

## Gold Immuno-filtration (GIFA)

### Dot Rapid Assay Kit

## For the detection of IgG Antibody to Extractable Nuclear Antigen (ENA)

### Test Principle

Antibody of extractable nuclear antigen (ENA) in specimen combines with the solid-phase ENA in the reaction plate and forms complexes. Then, the complexes combine with colloidal gold marked anti-human IgG, and finally red visible dots will take on. (T: Test Point, C: Quality Control Point.)

### Scope of Application

This kind kit is used to detect qualitatively IgG antibody of ENA in human serum.

### Attentions

1. It must be fresh, clear serum for detection. A few samples (hyperlipidemia blood, hemolysis, etc.) could deepen the background color, but this generally will not affect the results.
2. There must not be time intervals between steps of test; the liquid during one step should be added at one time quickly and adsorbed completely.
3. The result observed exceeding stated time is invalid.
4. Dilute the positive serum specimen times by normal salt solution to test its titre;
5. The depth of the dot color in quality control area(C) does not indicate the quality of reagents. Reagents are valid as long as the dot is just clear to identify.
6. Colloidal Gold Conjugate Liquid of different products and different lots of one product mustn't be cross-used.

### Specimen Collection:

Take venous blood and put it into a clean disposable container without anticoagulant or coagulant, incubate it at 37°C for 20 – 30 minutes, or set it at room temperature for more than 1 hour; centrifuge it at the speed of 4000r/min for at least 5 minutes, and take the serum for detection.

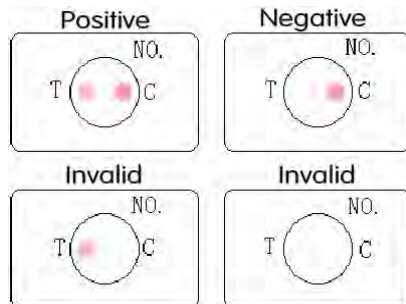
In case of not being detected in time, the specimen should be stored at -20°C or lower. Dissolve it, centrifuge it, and take the clear serum immediately prior to use. The titer of the antibody in the sample freeze-thawed may be reduced. **All samples must be centrifuged well immediately prior to use and take the clear serum for detection.**

### Test Procedure

1. Take out the kit and put it at room temperature for 20~30 min;
2. Dispense 1 drop of Wash Buffer to the test window, waiting for the liquid to wet the membrane well;
3. Add 150µl of serum (4 drops if with a sample pipet) into the test window, waiting for the liquid to be absorbed completely;
4. Add 3 drops of Colloidal Gold Conjugate into the test window, waiting for the liquid to be absorbed enough;
5. Add 3 drops of Wash Buffer into the test window, and interpret the result within 3 minutes immediately after the liquid is absorbed adequately.

### **Result Judgment**

1. Negative— Only the quality control area(C) shows a red dot;
2. Positive— Both the quality control area(C) and the test area(T) show red dots;
3. Invalid— That a red dot does not present in the quality control area(C) indicates operation faults or reagents invalidation.



### **Limitations**

1. This kit is only applied to qualitative screening tests.
2. There will be differences in results for some immune suppressive individuals or immune hyperthyroidism individuals.

### **Storage and Transportation**

1. The kit should be stored at 2~8°C.
2. The kit could be transported at normal temperature for short term. Take protective measures in winter and summer, and avoid freeze-thawing or high temperature for a long term.

**Expiry** 12 months from production date.

### **Manufacturer**

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