COD 31013 50 tests	COD 31313 100 tests	COD 31014 150 tests	COD 31108 50 tests
STORE AT 2-8ºC			
Reagents for determination of RF Only for *in vitro* use in the clinical laboratory			

RHEUMATOID FACTORS (RF) - SLIDE

BioSystems

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RHEUMATOID FACTORS
LATEX

PRINCIPLE OF THE METHOD

Serum rheumatoid factors (RF) causes a visible agglutination on slide of a suspension of latex particles coated with human gamma-globulin [1].

CONTENTS

	COD 31013	COD 31313	COD 31014	COD 31108
A. Reagent	1 x 3 mL	2 x 3 mL	1 x 8 mL	1 x 3 mL
C-. Negative Control	1 x 1 mL	1 x 1 mL	1 x 1 mL	-
C+. Positive Control	1 x 1 mL	1 x 1 mL	1 x 1 mL	-
Test Cards	3	6	6	-
Disposable Stirrer Sticks	1 x 50	1 x 150	1 x 150	-

COMPOSITION

A. Reagent: Suspension of latex particles coated with human gamma-globulin, sodium azide 0.95 g/L, glycine buffer 100 mmol/L, pH 8.2.

C-. Negative Control: Serum containing RF < 30 IU/mL.

C+. Positive Control: Human serum containing RF > 30 IU/mL.

Human sera used in the preparation of the positive and negative controls have been tested and found to be negative for the presence of antibodies anti-HIV and anti-HCV, as well as for HBs antigen. However, the controls should be handled cautiously as potentially infectious.

Test Cards. (Note 1)

Disposable Stirrer Sticks.

STORAGE

Store at 2-8ºC. Cards and stirrer sticks may be kept at room temperature.

Reagent and Controls are stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during their use.

Indications of deterioration:

- Reagent: Visible agglutination in the flask.
- Controls: Presence of particulate material.

REAGENT PREPARATION

Reagent and controls are provided ready to use.

ADDITIONAL EQUIPMENT

- Mechanical rotator adjustable to 100 r.p.m.
- For code 31108 test cards and stirrer sticks will be required.

SAMPLES

Serum collected by standard procedures.

Rheumatoid factors in serum is stable for 2 days at 2-8ºC.

PROCEDURE

1. Bring test reagents and samples to room temperature (Note 2).
2. Place 50 µL of the sample and 1 drop of each Control into separate circles on the test card.
3. Shake the latex vial (A) gently repeatedly until complete resuspension of the latex particles.. Hold the Reagent vial (A) in vertical position and add 1 drop of Reagent (A) to each circle next to the sample to be tested (Note 3).
4. Mix with a disposable stirrer stick and spread over the entire area enclosed by the ring. Use a new stirrer stick for each sample.
5. Rotate cards at 100 r.p.m. for 2 minutes.

READING

Examine the presence of visible agglutinantion within a minute after removing the card from the rotator (Note 4).

Positive results: The presence of a visible agglutination indicates an RF concentration ≥ 30 IU/mL. Positive sera may be titered. To titer make serial two-fold dilutions in 9 g/L NaCl. The serum titer is defined as the highest dilution showing a positive result. The approximate RF concentration in the sample may be obtained by multiplying the titer by 8 IU/mL (Note 5).

Negative results: The absence of a visible agglutination indicates an RF concentration < 30 IU/mL.

QUALITY CONTROL

Positive (C+) and Negative (C-) Controls provided with kits should be tested toghether with the patients samples, in order to verify the assay performance.

Positive Control (C+) should cause a clear visible agglutination of the latex particles.

Negative Control (C-) should not cause any agglutination of the latex particles.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

ASSAY CHARACTERISTICS

- Detectability: 30 IU/mL RF, using an internal standard traceable to the WHO Reference Material W1066 (International Laboratory for Biological Standards, Amsterdam). The cut off value may vary up to 25% depending on uncontrolled variations in the procedure and on the operator experience in reading.
- High dose (zone) effect: False negative results due to high dose effect are absent at least up to 800 IU/mL RF.
- False results: Results obtained with this reagent did not show significative differences when compared with reference reagents. Details of the comparison experiments are available on request.
- Interferences: Hemoglobin (5 g/L), bilirubin (15 mg/dL) and lipemia (5 g/L) do not interfere. Other drugs and substances may interfere[2].

DIAGNOSTIC CHARACTERISTICS

Rheumatoid Factors (RF) are a group of IgM antibodies (although IgG and IgA have been also described) directed against the Fc fragment of the IgG molecules.

RF is mainly present in the serum of patients with rheumatoid arthritis but other diseases may also produce RF: chronic inflammatory processes, infectious diseases such as subacute bacterial endocarditis, malaria, syphilis, leprosy, leishmaniasis, tuberculosis and a variety of autoimmune diseases such as systemic lupus erythematosus[3-6].

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

NOTES

1. The test cards are reusable, and must be washed out and thoroughly rinsed with distilled water free of all detergents.
2. The sensitivity of the test may be reduced at low temperatures.
3. The presence of agglutinated particles at this point may be due to a lack of homogenization of the reagent.
4. Delay in reading may cause false positive results.
5. Dilution of the serum in saline causes a change in the sensitivity of the test from 30 IU/mL to 8 IU/mL due to the strong sample matrix effect on latex agglutination.

BIBLIOGRAPHY

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