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

Human Rubella Virus (RV) IgG Lateral Flow Assay Kit

Catalog No: E-HD-C027

20/40T

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 qualitative detection of Rubella Virus (RV) IgG in human serum. The quality control (C) line is pre-coated with Protein-A antibody, and the detection (T) line is pre-coated with RV antigen. The gold pad is coated with Gold-labeled Protein-A. RV IgG in sample will combine with gold-labeled Protein-A on the detection card and form a gold-labeled Protein-A - RV IgG antibody complex. The complex will then move along the detection card and react with the pre-coated RV antigen on the detection line (T-line) and form the RV antigen- RV IgG antibody- Gold-labeled Protein-A immunological complex, then a visible line will appear in the detection area. If there is no RV IgG antibody or RV 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
Sample Diluent	4 mL /4 mL*2
Manual	1 copy

Requirements of sample

1. The sample must be serum.
2. Whole blood samples should be used immediately after collecting, and the prepared serum samples should be stored at 2-8 ℃ temporally for detection, or at -20℃ for long-term storage.
3. Heat treated samples may interfere the detection result.
4. Avoid of samples with hemolysis, turbidity, lipidemia, bacterial or polluted and repeated frozen/thawed samples, which will cause false-positive results.

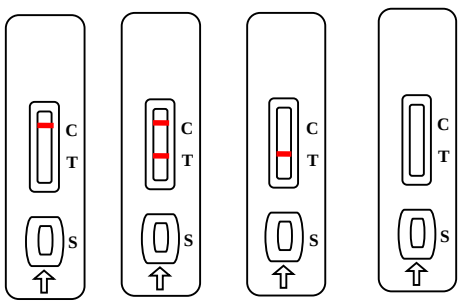
Assay procedure

Read the manual carefully before detection. The reagent and sample should be adjusted to room temperature (15℃ to 30℃) 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 10 μL of serum to the sample well. Then add another 90 μL of **sample diluent** (or 2-3 drops) to the sample well.
3. Observe the result within 10-20 min. The result is invalid after 30 min.

Judgment of result

1. **Positive:** Red line appears in both test line (T) and control line (C).
2. **Negative:** Red line only appears in 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 RV IgG, and clinical information needs to be combined to determine whether the patient has been infected with RV.
2. **Negative result:** No RV IgG was detected in the sample, or the content is too low to the detection limit. The possibility of being infected can not be completely excluded at this situation.

Limitations of this test method

This product is for qualitative detection of RV IgG in human serum sample, while the detection effect for plasma samples or samples from other parts is still unclear.

Product performance index

1. **Coincidence of positive reference:** The detection result of 9 positive references were all positive.
2. **Coincidence of negative reference:** The detection result of 9 negative references were all negative.
3. **The minimum detection limit reference:** L1, L2, L3, L4 should be tested all positive, L5 should be negative.
4. **Precision reference:** Detect 10 precision references, th**e results are consistent.**
5. **Cross reaction:** This kit has no cross reaction with TOX-IgG, CMV-IgG, HAV-IgG, HBc-Ab, HCV-IgG, HEV-IgG, HSV-Ⅱ IgG, ANA positive sample.
6. Hemolysis samples with ≤450 mg/mL hemoglobin, jaundice sample with ≤1.6 mmol/L bilirubin and high fat sample with ≤160 mmol/L glycerin trilaurate will not interfere the detection of RV IgG antibody with this kit.
7. For RV IgG strong positive samples with a titer of $\leqslant 2^6$, detect the sample of its original concentration with this kit, there will be no hook effect.

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.