Reuma Latex Test

IVD CE

Latex card test for the qualitative and semi-quantitative detection of Rheumatoid Factor without sample predilution.

Technical sheet

ORDERING INFORMATION

Form	Code	Composition
Kit 100 test	**REF CSA087026**	**n° 1 fl. x 5 ml** (RF Reagent) **n° 1 fl. x 1 ml** (Positive Control) **n° 1 fl. x 1 ml** (Negative Control)

INTENDED USE

In vitro diagnostic medical device for the execution of the rapid latex agglutination test for qualitative research, and / or semi-quantitative dosage, of Rheumatoid Factors in human serum. Test results should always be interpreted in relation to the clinical context. For professional use only.

CLINICAL SIGNIFICANCE

Rheumatoid factors (RF) are immunoglobulins (mostly IgM) with anticorpal activity. These factors are present in the majority of patient affected from Rheumatoid arthritis. There are several rheumatoid factors, but there is no test that can reveal them all since some of them act against human IgG, others against animal IgG, and still others against both types of IgG. Sclavo also recommends the use of Waaler Rose test (code CSA087025), specific for the detection of rheumatoid factors against animal IgG.

PRINCIPLE

Reuma Latex reagent is a polistyrene latex suspension coated with human IgG, treated to avoid aspecific agglutinations, for the qualitative and semi-quantitative detection of Rheumatoid Factors in human serum. The Reuma Latex reagent is able to reveal at least 8 IU/mL of Rheumatoid Factor according to the International Standard WHO (without sample pre-dilution).

Storage and stability

= **Storage temperature 2-8 °C**

Swirl gently the Reagent RF before using: suspension must appear uniform and free from visible particles. Sensitivity of the test depends on the volume of the drop of reagent dispensed (50 µL). Do not use dropper different than that supplied in the kit and place it perpendicularly to the slide surface. If stored closed at 2-8°C, avoiding direct light, the reagent is stable until the expiration date printed on the label. Do not freeze.

CONTENTS OF THE KIT AND PACKAGING

RF Reagent	Ready to use. Suspension of latex particles coated with human IgG, pH 8.2. *Contains preservatives*
Reagent 2	Positive Control containing at least 30 UI/mL of RF*.
Red Cap	Human serum. *Contains preservatives*
Reagent 3	Negative Control. Normal Serum
Blue Cap	*Contains preservatives*

*Warning: biohazard. Human sera used in control sera have been tested and found to be negative for the presence of HBsAg and HCV and anti-HIV antibodies. However, handle cautiously as potential infectious human material (Biosafety Level 2).

16 x 6	Six circles Slides black screen
n. 50	Disposable stirrers for mixing the reaction mixture

OTHER REQUIRED MATERIALS, BUT NOT SUPPLIED

- 50 µl micropipettes; Isotonic saline
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PRECAUTIONS AND WARNINGS

1. Reagents and waste materials shall be disposed of in accordance with Community waste provisions or national or regional provisions.
2. In addition to any risk claims relating to active components, reagents may contain non-active components such as preservatives and detergents. The total concentration of these components is below the limits set out in Directive 1272/2008 EC and subsequent amendments and additions.
3. It is recommended that the reagent be handled in accordance with the rules of good laboratory practice and that appropriate personal protective equipment be used.
4. All human samples must be handled and disposed as potentially infectious materials.
5. The kit should only be used by qualified and properly trained technical personnel.
6. Diagnoses shall only be carried out by authorised and qualified personnel.
7. It is recommended to handle the reagent according to the rules of good laboratory practice and to use appropriate personal protective equipment.
8. Comply with national directives on occupational safety and quality assurance.
9. Use equipment that comply with current standards.
10. Laboratory standards for protection against infection shall be used.

Reporting of serious incidents

Please inform the manufacturer (through your distributor) and the competent authority of the member state of the European Union in which the user and/or patient is established, of cases of serious incident that has occurred in relation to the device. For other jurisdictions, reports of serious incidents must be made in accordance with the regulatory requirements of the home Member State. By reporting serious incidents, you help provide more information about the safety of your in vitro medical diagnostic device.

