



# Rubella Latex Test Kit

## Latex agglutination test for the qualitative and quantitative determination of Rubella virus antibodies in human serum

For *In-Vitro* and professional use only

Store at 2°-8°C

### PRINCIPLE

The Rubella Latex test is a rapid agglutination procedure for the qualitative and quantitative determination of rubella virus antibodies in serum.

The determination is made by specific agglutination of a latex suspension coated with rubella inactivated virus antigen with rubella virus antibodies present in the sample.

Rubella is a mild viral disease, but when contracted in the first trimester of pregnancy, rubella virus may infect the fetus through the placenta causing the congenital rubella syndrome. The consequences of rubella infection may include spontaneous abortion, stillborn or multiple abnormalities in the fetus.

### KIT COMPONENTS

- Rubella Latex: Suspension of latex particles coated with rubella virus antigen, sodium azide 0.1%.
- Positive Control: Human serum, sodium azide 0.1%.
- Negative Control: Non-reactive human serum, sodium azide 0.1%.
- Sample dilution buffer. Phosphate buffered saline, albumin, and sodium azide 0.1%.
- Reaction slides.
- Stirring sticks.

### SAMPLES

Fresh or frozen serum. Stable for 48 hours at 2-8 °C. For diagnosis of rubella infection is recommendable to collect paired sera, correspondent to acute and convalescent phases.

Hemolyzed samples are not suitable for testing.

Do not use plasma.

### ANALYTICAL PROCEDURE

#### *Predilution sample.*

Using the sample dilution buffer, dilute the sample ten times by adding 10µl of sample to 90µl of sample dilution buffer.

**NOTE:** Do not dilute the controls. They are prediluted.

#### *Qualitative test*

1. Bring the reagents and the samples to room temperature.
2. Resuspend the latex reagent gently.
3. Place 25 µl of diluted sample and both positive and negative controls into the individual circles of the card.
4. Add into each circle one drop of the Rubella Latex reagent, near to the sample to be tested. Helped with a little stirrer mix the components covering all the surface of the circle.
5. Rotate the slide slowly either by hand or by means of a mechanical rotator (100 r.p.m) for a period of 8 minutes.

#### *Quantitative test*

1. Bring the reagents and the samples to room temperature.
2. Using the serum dilution performed in the qualitative assay, prepare the sample dilution tubes following the descriptive table:

| Tubes  | 1     | 2                          | 3     | 4     | 5     | 6     |
|--------|-------|----------------------------|-------|-------|-------|-------|
| Buffer | 25 µl | 25 µl                      | 25 µl | 25 µl | 25 µl | 25 µl |
| Sample | 25 µl | -Serial dilution of 25 µl- |       |       |       |       |

1. Place 25 µl of each sample dilution tube into the individual circles of card.
2. Add into each circle one drop of the Rubella Latex reagent, near to the sample to be tested. Helped with the little stirrer mix the components covering all the surface of the circle.

3. Rotate the slide slowly either by hand or by means of a mechanical rotator (100 r.p.m) for a period of 8 minutes.

### INTERPRETATION OF THE RESULTS

#### *Qualitative test*

Any degree of agglutination visible macroscopically indicates positive reaction.

Smooth suspension with no visible agglutination indicates negative reaction.

#### *Quantitative test*

When expressing the titer in IU/ml the sensitivity of the latex reagent which is printed on the outside of the box must be multiplied by the reciprocal of last dilution of sample giving a positive result. The next higher dilution should be negative.

Example:

|                                  |                         |
|----------------------------------|-------------------------|
| Reagent sensitivity:             | Last positive dilution: |
| 1.5 IU/ml                        | 1/40                    |
| Titer: 40 x 1.5 IU/ml = 60 IU/ml |                         |

### LIMITATIONS OF THE PROCEDURE

The delays in reading may cause an over-estimation of the results.

Do not use latex reagent or controls if they become contaminated.

### NOTES

The reagents have sodium azide. Avoid any contact with skin or mucous.

The reagents from human donors have been given negative results to anti-HIV1/2, HBsAg and Anti-HCV. Handle cautiously is recommended.

\* Reagent sensitivity 1.5 IU/ml

### REFERENCES

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2. Stewart, G.L. et al., The new England J. of Medicine, 276:554 (1967)
3. Meegan, J.M. et al., J. Clin. Mic., 16:644 (1982)

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