Waaler Rose

IVD CE

Passive hemoagglutination slide method for Rheumatoid Factors determination.

Instructions for Use

ORDERING INFORMATION

Form	Code	Composition
Kit 100 test	**REF CSA087025**	**n° 1 fl. x 5 ml** (Reagent 1) **n° 1 fl. x 1 ml** (Reagent 2) **n° 1 fl. x 1 ml** (Reagent 3)

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.

INTRODUCTION

Rheumatoid factors (RF) are auto-antibodies which reacts with Fc fragment of human IgG. They are present, in particular, in patients affected by rheumatoid arthritis (RA), and their presence can be considered as an indication of the inflammatory process. High RF concentrations often indicate a marked degeneration of the disease. A study of the "American College of rheumatology" shows that the 80,4% of patients with Rheumatoid Artritis were RF positive. Together with Waaler Rose test, the use of Reuma test (ref. CSA087026) is recommended.

PRINCIPLE

The Waaler-Rose reagent is a sheep red cells suspension sensitized with anti-sheep IgG from rabbit. The WR reagent test sensitivity is calibrated to detect also low titers corresponding at 8 UI/mL of Rheumatoid factors **without sample predilution**.

Storage and stability

= Storage temperature 2-8 °C

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

Reagent 1 white cap — Stabilized suspension of sheep erythrocytes sensitized with rabbit IgG anti-sheep erythrocytes. pH 8,2. *Contains Sodium azide 0,95 g/L.*

Reagent 2 Red Cap — Positive control containing up to 30 UI/mL of RF*. Human serum. *Contains Sodium azide 0,95 g/L.*

Reagent 3 Blue Cap — Negative Control. Animal serum. *Contains Sodium azide 0,95 g/L.*

*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, white screen

50 Disposable stirrers for mixing the reaction mixture

OTHER REQUIRED MATERIALS, BUT NOT SUPPLIED

50 µl micropipettes; Isotonic saline

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

The WR reagent test sensitivity is calibrated against the International RF Reference WHO 64/1 Rheumatoid Arthritis Serum

REAGENT PREPARATION

Reagents are liquid and ready to use. Swirl gently Reagent 1 (Red Blood Cells) before using. Suspension must appear uniform and free of visible particles. The sensitivity of the test depends on the volume of the drop of reagent dispensed (50 µL). Do not use droppers different than that supplied in the kit and place it perpendicularly to the slide surface.

PREPARATION AND STORAGE OF SAMPLES

Use fresh sera obtained by centrifugation of coagulated blood. Samples can be stored at 2-8°C for 48 h before testing. For longer time of storage samples must be frozen (-20°C). Highly hemolyzed, lipemic or contaminated samples cannot 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. Low temperature can reduce the method sensitivity.
2- Swirl gently the WR Reagent before using. Suspension must appear uniform and free from visible particles.
3- Place 50 µL of each Positive and negative controls into separate circles on the slide test.
4- Place a drop (50 µL) of Undiluted sera in another circle on the slide test.
5- Add a drop of Reagent 1 (erythrocytes) near the sample/control drop.
6- Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use a different stirrer for each sample.
7- Let the slide undisturbed on a flat surface for two minutes.
8- Twist very carefully the slide once to about 45° from the horizontal and let the slide to stay again on a flat surface for one minute more.

Reading

Examine macroscopically for the presence or absence of visible agglutination avoiding any movement or lifting the slide during the observation

- The presence of visible agglutination indicates a RF concentration equal or greater than 8 IU/mL.
- The absence of visible agglutination indicates a RF concentration lower than 8 IU/mL.

Late readings could evidence aspecific agglutinations.

SEMI-QUANTITATIVE TEST

It must be executed by the same method as qualitative test, after a two-fold dilution of the sample in saline solution, PBS or glycine buffer.

Diluitions	**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
The titer will be given by the reciprocal of the last dilution positive				
8 x titer /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 800 IU/mL.
3. Diagnostics Sensitivity: 100%
4. Diagnostics Specificity: 93.6%

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. So, diagnosis should be complemented with a RF-Latex along with the clinical examination.

NOTE:

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

Bibliography

1. Robert W. Dorner et al. Clinica Chimica Acta 1987; 167: 1-21
2. Frederick Wolfe et al. Arthritis and Rheumatism 1991; 34: 951-960
3. Robert H Shmerling et al. The American Journal of Medicine 1991; 91: 528-534
4. Koriz T N et al. Journal of Immunological Methods 1980; 32: 1-9
5. Assameh S N et al. Journal of Immunological Methods 1980; 34: 205-215
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	11-2022	Modified for IVDR and 1272/2008 Compliance

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