ACCUCARE
RHEUMATOID FACTOR (RF) REAGENT
Latex test without predilution

Qualitative determination of Rheumatoid Factors (RF) in Serum.
For In vitro Diagnostic Use Only

ORDER INFORMATION

REF	CONT.
RF 25	25 TESTS
RF 50	50 TESTS
RF 100	100 TESTS

INTRODUCTION

Rheumatoid factors (RF) are antibodies directed against antigenic sites in the Fc fragment of human and animal IgG. Their frequent occurrence in rheumatoid arthritis makes them useful for diagnosis and monitoring of the disease. One method used for rheumatoid factor detection is based on the ability of rheumatoid arthritis sera to agglutinate sensitized sheep red cells, as observed by Waaler and Rose. A more sensitive reagent consisting of biologically inert latex beads coated with human gamma globulin was later described by Singer and Plotz. The RF kit is based on the principle of the latex agglutination assay of Singer and Plotz. The major advantage of this method is rapid performance (2 minute reaction time) and lack of heterophile antibody interference.

PRINCIPLE

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

TEST SENSITIVITY

The sensitivity is of 8 IU/ml of rheumatoid factor according to the World Health Organization (WHO) International Reference preparation.

REAGENT COMPOSITION

Reagent 1 :	RF Latex Reagent
Reagent 2 :	Positive Control Sera
Reagent 3 :	Negative Control Sera

ACCESSORIES

Slides, Stirrer rods, Sample Droppers

SAFETY PRECAUTIONS AND WARNINGS

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.

SAMPLE COLLECTION AND PRESERVATION

Fresh serum. Stable 7 days at 2-8ºC or 3 months at –20ºC.
Samples with presence of fibrin should be centrifuged before testing. Do not use highly haemolized or lipemic samples.

REAGENT PREPARATION AND STORAGE

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.

ASSAY PROCEDURE

QUALITATIVE DETERMINATION	
Add in different circles of the slide :	
Serum to be tested	1 drop
Positive Control	1 drop
Negative Control	1 drop
In all circles add :	
RF latex Reagent	1 drop

Mix and spread with the stirring rod to fill the test circle. Rotate the slide and observe for any agglutination which should occur within two minutes.

INTERPRETATION OF THE RESULTS

Marked agglutination indicates an RF concentration above 8 IU/ml. All the positive samples should be tested by a semi quantitative method.

SEMI-QUANTITATIVE DETERMINATION

Prepare sample dilutions with saline 1:2, 1:4, 1:64. Test each dilution according to the qualitative procedure until no further agglutination is observed. The RF concentration can then be estimated from the last dilution with the visible agglutination. RF (IU/ml) = Highest dilution with positive reaction x reagent sensitivity (8 IU/ml).

CALCULATION

RF (IU/ml) = Highest dilution with positive reaction x reagent sensitivity (8 IU/ml).

QUALITY CONTROL

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

REFERENCE INTERVAL

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

BIBLIOGRAPHY

Waaler. E., Acta Path. Micr. Scand., 17,1 & 2 (40). Bandila, K.L., & Mc Duffie, F.c., Arthritis Rheum. 12 (1969) 74.

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