

(FOR RESEARCH USE ONLY. DO NOT USE IT IN CLINICAL DIAGNOSIS !)

Human Mycobacterium Tuberculosis (MT) IgG Lateral Flow Assay Kit

Catalog No: E-HD-C009

20T/40T

This manual must be read attentively and completely before using this product.

If you have any problems, please contact our Technical Service Center for help.

Toll-free: 1-888-852-8623 Tel: 1-832-243-6086 Fax: 1-832-243-6017

Email: techsupport@elabscience.com

Website: www.vetassay-elab.com

Please kindly provide us the lot number (on the outside of the box) of the kit for more efficient service.

Test principle

This kit applies the Indirect-GICA (Gold Immunochromatography) method as its principle, and can be used for the detection of Mycobacterium Tuberculosis IgG (MT-IgG) in human serum or whole blood. The quality control (C) line is pre-coated with Goat-anti-Mouse IgG antibody, and the detection (T) line is pre-coated with MT antigen. The gold pad is coated with Gold-labeled Mouse-anti-Human IgG antibody. MT-IgG in sample will combine with gold-labeled recombinant mouse-anti-human IgG antibody on the detection card and form a gold-labeled antibody-antibody complex. The complex will then move along the detection card and react with the pre-coated MT antigen on the detection line (T-line) and form the MT antigen- MT-IgG antibody-Mouse-anti-Human IgG antibody immunological complex, then a visible line will appear in the detection area. If there is no MT-IgG antibody or MT-IgG antibody content is lower than the detection limit, there will be no complex and precipitation line appeared. The quality control line is standard reference to determine whether the chromatography is normal and whether the detection system is effective. The immunological complex and color reaction will occur in the quality control under all conditions, otherwise the detection result is considered invalid and re-test will be required.

Kit components

Item	Specification
Detection Card	20T/40T
Manual	1 copy

Requirements of sample

1. The sample must be serum or whole blood.
2. Whole blood samples should be used immediately after collecting, while serum samples can be stored at 2-8 °C temporally for detection, or at -20°C for long-term storage.
3. Avoid of samples with hemolysis, turbidity, lipidemia, bacterial or polluted and repeated frozen/thawed samples, which will cause false-positive results.

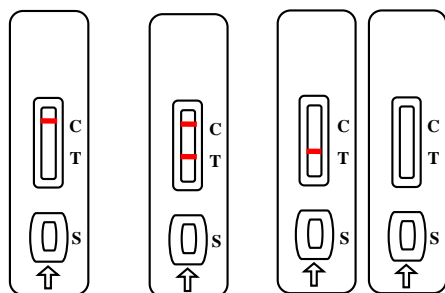
Assay procedure

Read the manual carefully before detection. The reagent and sample should be adjusted to room temperature (15°C to 30°C) before use. The detection card cannot be opened before the experiment condition is ready.

1. Take the detection card out and put it on flat and clean table.
2. Add 2 drops of serum (or 100 µL of whole blood) to the sample well.
3. Observe the result within 15-20 min. The result is invalid after 20 min.

Judgment of result

1. **Negative:** Red line only appears in control line (C).
2. **Positive:** Red line appears in both test line (T) and control line (C).
3. **Invalid:** No color line appears in control line (C). It indicates that the operation is wrong or the detection card is invalid, please carry out another detection.



Negative Positive Invalid

Interpretation of results

1. **Positive result:** The sample contains MT-IgG, and clinical information needs to be combined to determine whether the patient has been infected with MT.
2. **Negative result:** No MT-IgG was detected in the sample, or the concentration of MT-IgG is too low to the detection limit. The possibility of being infected cannot be completely excluded at this situation.

Limitations of this test method

This product is for qualitative detection of MT-IgG of serum or whole blood, while the detection effect for samples from plasma or other parts is still unclear.

Notes

1. The test temperature should be kept constant. Avoid of operating under high temperature condition.
2. The detection card should be adjusted to room temperature after removed from the refrigerator before opening.
3. The opening detection card should be used as soon as possible so as not to be invalid because of moisture.
4. The result should be read within 20 min.
5. Components from different batches and kinds of kit cannot be mixed. Do not mix reagents with other producers.

Storage and expiry date

Storage: Store at 4-30℃. With dry condition.

Expiry date: expiration date is on the box.