IVD

Specific Antibody to Mycobacterium Tuberculosis (TB Dot)

Catalog No. 09C0201

20 /40 tests

INTENDED USE

This is an assay combining two methods which are indirect ELISA and dot immunogold filtration assay (DIGFA), intended for the qualitative detection of biologically active specific IgG antibodies to *Mycobacterium tuberculosis* in human serum or plasma specimens, acting as an important aid in the diagnosis of *Mycobacterium tuberculosis*.

INTRODUCTION

Mycobacterium tuberculosis (MTB) is a pathogenic bacterial species in the genus *Mycobacterium* and the pathogen of most cases of tuberculosis (TB)[1].

Globally, the TB disease is an enormous problem. TB is the world's most significant infectious disease from a single infection agent[2].

Hence, the early screening and detection of MTB infection is of great benefit to the control of this disease.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

Through immunological reactions, the analyte present in the specimen binds to the antigen pre-coated on the solid phase. The antigen-antibody complex in turn combines with added gold labeled anti-human IgG. The result can be read through the red mark displayed on the single well cassette.

MATERIALS PROVIDED

1. Single Well Cassette: single well cassette coated with TB antigens (20/40 cassettes)
2. Gold Conjugate Reagent: gold particle labeled anti-human IgG (1 vial, 2.5 /5.0mL)
3. Negative Control: buffer solution containing bovine serum (1 vial, 0.5 mL)
4. Positive Control: positive specimens diluted in bovine serum containing buffer solution (1 vial, 0.5 mL)
5. Wash Fluid: Tris-NaCl-Tween (1 vial, 12 .0mL/2vial, 12 .0mL)
6. Blocking Buffer: water solution containing bovine serum albumin (1 vial, 2.5 /5.0mL)

STORAGE OF TEST KIT AND INSTRUMENTATION

1. Unopened test kits should be stored at 2 – 8℃ upon receipt. Do not freeze. Do not expose to strong sunlight. The test kit may be used throughout the expiration date of the kit (1 year from the date of manufacture). Refer to the package label for the expiration date.

2. Opened components will remain stable for at least 30 days, or the labeled expiration date, whichever is earlier, provided they are sealed and stored under conditions as prescribed above.

SPECIMEN COLLECTION, PREPARATION, TRANSPORT AND STORAGE

1. Serum or plasma specimens may be used.
2. Specimens must be collected using correct venipuncture techniques. Sodium azide is not allowed to be added into the specimen as a preservative.
3. Ensure the collected specimens are clotted naturally. Serum specimens must be fully clotted. Any particulate matter must be removed by centrifugation.
4. It must be confirmed that the specimen is not decayed prior to use.
5. Specimens can be stored at room temperature for no more than 24 hours. In case the specimen is not going to be assayed within 24 hours, store at 2 – 8℃. Specimens going to be stored or transported for a longer period must be stored frozen (- 20℃ or lower). Avoid multiple freeze-thaw cycles. After thawing, ensure specimens are thoroughly mixed and brought to room temperature before being assayed.

PRECAUTIONS AND WARNINGS

1. for *in vitro* diagnostic use only
2. This package insert must be fully understood prior to operation. The operation must be stringently in accordance with the instruction for use.
3. Unused microplate strips must be stored sealed in an airtight bag, then placed in the original wrap, in order to avoid being dampened.
4. Micropipette tips are not interchangeable to eliminate cross contamination.
5. Please wait until the reagent being fully absorbed prior to proceeding to the next step.
6. Wear disposable gloves when dealing with specimens and reagents. Wash hands after operations. All specimens must be regarded as potentially infectious materials. Waster material must be disposed of safely according to relevant local and national requirements.
7. Reagents must be used within the expiration date. Unused reagents must be sealed immediately, then be stored at 2 – 8℃.
8. Components with different lot numbers are not allowed to be exchanged.

ASSAY PROCEDURE

1. Obtain the assay from fridge environment, place at room temperature (18 – 25℃) and equilibrate for 30 minutes.
2. Unwrap the Single Well Cassette. Number it.
3. Add 2 drops (100 L) of Blocking Buffer onto each Single Well Cassette, and wait for being fully absorbed, then add 30 L of the specimen.
4. After the specimen has been fully absorbed, add 5 drops (250 L) of Wash Fluid.
5. Add 2 drops (100 L) of Gold Conjugate Reagent.
6. Wait for the liquid to be fully absorbed, then add 5 drops (250 L) of Wash Fluid. Observe the result with naked eyes after the liquid has been fully absorbed.

INTERPRETATION OF RESULTS

1. The presence of a pink/red spot to the C edge of the reaction well indicates the assay is still within its expiry date.
2. The absence of a pink/red spot at the center of the reaction well indicates a negative specimen.
3. The presence of a pink/red spot at the center of the reaction well indicates a positive specimen.
4. Ignore the difference in color intensity between control spot and specimen spot.
5. No presence of control spot means the specimen should be assayed on another Single Well Cassette.

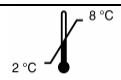
PERFORMANCE CHARACTERISTICS

1. Assay results from 218 tuberculosis infected specimens were all positive.
2. Assay results from 361 healthy specimens were all negative.

LIMITATIONS

1. This assay is only intended as an aid in clinical diagnosis. Assay values must be considered in combination with clinical examination, patient history and other assay values.
2. Specimens containing heterophilic antibodies may interfere with this assay. This type of specimen is not suitable for this assay.
3. Grossly hemolytic or microbial contaminated specimens might generate incorrect results.
4. Assay values from this product cannot be compared directly with assay values from other manufacturers or assays with different methodologies.

SYMBOLS

	**BATCH CODE**
	**USE BY**
	**MANUFACTURER**
	**CONTAINS SUFFICIENT FOR <n> TESTS**
	***IN VITRO* DIAGNOSTIC MEDICAL DEVICE**
	**TEMPERATURE LIMITATION**
	**CATALOGUE NUMBER**
	**CONSULT INSTRUCTIONS FOR USE**

REFERENCES

1. Kenneth James Ryan, C. George Ray, John C. Sherris *Sherris Medical Microbiology : An Introduction to Infectious Diseases;* McGraw-Hill Professional: 2003;
2. Barry R. Bloom *Tuberculosis: pathogenesis, protection, and control;* ASM Press: 1994;

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