TB) antibody in human serum and plasma collected from vein.

PRINCIPLE

This kit uses indirect immunocolloidal gold technology to detect the TB IgG antibody in samples. The colloidal gold pad of the reagent contained the colloidal gold particles labeled with monoclonal antibody mouse anti-human (IgG1 subtype). The T-zone of NC membrane is coated with recombinant expression of mycobacterium tuberculosis 38KD and 16KD antigen, and the C-zone is coated with goat anti-mouse IgG polyclonal antibody. During the testing, When labeled colloidal gold chromatography to the T zone, if there is human IgG antibody bound to the T zone, it will bind with the colloidal gold to form a mouse anti-human labeled colloidal gold-tuberculosis specific IgG-tuberculosis specific antigen complex, and present a red colloidal gold line on the T zone. If there is no binding human IgG antibody on the T zone, it will not form complex and the T zone does not show color. When the labeled colloidal gold passes through the C zone, it will combine with the goat anti-mouse IgG to form the colloidal gold-goat anti-mouse IgG complex labeled with mouse anti-human, and present a red colloidal gold line on the C zone. If the C zone does not show color, it indicates that there is a problem in the test, and the result is invalid, it should be retried. This kit adopts the detection method of adding samples on the membrane, which can avoid the Hook effect caused by too much non-specific IgG in samples.

REAGENTS AND MATERIALS PROVIDED

Each kit contains:

1. Test cassette (individually pouched)
2. Each pouch contains one cassette, one desiccant bag
3. One bottle of diluent buffer
4. Instruction for use

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer or stopwatch
2. Blood collection devices, for the testing of serum or plasma
3. Biohazard disposal container
4. Disposable gloves

WARNING

For in vitro diagnostic use ONLY

Read the package insert completely before use. It is very important that the correct procedure is followed. Fail to add the patient sample may lead to a false negative result (i.e. a missed positive).

PRECAUTIONS

1. All the waste and specimen should be treated in case of transmitting disease and must be properly disinfected (autoclaving is preferred) before disposal.
2. Make sure the test is not expired (EXP Date is indicated on the kit box).
3. Do not use the test if the pouch has been perforated.
4. Do not modify the test procedure.
5. Each test is for single use only.
6. Blood that has been chemically treated, heated, diluted, or otherwise modified may result in inaccurate results.
7. Always interpret the results under good light conditions to avoid misreading of the results.
8. Different batch of product components cannot be mixed.
9. If desiccant bag is not present in the pouch, DO NOT USE the test.
10. Use the supplied disposable droppers for transfer of specimens onto the test cassette.
11. Always add accurate volume of specimen by following the instruction.
12. The test cassette must be used directly after unsealing. It is not allowed to divide it for use.
13. Observe the result in 15 minutes. A strongly positive sample can show results in a few minutes.

STORAGE

The kit should be stored at room temperature (2-30°C, do not freeze) for 18 months from the date of manufacture. Keep the test cassette in sealed pouch until use. Once you have taken the test cassette out of the pouch, perform the test as early as possible (within 1 hour) to avoid test cassette from becoming moist. Do not use the test beyond the indicated expiration date.

The diluent buffer should be stored at room temperature (2-30°C, do not freeze).

SPECIMENS COLLECTION AND STORAGE

Plasma

1. Have a certified phlebotomist collect whole blood into collection tube(containing EDTA, citrate or heparin) by veinpuncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma for testing, or label and store it at 4° C for up to five days. Plasma may be frozen at -20° C for at least three months.

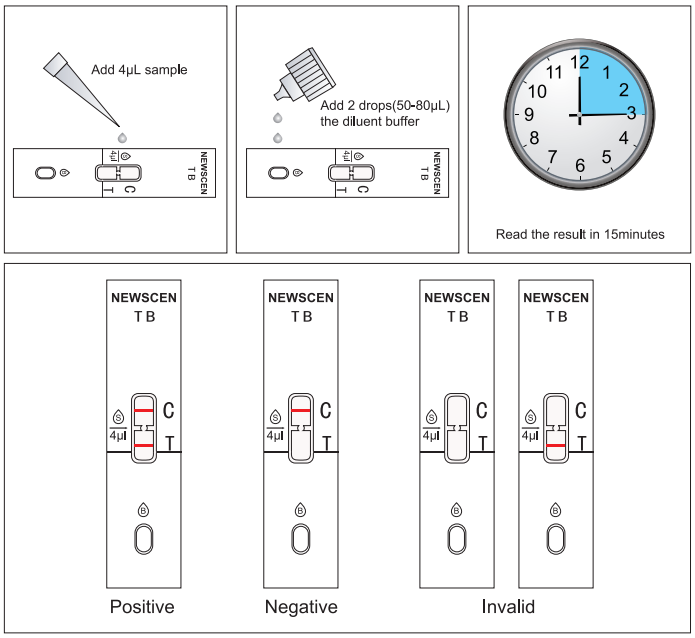
Serum

1. Have a certified phlebotomist collect whole blood into collection tube (containing no anticoagulants) by veinpuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum for testing or label and store it at 4° C for up to five days. Serum may be frozen at -20° C for at least three months.

