

User's Manual and Instructions

Rapid Gold Immuno-assay Kit for Antibody IgG to Tuberculosis (TB)

Catalog No.: Z7010010

NAME AND INTENDED USE

Rapid Gold Immuno-assay Kit for Antibody IgG to Tuberculosis (TB) is an *in vitro* immunoassay for the detection of Anti-TB antibody IgG in human serum or plasma in one step.

PRINCIPLE

This kit uses one step method to detect anti-TB antibodies IgG in serum or plasma. The purified recombinant TB antigen and gold labeled conjugate are coated on the the surface of nitrocellulose membrane. Add blood or serum sample on the membrane, if anti-TB antibody is present in the sample, a complex of TB-anti-TB will form, the interaction of the complex and gold labeled conjugate will produce pink color on the membrane. The pink color intensity will reflect the antibody intensity in the sample. The test is fast and easy to operate.

MATERIALS PROVIDED 15 tests

- | | |
|---------------------------------------|-----------------|
| 1. Antigen and gold labeled conjugate | 15/pack with 12 |
| Coated Membrane Plate | packs per box |

SAMPLE COLLECTION AND PRESERVATION

Blood serum samples are routinely prepared from vein. Blood plasma sample are routinely prepared with routine amount of anticoagulant such as heparin or sodium citrate. Sample can be stored at 4°C if tested within five days. Sample can be stored at -20°C at least for 3 months. Avoid hemolysis and repetitive freeze and thaw of samples. Samples that are cloudy or contain precipitates should be centrifuged or filtered before test. Take precautions to prevent serum from bacterial contamination during collection and storage.

TEST PROCEDURE

1. Bring Membrane Plate and samples to room temperature before use (approximately 30 minutes).
2. Place the plate on flat bench top.
3. Drop 100 µl sample on the well in the plate
4. Wait for 15-20 minutes

INTERPRETATION OF RESULTS

Positive Two pink lines appear in both C and T position

Negative Only one pink line appear in C position

LIMITATION

This testing is for qualitative purposes. Confirmation of infection should be performed using other means.

QUALITY CONTROL

If the OD of positive controls is not below 1.5, OD of negative is not higher than 0.1, the assay result is validated. Otherwise, repeat the test.

PRECAUTIONS

1. Both plate and sample should be with room temperature 20-25°C
2. Test sample must be fresh
3. The result after 20 minutes is invalid.
4. Diluted sample may generate false positive result
5. Bacterial contamination, serious hemolysis, jaundice or high lipid blood will cause wrong result. The sample should be re-collected
6. Wrong result might be caused by expired kit or problematic samples.

PACKAGE SIZE

15 tests/pack with 12 packs/Kit

STORAGE AND STABILITY

2-8°C

EXPIRATION

The shelf life is 12 months from the receiving date.

This Kit is for Research Use Only

Diagram of the Procedure

