

RF D-test

RF 0100 CH

100 tests

SUMMARY OF TEST

The sera of most rheumatoid arthritic patients will react with human IgG and the IgG of other animals due to the presence of an immunoglobulin (in most cases of the IgM type) known as rheumatoid factor (RF). During this reaction, which is of the antigen-antibody type, rheumatoid factor acts as an anti-IgG antibody.

A positive latex test, indicating the existence of the rheumatoid factor, is practically a decisive test for the diagnosis of rheumatoid arthritis in patients with inflammatory arthritis. Since the rheumatoid arthritis is probably a set of various immunologically different factors, it is recommended to do in pairs the latex test and the Waaler-Rose test.

PRINCIPLE OF THE METHOD

Due to the presence of rheumatoid factor in the serum, the latex suspension changes its uniform appearance and a clear agglutination becomes evident. This change occurs because the rheumatoid factor present in the serum reacts with the IgG coated to the latex particles, starting the formation of a web between them.

KIT COMPONENTS

For in vitro diagnostic use only.

The components of the kit are stable until expiration date on the label.

Keep away from direct light sources.

Latex reagent: 1 x 5 ml (suspension) 100 tests

Composition: suspension of polystyrene latex particles coated with IgG, preservatives.

Store all components at 2-8°C.

MATERIALS REQUIRED BUT NOT SUPPLIED

Saline solution, agglutination slide, disposable stirring devices.

REAGENT PREPARATION

Use reagent ready to use.

Stability: up to expiration date on labels at 2-8°C.

Stability since first opening of vials: ≥ 60 days at 2-8°C.

Do not freeze.

PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.

Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

Fresh serum.

Sample is stable 7 days at 2-8°C. Store at -20°C for prolonged periods. Bring at room temperature before analysis. Centrifuge samples if a turbidity appears.

QUALITATIVE TEST PROCEDURE

Allow the reagent to reach room temperature (20 to 30°C). Gently shake the reagent vial to disperse and suspend the latex particles in the buffer solution. Use the supplied pump dropper to mix well.

Place 0.050 ml of the serum on one section of the disposable slide.

Place a drop of reagent next to the drop of serum.

Mix both drops with a disposable stirrer covering the whole surface of the slide section.

Gently rotate the slide for 2 minutes manually or on a rotatory shaker (100 rpm).

Look for the presence or absence of agglutination after the aforementioned period of time under an artificial light source

INTERPRETATION OF THE RESULTS:

The presence of agglutination indicates a positive result.

The absence of agglutination indicates a negative result.

It is recommended to execute a semi-quantitative procedure on positive samples.

SEMI-QUANTITATIVE TEST PROCEDURE

Organize serial dilutions of serum, pipetting in six different areas of test slide 50 μ l of saline and 50 μ l of sample only in first area.

Always using the same pipette (loading and unloading several times) mix carefully content of first area, transferring 50 μ l in subsequent area and so on.

Discard 50 μ l from last (sixth) area.

Perform the test as described in previous qualitative section. The last evident agglutination will mark the sample approximate title.

Dilution	Approximate value of RF (undiluted samples)
(1 : 2)	16 UI/ml
(1 : 4)	32 UI/ml
(1 : 8)	64 UI/ml
(1 : 16)	128 UI/ml
(1 : 32)	256 UI/ml
(1 : 64)	512 UI/ml

EXPECTED VALUES

Clinical significance of RF determination consists in distinction between rheumatoid arthritis, in which RF is present in at least 80% of cases and rheumatoid disease, in which RF is almost absent. RF is frequent in chronic processes more than acute diseases or at first stage.

Positive results has been occasionally observed in poliartthritis, LES and hepatitis, too.

NOTICE

- Reaction times over 2 minutes could yield an overestimation of sample concentrations.

- As in any diagnostic procedure, if results appear to be incompatible with clinical picture, physician should evaluate data using this test together with other information.

QUALITY CONTROL

It is suggested to perform an internal quality control. For this purpose a suitable human based control sera has to be used.

Please contact Customer Care for further information.

TEST PERFORMANCE

Sensitivity

test will show positive results from a level of 8 UI/ml.

Existence of prozone at high titer levels is unknown up to 800 UI/ml.

Specificity

a comparison between Chema and a commercially available product gave a specificity of 98% on 118 different samples.

Interferences

no interference was observed by the presence of:

hemoglobin ≤ 1000 mg/dl

bilirubin ≤ 20 mg/dl

lipids ≤ 1000 mg/dl

Turbid or lipemic samples could give false positives.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.

S56: dispose of this material and its container at hazardous or special waste collection point.

S57: use appropriate container to avoid environmental contamination.

S61: avoid release in environment. Refer to special instructions/safety data sheets.

REFERENCES

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SYMBOLS

	for in vitro diagnostic use only
	lot of manufacturing
	code number
	storage at temperature interval
	expiration date (year/month)
	warning, read enclosed documents
	read the directions