ASSAY PROCEDURE

1. Place the test cassette on flat surface. Use it immediately once unsealed.
2. Open the pouch and add 4μL specimen (serum/plasma) into the middle position of NC membrane area of the cassette.
3. After the sample is completely absorbed, add 2 drops (50~80μL) diluent buffer to the sample hole and start the timing.
4. Observe the result in 15 minutes.

INTERPRETATION OF RESULTS



Note: 'C' – Control line; 'T' Test line

1. ***Negative***: No red line appear in the test zone (T) in 15 minutes only a red line shows in the control zone (C), indicates that no TB antibodies have been detected with this test.
2. ***Positive***: One red line shows in the control zone (C) and one in the test zone (T) indicates the specimen infect TB possibly, recommend further testing.
3. ***Invalid***: No red lines appear in the control zone (C) indicates that the test is invalid. Discard the test cassette and perform with new cassette.

Built-In Control

The kit has a built-in procedural control that demonstrates assay validity. If a red line appeared in the control zone (C), it indicates that the test runs correctly.

LIMITATION

1. The kit is intended for qualitative detection of antibodies to TB in samples.
2. The positive result cannot be the final diagnosis of TB. Any positive result must be interpreted in conjunction with the patient clinical history and another laboratory testing results. Follow-up and supplementary testing of all positive specimens with other tests is required to confirm any reactive result.
3. The kit is a qualitative assay and the results cannot be used to measure concentration of antibodies.

PERFORMANCE CHARACTERISTICS

1. ***Coincidence rate of positive reference materials***: 15 positive reference materials were tested, and the results were all positive.
2. ***Coincidence rate of negative reference materials***: 15 negative reference samples were tested and all the results were negative.
3. ***Minimum detection amount***: 3 samples of internal quality control sensitivity reference materials should be used for testing, L3 should be negative, L2 can be positive or negative, L1 should be positive.
4. ***Repeatability***: 10 test cards were tested in parallel with reference materials of internal quality control blood liquidation repeatability of the enterprise, and the test results should all be positive with consistent color intensity.
5. ***Interference factors***: Hemolytic hemoglobin > 5mg/mL, triglyceride > 8mmol/L in hyperlipidemia samples, and bilirubin > 300μmol/L in jaundice samples may affect the detection results and cannot be used for detection.
6. ***Cross reaction***: The kit has no cross reaction to HIV, HBV, HCV, TP, Streptococcus pneumoniae, Mycoplasma pneumoniae, influenza A virus, Helicobacter pylori and RF factor antibody positive samples.
7. ***Clinical sample compliance***: A total of 1031 clinical samples were tested for validation, of which 410 were positive and 621 were negative. The test results are as follows:

The positive, negative and total coincidence rates were 90.0%, 87.0% and 88.2%. The consistency coefficient Kappa (K) value was 0.76, greater than 0.75, indicating a good consistency between the two kits.

Table 1

The inspection reagent (NewScen)	Contrast reagent (Shanghai Aopu)		Total
	+	−	
+	369	81	450
−	41	540	581
Total	410	621	1031

Performance statistics are as follows:

Positive coincidence rate＝369/410×100%=90.0%;

Negative coincidence rate＝540/621×100%=87.0%;

Total coincidence rate＝(369+540)/(410+621)×100%=88.2%.

REFERENCE

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INDEX OF SYMBOLS

	Do not re-use
IVD	For In Vitro Diagnostic medical device
	Use by date
	Date of manufacture
2C 30C	Temperature limitation
	Consult instructions for use
EC REP	Authorized Representative in the European Community
LOT	Batch code
CE	CE Mark
	Manufacturer

Product disclaimer: This product has been manufactured under strict GMP regulation to ensure the diagnostic accuracy of the test. It is out of control of the manufacture when the test is performed in diverse environment and by diverse group of individuals that may affect the results to a certain degree.

Note: The manufacturer, the distributor, or its associates will not be liable for any losses, claims, liability, costs or damages, whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether a positive or negative by use of this product.

NEWSCEN COAST BIO-PHARMACEUTICAL CO., LTD.
No. 65, 6th Street, Tianjin TEDA, 300457, Tianjin,
PEOPLE'S REPUBLIC OF CHINA

EC REP **Riomavix S.L.**
Calle de Almansa 55, 1D, Madrid 28039 Spain