RUBELLA LATEX KIT

IVD For *in vitro* diagnostic and professional use only

Store at 2 - 8°C

INTENDED USE

ATLAS Rubella latex kit used for qualitative and quantitative detection of Rubella virus antibodies in human serum.

INTRODUCTIION

Rubella is a mild viral disease affecting children and adults, 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.

The availability of an attenuated rubella virus vaccine has greatly reduced the natural incidence of rubella infection. Nevertheless, it is recommended that all women of childbearing age be tested for the presence of rubella antibody to assure that nonimmune individuals are detected and subsequently vaccinated. The detection of rubella immune status was performed during many years by various serological methods, specially the hemagglutination inhibition test (HAI). However, latex agglutination in comparison with HAI is quicker and easier to perform. The sensitivity of Atlas Rubella latex kit correlates perfectly with that of the HAI test.

PRINCIPLE

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

When the latex reagent is mixed with the serum, if the serum contains approximately more than 10 IU/ml of rubella virus antibodies, a clear agglutination will appear.

MATERIALS

Materials Provided

- **Rubella Latex:** Suspension of polystyrene latex particles coated with rubella virus antigen, contains < 0.1% sodium azide**(Mix well before use).**
- **Positive Control:** Diluted positive human serum contains < 0.1% sodium azide.
- **Negative Control:** Diluted normal human serum contains < 0.1% sodium azide.
- **Sample Dilution buffer**. Phosphate buffered saline with bovine serum albumin and < 0.1% sodium azide.
- Glass Slide.
- Stirring sticks
- Package Insert.

Material required but not provided

- Test tubes.
- Mechanical rotator, adjustable at 100r.p.m
- Timer.
- Serological pipettes.

Packaging contents

REF **8.00.14.0.0100: 1x1.6 ml Latex, 1x1 ml Positive Control, 1x1 ml Negative Control, 1x50 ml Dilution Buffer.**

REAGENT STORAGE AND STABILITY

- All reagents are stable for until the expiry date stated on the label when stored at 2-8 °C.
- Do not Freeze.

PRECAUTIONS

- For *In Vitro* diagnostic and professional use only.
- All reagents contain 0.1 %(w/v) sodium azide as a preservative. Avoid any contact with skin or mucous.
- Protective clothing should be worn when handling the reagents.
- Wash hands and the test table top with water and soap once the testing is done.
- Reagents containing sodium azide may be combined with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide buildup.
- Components prepared using human serum found negative for hepatitis B surface antigen (HBsAg), HCV and antibody to HIV (1/2) by FDA required test. However, handle controls as if potentially infectious.
- Do not use the reagent if the label is not available or damaged.
- Test materials should be discarded properly in a biohazard container.

COLLECTION, HANDLING AND PREPARATION OF SPECIMEN

- For diagnosis of rubella, infection is recommendable to collect paired sera, correspondent to acute and convalescent phases.
- The first specimen should be collected as early as possible after rash onset or exposure and the second one should be obtained 1-3 weeks later. Both sera should be tested simultaneously using the quantitative procedure.
- Hemolyzed specimen s are not suitable for testing.
- **Do not use plasma.**

SPECIMEN STORAGE AND STABILITY

- Fresh, Clear serum Stable for 8 days at 2-8°C. For longer periods at -20°C.

REAGENT PREPARATION

All reagents are ready to use.

PROCEDURE

NOTE: Do not dilute the controls. They are pre-diluted.

Qualitative test

1. Allow the reagents and specimen s reach room temperature.
2. Dilute the specimen with dilution buffer according to the sensitivity of the latex reagent (see the below table), which is printed on the latex vial label.

Sensitivity level of 10 IU/ml	
Latex sensitivity	Dilution
1.5 IU/mL	1:6.7 (50 µL serum+285 µL Dilution buffer)
2.0 IU/mL	1:5 (50 µL serum+200 µL Dilution buffer)
2.5 IU/mL	1:4 (50 µL serum+150 µL Dilution buffer)

3. Mix latex reagent gently before use.
4. Place one drop (25 µL) of diluted specimen and both positive and negative controls into the individual circles of the glass slide.
5. Add into each circle one drop of the Rubella Latex reagent, near to the specimen to be tested. Helped with a little stirrer mix the components covering all the surface of the circle.
6. Rotate the slide slowly either by hand or by means of a mechanical rotator (100 r.p.m) for a period of **8 minutes**.
7. Observe for presence or absence of agglutination.

Quantitative test

1. For each specimen to be tested place 25µL of diluents in to each of the circles of the glass slide. Do not spread diluents.
2. To circle one add 25µL of diluted specimen used in the qualitative test to the Diluent and, using the same tip , mix the Diluent with the specimen by repeated aspiration and expulsion of the saline Diluent in the second circle.
3. Continue with the 2-fold serial dilution in a similar manner up to the sixth circle, and discard 25 from this circle. Final specimen dilutions of the diluted specimen will be: 1:2, 1:4, 1:8, 1:16, 1:32, 1:64.
4. Test each dilution as described in the qualitative test.

INTERPRETATION OF THE RESULTS

Qualitative test

Positive	Any presence of agglutination.	
	+3	Large clumping with clear background
	+2	Moderate clumping with fluid slightly opaque in background
	+1	Small clumping with opaque fluid in background
Negative	Absence of agglutination, Uniform suspension	

Quantitative test

The approximate titer will correspond to the highest serum dilution that still presents a clearly visible agglutination.

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

Example:

Reagent sensitivity: 2 IU/ml	Last positive dilution: 1:20
Titer: 20 x 2 IU/ml = 40 IU/ml	

REFERENCE VALUES

Antibodies against natural infection or vaccine rubella virus are prevalent in 80% of young adults. Adults are rarely afflicted with rubella, but women of childbearing age can acquire primary rubella infection by intensive contact with young children.

The prevalence data reported for rubella vary depending of the country. A revision study reported seroprevalence of rubella in women of childbearing age varying from 81.1% (Korea), 83.9 (Cameroon), 89.6% (Spain) to 94.3% (Switzerland) (10).

QUALITY CONTROL

Before performing a set of determinations, it is advisable to test the reagent with each of the controls included in the kit. Both controls should be used following the steps mentioned in the Qualitative test but without doing any dilution, as they are pre-diluted. The reaction between the positive control and the reagent should show a clear agglutination, different from the uniform appearance of the negative control. If these results are not obtained, do not use the kit.

For correct delivery, reagent and controls droppers must be held vertically.

LIMITATIONS OF THE PROCEDURE

- Test result are obtained must be evaluated by the physician in light of the clinical symptoms shown by the patient.
- Acute and convalescent sera must be tested at the same time. The absence of a four fold rise in titer does not exclude the possibility of exposure and infection.
- In the evaluation, a prozone effect was observed with one strong positive IgM serum specimen . If this possibility is suspected, the test should be repeated using a 1:20 dilution of the serum.

PERFORMANCE CHARACTERISTICS

ATLAS Rubella latex kit was studied in comparison to a commercially available IgG and IgM Micro-particle Enzyme Immunoassays (MEIA) using a serum panel of 77 positive samples for IgG antibody, 16 positive samples for IgG and IgM rubella antibodies, and 69 negative samples.

Sensitivity: 100%.

Specificity: 98.1%.

Precision: 10 serum samples were quantified 3 times on different days. The results indicate that the reproducibility of the reagent (within one dilution) was 100%.

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry
CONTROL +	Positive control	CONTROL -	Negative control