PROCEDURE

Quality control

Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.

CALIBRATION

RF-latex sensitivity is calibrated against the *RF International Standard NIBSC 64/002*

REAGENT PREPARATION

Reagents are liquid and ready to use. Swirl gently Reagent RF before using.

PREPARATION AND STORAGE OF SAMPLES

Use fresh sera obtained by centrifugation of coagulated blood. Samples can be stored at 2-8°C for 48h before testing. For longer time of storage samples must be frozen (-20°C). Highly hemolyzed, lipemic or contaminated samples can't be used. Samples with the presence of fibrin should be centrifuged before testing.

PROCEDURE

Qualitative test

1 - Allow the reagent and samples to reach room temperature before use.
2 - Transfer one drop of control or undiluted sample serum (50 µl) to different test circle on the slide.
3 - Shake the Latex reagent until homogeneous suspension, then, using the dropper provided, add one drop of reagent to the test circle.
4 - By using a disposable stirrer, mix and spread the drops on the surface of test circle.
5 - Examine macroscopically the presence or absence of visible agglutination immediately after two minutes. The presence of visible agglutination indicates a RF concentration equal or greater than 8 IU/mL. Aspecific agglutination could appear if the test is read later than two minutes.

Reading: The presence of agglutination indicates a concentration greater than or equal to 8 IU/mL of FR in the sample. The absence of agglutination indicates an amount of FR less than 8 IU/mL.

Semi-Quantitative technique

It must be executed by the same method as qualitative test. Make serial two-fold dilutions of the sample in 9 g/L NaCl solution, PBS or glycine buffer:

Dilutions	**1:2**	**1:4**	**1:8**	**1:16**
Diluent	100 µL	100 µL	100 µL	100 µL
Serum	100 µL			
	⇒	100 µL		
		⇒	100 µL	
			⇒	100 µL
Volume/Reaction	50 µL	50 µL	50 µL	50 µL
Titer will be the reciprocal of the last dilution				
6x n°dil	8 x 2	8 x 4	8 x 8	8 x 16
UI/mL	16	32	64	128

REFERENCE VALUES

Adults <8 UI/mL (Each laboratory should establish its own reference range).

PERFORMANCE CHARACTERISTICS

1. *Analytical Sensitivity*: 8 6-16) IU/mL, under the described assay conditions
2. *Prozone Effect*: no prozone effect was detected up to 1500 IU/mL.
3. *Diagnostics Sensitivity*: 100%
4. *Diagnostics Specificity*: 100%

INTERFERENCES

Hemoglobin (< 10g/L), bilirubin (< 20mg/dL) and e lipemia (< 10g/L) do not interfere. Other substances may interfere

LIMITATION OF PROCEDURE

The incidence of false positive is about 3-5%. Patients suffering from infectious mononucleosis, hepatitis, syphilis as well as elderly people may give positive results. Diagnosis should not be solely based on the results of Reuma Latex Test but also should be complemented with a RF-Latex test along with the clinical examination.

NOTE: Results obtained with the Reuma Latex test method do not compare with those obtained with Waaler Rose method. Differences in the results between methods do not reflect differences in the ability to detect rheumatoid factors

Bibliography

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3. ***Robert H Shmerling et al. The American Journal of Medicine 1991; 91: 528 - 534.***
4. ***Adalbert F. Schubart et al.*** *The New England Journal of Medicine 1959; 261: 363-368.*
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6. ***Young DS.*** *Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.*

Symbols used for IFU and Packaging	
IVD In vitro diagnostics medical device	Manufacturer
REF Catalog number	Instruction for Use
LOT Lot Number	Storage Temperature
Expiration Date	Biological Risk

REVISION	DATE	CHANGES
D	10-2022	Modified for IVDR and 1272/2008 Compliance

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