Instruction for Tuberculosis IgM (TB-IgM) Test Kit (Immunofluorescence)

1. PRODUCT NAME

Generic name: Tuberculosis IgM (TB-IgM) Test Kit (Immunofluorescence)

Trade name: TB-IgM

2. PACKAGE

Specification 1: 25T/kit REF:52026133

Specification 2: 50T/kit REF:52027124

Quality Control (optional):

Specification: Level 1 : 0.5mL × 1 REF: 52105121

Level 2 : 0.5mL × 1 REF: 52105122

3. INTENDED USE & INDICATION

For in vitro qualitative determination of TB-IgM antibody in human serum, plasma, or whole blood. This test is intended to support the diagnosis of active tuberculosis(TB) and is not suitable for contact screening of populations.

For professional use only.

4. TEST PRINCIPLE

After the samples containing TB-IgM are taken and added into the sample well, the TB-IgM in the sample binds to the TB antibody coupled to the fluorescent particles to form a immune complex. This immune complex is then chromatographed along the nitrocellulose membrane to the determination area (T), combined with the pre-coated TB antigen and continues to chromatograph to the quality control area (C). The fluorescent particle-labeled goat anti-rabbit IgM binds to the precoated rabbit IgM and presents the quality control line. The fluorescence intensity of the assay area is directly proportional to the level of TB-IgM in the sample.

5. MAIN COMPONENTS& ADDITIONAL REQUIRED EQUIPMENT

The test kit consists of test card, magcard, sample diluent, quality control (optional) and the instruction.

(1) The test card consists of card shell and test strip. The test strip contains sample pad/marking pad, nitrocellulose membrane, absorbent paper and PVC plate.

(2) Magcard: load calibration curve information for this batch of reagents.

(3) Sample diluent: The main ingredient is phosphate buffer(PBS).

(4) Quality control (optional): Self-prepared lyophilized powders, mainly consist of TB-IgM recombinant antigen and PBS. All are free of human-derived substances and have batch specificity. Please find target values in the target value list.

(5) Equipment: Applicable to FA50 and FA120 Quantitative Immunoassay Analyzer manufactured by Genrui Biotech Inc.

Note: Components of kits from different batches should not be used interchangeably.

6. ACCESSORIES REQUIRED BUT NOT PROVIDED

(1) Pipettes and pipette tips: 100 μL

(2) Timer

7. SPECIAL STORAGE &TRANSPORT CONDITIONS

(1) The test kit should be stored at 2-30℃, and the shelf life of test cards and sample diluent is 18 months when sealed. After the test card and sample diluent are opened, the shelf life is 1 hour at 18-30℃ and 40%-65% humidity. When the humidity is > 65%, it should be used right after opened.

(2) The unopened QC is stable for 18 months (see the label for specific date) at -25℃ to 8℃, the reconstituted QC is stable for 6 days at -20℃ or 1 day at 2-8℃ in the shade, and can be freeze-thawed once.

(3) Transport: The test kit is at 2-30℃, the QC is at -25-8℃.

8. SAMPLE REQUIREMENTS

(1) The optimal sample is fresh non-hemolyzed serum, plasma or whole blood. It is recommended to use sample from venous blood, as results of other body fluids and samples may not be accurate.

(2) Serum/plasma: After sample collection, serum should be separated as soon as possible to avoid hemolysis. Serum and plasma should complete the test within 6 hours at room temperature. The samples that cannot complete the test should be refrigerated at 2-8℃ for no more than 7 days; serum and plasma should be frozen below -18℃ for no more than 1 month.

(3) Whole blood: It should be used immediately after collection. If it cannot be tested within 4 hours, it should be refrigerated at 2-8℃ for no more than 3 days. Samples should not be frozen.

(4) The samples should be brought to room temperature before determination. The frozen samples should be completely thawed, rewarmed and mixed well before use. Do not freeze and thaw repeatedly.

(5) Human serum is preferred for determination, and EDTA-K_2 is recommended as an anticoagulant for plasma and whole blood testing.

9. TEST METHOD

Carefully read the instruction before using the test kit and operate in strict accordance with the instruction to ensure reliable results. Bring all reagents to room temperature (18-30℃) before use.

(1) Startup: Click “STD Mode” in the main menu to enter the measurement interface, click “Item” to select the test item and click “Type” to select the sample type.

(2) Click “Lot No.” to enter the card reading interface, place magcard of the corresponding item to the magnetic card reader area, when the magcard is read successfully, check whether the magcard and the test card are of the same batch. (Note: reagents are precalibrated and specific calibration curve parameters for each batch of reagents have been stored in the magcard.)

(3) Quality control procedure: It is recommended to refer to the instrument manual and use the Genrui quality control to verify whether the target value of the test quality control is under control during the measurement procedure after calibration. The quality controls should be used as follows.

a）Bring the quality control to room temperature (18-30°C) before use.

b）Carefully open the bottle cap to avoid spraying of the contents.

c）Add 0.5 mL of purified water.

d）Put on the bottle cap and leave it at room temperature for 15 minutes, gently shake the bottle to fully dissolve the dry powder.

e）After the dry powder is fully dissolved, repeat the operation for the sampling.

