

**Instructions for Use**

Version: 1.0.1  
Revision date: 8-Nov-24

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**Human Rubella IgM Rapid Test Kit**

**Catalog No.:** abx472032

**Size:** 50 tests

**Storage:** Store all reagents at 2°C – 30°C.

**Sensitivity:** 95 %

**Specificity:** 99.3 %

**Application:** For qualitative detection of Human Rubella IgM in serum, plasma, and whole blood samples.

**Introduction and Assay Principle**

Abbexa's Human Rubella IgM Rapid Test Kit is based on the gold immuno-chromatography assay (GICA) principle. Any Human Rubella IgM present in the samples combines with the colloidal gold particle-labelled anti-Human IgM antibodies in the sample well, and the complex migrates to the test area. The complex is captured by Rubella antigen coated in the test line. When the concentration of Human Rubella IgM in the sample is more than the detection limit, there is a color change in the detection line and the result is positive. When the concentration of Human Rubella IgM in the sample solution is less than the detection limit, there is no color change in the detection line and the result is negative.

**Kit Components**

- Test cassettes with pipettes
- Buffer Solution

**Material Required But Not Provided**

- High-precision pipette and sterile pipette tips
- Timer
- Centrifuge (plasma samples)

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### A. Sample preparation

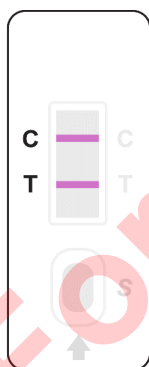
- **Serum and Plasma:** Serum and plasma samples should be collected using conventional methods and stored between 2 – 8°C for short-term storage (up to 3 days) or -20 °C for long-term storage. Fresh samples are recommended. Avoid repeated freeze/thaw cycles, bacterial pollution, visible particles; and avoid cloudy, hemolytic, or viscous samples.
- **Whole Blood:** Collect using conventional methods. EDTA, Heparin, or Sodium Oxalate can be used as anticoagulant.

### B. Assay procedure

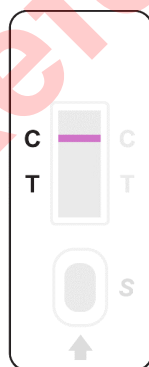
1. Take a test cassette and lay it flat on a clean table. Using the provided pipette, slowly and vertically add 1 drop (approximately 10 µl) of serum/plasma sample, or 2 drops (approximately 20 µl) of whole blood sample to the sample well on the test cassette. Avoid foaming.
2. Add 2 drops (approximately 80 µl) of Buffer Solution to the sample well on the test cassette. Avoid foaming.
3. Leave at room temperature for 10 minutes, then analyze the result. Results must be read before 15 minutes.

### C. Results analysis

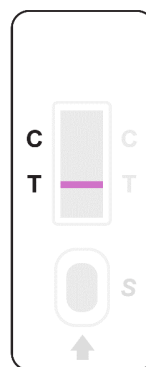
- **Positive result:** A colored line is observed in both the control (C) section and the test (T) section.
- **Negative result:** A colored line is observed in the control (C) section but not the test (T) section.
- **Invalid result:** No colored line is observed in the control (C) section.



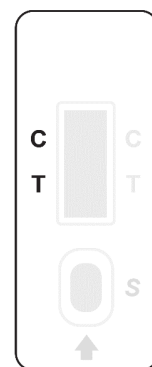
Positive



Negative



Invalid



Invalid

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### Notes

1. The test cassettes should be brought to room temperature before use.
2. After opening the aluminum foil, use the test cassette as soon as possible.
3. Samples should be clear with no visible particles, turbidity, or bacterial pollution.
4. Do not mix or re-use the disposable pipettes to avoid cross-contamination.
5. Do not use water, PBS, or similar solutions as the negative control.
6. Avoid touching the cassette membrane through the sample well or test result window.
7. This kit is for qualitative detection of Human Rubella IgM in serum, plasma, and whole blood samples. For other sample types, a preliminary experiment is recommended to determine compatibility with this kit. Positive samples can be tested with another method (e.g. HPLC, LC/MS) for quantitative results.
8. No cross-reactivity was observed during testing for antibodies to HIV, HCV, SYP, HBV and RF.
9. This kit is for research use only and the results are for reference only.
10. All waste should be disposed of appropriately. Please note that you may need to follow special waste disposal procedures for infectious samples. Please check local disposal regulations.

### Technical Support

For troubleshooting and technical assistance, please contact us at [support@abbexa.com](mailto:support@abbexa.com).