RF SLIDE

Latex agglutination

REF. 7705 100 tests with controls and accessories
REF. 7706 100 tests without controls and accessories
REF. 7790 50 tests with controls and accessories
REF. 7791 300 tests without controls and accesories

CE IVD

DNV CERTIFIED COMPANY
UNI EN ISO 9001:2008
UN EN ISO 13485:2012

GIESSE DIAGNOSTICS

INTENDED USE

Qualitative determination of Rheumatoid Factors (RF)

PRINCIPLE

RF SLIDE is a slide agglutination test for the qualitative and semi-quantitative detection of Rheumatoid Factor (RF) in human serum.
Latex particles coated with human gammaglobulin are agglutinated when mixed with samples containing RF.

SAMPLE

Fresh Serum. Stable 7 days at 2-8°C or 3 months at -20°C.
Samples with presence of fibrin should be centrifuged before testing.
Do not use highly hemolized or lipemic samples.

KIT COMPONENTS

Reagent (A) RF Latex Volume = 2.5/5.0 ml	Latex particles coated with human gamma-globulin, pH 8.2, Preservative.
Control (+) RF Volume = 0.5 ml	Human serum with a RF concentration > 30 U/ml Preservative.
Control (-) RF Volume = 0.5 ml	Animal serum Preservative.
Stirrers	1 o 2 pz
Reaction Slide	1 o 2 pz

The Reagents are stable until the expiration date printed on the label, when stored tightly closed at 2-8°C. Once opened, the reagents are stable one month at 2-8°C if contamination is avoided. Do not freeze.
Keep bottles closed when not in use.

REAGENT PREPARATION

All the kit components are ready to use.

PRECAUTIONS AND WARNINGS

Biological risk for Control (+) and latex

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Use the normal precautions required in the laboratory.
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.
Dispose of waste according to local laws.

PROCEDURE

Qualitative Method:

Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures. Gently mix the latex.
Dispense 50 µl of serum upon a selected spot of the reaction slide, add one drop of latex and accurately mix with a stirrer paying attention to uniformly distribute the liquid on the selected spot. Rotate the slide and observe within 2 minutes possible agglutination. False positive results could appear if test is read later than 2 minutes.

Semi-quantitative method:

Make serial two fold dilutions of the sample in saline solution.
Proceed for each dilution as in the quantitative method.

READING AND INTERPRETATION

Examine the presence or absence of visible agglutination.
The presence of agglutination indicates a RF concentration equal or greater than 12 U/ml.
The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

CALCULATIONS

The approximate RF concentration in the sample is calculated as follow:

12 x RF Titer = U/ml

EXPECTED VALUES

Up to: 12 U/ml

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL

Positive and Negative Controls are recommended to monitor the performance of the reagent and to have a better results interpretation.

PERFORMANCE

Sensitivity: 12 (9-15) U/ml
Prozone effect: No prozone effect up to 1500 U/ml.
Diagnostic sensitivity: 98 %
Diagnostic specificity: 97 %
Interferences: bilirubin does not interfere up to 20 mg/dl. Lipids and hemoglobin do not interfere up to 10 g/l.

METHOD 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 latex method but also should be complemented with a Waaler Rose test along with the clinical examination.

NOTE

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

REFERENCES

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