Instructions for use

NADAL® Waaler Rose

Agglutination Slide Test

REF 795017/795018

IVD

Version 1.0

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NADAL® Waaler Rose *Agglutination Slide Test* (50/100 tests)

Art. No. 795017/795018

1. Intended Use

Qualitative determination of Rheumatoid Factors (RF).

2. Clinical Significances

Rheumatoid factors are a group of antibodies directed against determinants in the Fc portion of the immunoglobulin G molecule. Although rheumatoid factors are found in a number of rheumatoid disorders, such as systemic lupus erythematosus (SLE) and Sjögren's syndrome, as well as in nonrheumatic conditions, its central role in clinic use lays its utility as an aid in the diagnosis of rheumatoid arthritis (RA).
A study of the "American College of Rheumatology" shows that the 80.4% of RA patients were RF positive.

3. Principle of the Test

The Waaler Rose test is a slide hemaglutination method for the qualitative and semi-quantitative detection of RF in human serum.
Stabilized sheep erythrocytes sensitized with rabbit IgG anti-sheep erythrocyte are agglutinated when mixed with samples containing RF.

4. Reagents and Materials Supplied

Waaler Rose	Stabilized sheep erythrocytes sensitized with rabbit IgG anti-sheep erythrocyte, pH, 8.2. Sodium azide 0.95 g/L.
Control + Red cap	Human serum with a RF concentration ≥ 30 IU/mL. Sodium azide 0.95 g/L.
Control - Blue cap	Animal serum. Sodium azide 0.95 g/L.

50 Tests:
- 2.5 mL Waaler Rose
- 1 mL Control +
- 1 mL Control -
- 8 x 6 disposable slides

100 Tests:
- 5 mL Waaler Rose
- 1 mL Control +
- 1 mL Control -
- 16 x 6 disposable slides

5. Storage & Stability

All the kit components are ready to use, and will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test.

Reagents deterioration: Presence of particles and turbidity.

6. Warnings and Precautions

Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.

7. Specimen Collection and Preparation

Specimen Storage

Fresh serum, stable 8 days at 2-8ºC or 3 months at –20ºC.
Samples with the presence of fibrin should be centrifuged before testing.
Do not use highly hemolized or lipemic samples.

8. Procedure of the Test

Qualitative method

1) Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
1) Place 50 µL of the sample and one drop of each positive and negative control into separate circles on the slide test.
2) Swirl the WR reagent gently before using and add one drop (50 µL) next to the samples to be tested.
3) Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
4) Let the slide undisturbed on a flat surface for 2 minutes
5) After this time, twist very carefully the slide once to about 45º from the horizontal and let the slide again to stay on a flat surface for 1 minute more.

Semi-quantitative method

1) Make serial two fold dilutions of the sample in 9 g/L saline solution.
2) Proceed for each dilution as in the qualitative method.

9. Interpretation of the Results

Calibration

The Waaler Rose sensitivity is calibrated against the International RF Reference WHO 64/1 Rheumatoid Arthritis Serum.

Reading and Interpretation

Examine macroscopically the presence or absence of visible agglutination immediately, avoiding any movement or lifting of it during the observation. The presence of visible agglutination indicates a RF concentration equal or greater than 8 IU/mL (Note 1).

The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

Calculations

The approximate RF concentration in the patient sample is calculated as follows:

8 x RF Titer = IU/mL

Reference Values

Up to 8 IU/mL. Each laboratory should establish its own reference range.

10. Quality Control

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

11. Limitations

- The incidence of false positive results is about 3-5 %. Individuals 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 Waaler Rose method but also should be complemented with a RF-Latex test along with the clinical examination.

Interferences

Hemoglobin (10 g/L), bilirubin (20 mg/dL) and lipemia (10 g/L), do not interfere. Other susbstances may interfere[6].

12. 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) *Diagnostic sensitivity:* 100 %.
4) *Diagnostic specificity:* 93.6 %.

13. References

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) Koritz T N et al. Journal of Inmmunological 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

Ref.: 2011-07-19 LE

Symbol	English	Deutsch	Français	Nederlands	Español	Italiano
	Consult instructions for use	Gebrauchsan-weisung beachten	Consulter les instructions d'utilisation	Gebruiksaanwij-zing	Consulte las instrucciones de uso	Consultare le istruzioni per l'uso
CE	European Conformity	CE-Konfirmitäts-kennzeichnung	Conformité aux normes européennes	Conform Europese richtlijnen	Conformidad europea	Conformità europea
IVD	In vitro diagnostic device	In-vitro-Diagnostikum	Usage Diagnostic in vitro	In vitro diagnostisch gebruik	Para uso Diagnóstico in vitro	Per uso Diagnostica in vitro
REF	Catalogue number	Katalog-Nr.	Numéro de catalogue	Catalogus nummer	Número de catálogo	Numero di Catalogo
LOT	Lot. No. / Batch code	Chargen-Nr.	Numéro de lot	Lot nummer	Número de lote	Numero di lotto
	Contains sufficient for <n> tests/	Ausreichend für "n" Ansätze	Contenu suffisant pour "n" tests	Geschikt voor <n> tests	Contenido suficiente para <n> ensayos	Contenuto sufficiente per "n" saggi
	Storage Temperature	Lagerungs-temperatur	Température de conservation	Opslag temperatuur	Temperatura de conservación	Temperatura di conservazione
	Expiration Date	Mindesthalt-barkeitsdatum	Date limite d'utilisation	Houdbaarheids datum	Fecha de caducidad	Data di scadenza
	Legal Manufacturer	Hersteller	Fabricant	Fabrikant	Fabricante	Fabbricante
Distributed by	Distributor	Vertreiber	Distributeur	Distributeur	Distribuidor	Distributore
Cont.	Content	Inhalt	Conditionnement	Inhoud	Contenido	Contenuto

Symbol	Polski	Suomi	Portugues	Dansk	Svenska	Ελληνικά
	Patrz: ulotka informacyjna	Katso käyttöohjeet	Consulte as instruções de utilização	Se brugsanvisning	Se bruksanvisning en	Εγχειρίδιο χρήστη
CE	Znak zgodności CE	CE-merkitty	Conformidade com as normas europeias	Europaeisk overensstemm else	Europeisk överensstämm else	Ευρωπαϊκή Συμμόρφωση
IVD	Tylko do użytku in-vitro	In vitro-diagnostiikka	Diagnóstico in vitro	In vitro diagnostik	In vitro diagnostik	in vitro διαγνωστικό
REF	Numer katalogowy	Luettelo-numero	Catálogo n.º	Katalognummer	Katalognummer	Αριθμός καταλόγου
LOT	Numer serii	Eränumero	No do lote	Lot nummer	Batchnummer	Αριθμός Παρτίδος
	Wystarszajonce na "n" powturzeń	Sisältää tarvikkeet "n" testiin	Contém o suficiente para <n> testes	Indeholder tilsttrækkeligt til "n" test	Innehåller tillräckligt till "n" tester	Περιεχόμενο επαρκές για «n» εξετάσεις
	Temperatura przechowywani a	Säilytys-lämpötila	Temperatura de conservação	Opbevarings-temperatur	Förvaringstemp ratur	Θερμοκρασία αποθήκευσης
	Data ważności	Viimeinen käyttöpäivä	Prazo de validade	Udløbsdato	Utgångsdatum	Ημερομηνία λήξης
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