If the measured values of quality controls meet the following: the Level 1 is negative, the Level 2 is positive, the determination of clinical samples and data analysis can be continued; otherwise, the causes should be identified before test.

(4) Sampling:

Add 0.1mL of serum, plasma or whole blood into the container with sample diluent, mix thoroughly. Take 0.1mL of diluted sample, and drop it vertically to the sample well on the test card directly and start timing.

(5) Insert it into the analyzer’s test card slot (the sample well end towards the inside). Click “Measure”, the instrument will automatically detect and print out the results after 15 minutes (If using “Fast Mode”, after 15 minutes of external incubation, quickly insert card and click “Measure”, then instantly the instrument will detect and print out the results).

Note: For detailed instructions on how to operate the instrument, please refer to the manual of Quantitative Immunoassay Analyzer.

10. INTERPRETATION OF TEST RESULT

The results of instrument printing are presented in the form of fluorescent signal value (FSV) as follows.

Fluorescent signal value (FSV)	Interpretation	Note
≤0.9	Negative for Tuberculosis IgM (TB-IgM)	No need to additional test
>0.9	Positive for Tuberculosis IgM (TB-IgM)	Need for further confirmation test.

11. INTERFERING SUBSTANCE

(1) Cross-reactivity

Materials	Tuberculosis IgM (TB-IgM)
HAV	Negative
HIV	Negative
HBV	Negative
HCV	Negative
CMV	Negative
TP	Negative

(2) Interference

There was no significant interference from these materials

Clinical category	Concentration
Bilirubin	0.5 mmol/L
Hemoglobin	2 g/L
Triglycerides	1.5 mg/mL
RF	2000 U/mL

12. **PERFORMANCE CHARACTERISTICS**

810 samples which include 181 confirmed as TB-IgM positive and 629 confirmed as TB-IgM negative by contrast reagent, were obtained for testing, and then compared the test results of Genrui Tuberculosis IgM (TB-IgM) Test Kit with contrast reagent results. The results are shown below.

		Contrast reagent		Subtotal
		Positive	Negative	
Tuberculosis IgM (TB-IgM) Test Kit	Positive	152	10	162
	Negative	29	619	648
Subtotal		181	629	810

Sensitivity：83.98% (95%CI: 77.81%~89.00%)

Specificity：98.41% (95%CI: 97.10%~99.23%)

Overall Percent Agreement：95.19% (95%CI: 93.48%~96.55%)

13. PRODUCT PERFORMANCE INDICATORS

(1) Limit of detection:

Titre of TB-IgM antibody	Fluorescent signal value (FSV)	Result
Test samples when determining antibody titer	0.91	Pos

(2) Precision: intra-batch precision: CV ≤ 15%; inter-batch precision of the kit CV ≤ 15%

14. PRECAUTIONS

(1) Once opened, use the test cards as soon as possible, which may be exposed to moisture in the air. Do not reuse the test cards.

(2) Components in test kit of different batches cannot be used interchangeably.

(3) For substances containing sources of infection or suspected of containing sources of infection, there should have proper bio-safety assurance procedures. Pay attention to the following notes:

-- Wear gloves when handling sample or disinfecting the reagent.

-- Disinfect spilled sample or reagent with disinfectant.

-- Disinfect or handle potential contamination sources of all samples or reagents in accordance with local regulations.

15. EXPLANATION OF GRAPHIC SYMBOL

	Consult instructions for use		Temperature limit
LOT	Batch code		Use-by date
IVD	*In vitro* diagnostic medical device	CE	CE Marking
	Date of manufacture		Biological risks
	Manufacturer		Volume
Σ	Contains sufficient for < n>tests		Keep away from sunlight
	Do not re-use		Keep dry
EC REP	Authorized representative in the European community	REF	Catalogue number

16. REFERENCE

(1) Schaaf, H . S. P . Botha, N. Beyers, R. P. Gie, H. A. et, al 1996. The 5-year outcome of multi drug resistant tuberculosis patient in the Cape Province of South Africa. Trop. Med. Int. Health 1:718-722.

(2) Havlir, D. V, and P. F. Barnes, 1999. Tuberculosis in patients with human immunodeficiency virus infection. N. Engl .j. Med. 340:367-373.

17. HELP INFORMATION

If you need help, please contact after sales department.

18. MANUFACTURER

Genrui Biotech Inc.

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19. INSTRUMENTS & APPLICATIONS

Genrui's Immunofluorescence products are designed to work in automated lab, which are compatible with the FA50/FA120 Quantitative Immunoassay Analyzer. There may or may not be an application developed for your particular instrument, please visit the instrument section of our website.

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