

CORMAY RF



DIAGNOSTIC KIT FOR DETERMINATION OF RHEUMATOID FACTOR LEVELS

Kit name	Kit size	Cat. No
CORMAY RF	1 x 60 ml	6-308

INTRODUCTION

Rheumatoid factor (RF) is an autoantibody against human IgG commonly seen in sera at a high concentration in some conditions, particularly in patients with rheumatoid arthritis. The measurement of RF value is useful in evaluating the diagnosis, effects of therapy and prognosis of RA, systemic lupus erythematosus, chronic hepatopathy, etc.

METHOD PRINCIPLE

When an antigen-antibody reaction occurs between RF in a sample and denatured human IgG which has been sensitized to latex particles, agglutination results. This agglutination is detected as an absorbance change (550 – 660 nm), with the magnitude of the change being proportional to the quantity of RF in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration.

REAGENTS

Package	
1-Reagent	1 x 45 ml
2-Reagent	1 x 15 ml

Reagent preparation and stability

The reagents are ready to use.

The reagents are stable up to the kit expiry date printed on the package when stored at 2-10°C. Protect from light!

Concentrations in the test

suspension of latex particles sensitized with denatured human IgG (pH 7.3) 0.17 w/v%
glycine buffer solution (pH 8.3)

Warnings and notes

- Product for in vitro diagnostic use only.
- After measurements are taken, reagent bottles should be capped and kept at 2-10°C. Care should be taken not to interchange the caps of reagent bottles.
- Reagents with different lot numbers should not be interchanged or mixed.
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

ADDITIONAL EQUIPMENT

- automated clinical chemistry analyzer capable of accommodating two-reagent assays;
- general laboratory equipment;

SPECIMEN

Serum or plasma (Na-EDTA, K-EDTA, Na-Heparin, Li-Heparin, citric acid).

It is recommended to perform the assay with freshly collected samples. If the test cannot be done immediately, the sample should be placed in a tightly sealable container and stored at -20°C. Repeated freezing and thawing should be avoided. Samples which contain an excessive amount of RF should be diluted with physiological saline and re-tested.

PROCEDURE

wavelength	660 nm
temperature	37°C

These reagents may be used in automatic analysers according to their service manual. These reagents may be used directly in HITACHI 911/912 analysers. Applications for analysers are available on request.

REFERENCE VALUES

serum, plasma	< 18 U/ml
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It is recommended for each laboratory to establish its own reference ranges for local population. Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY IMMUNO-CONTROL I (Cat. No 4-288) with each batch of samples. For the calibration of automatic analysers systems the CORMAY RF CALBRATORS kit (Cat. No 4-277) is recommended. Renewed calibration is recommended: after 1 month when using the reagent on the analyser, after lot change, as required. The standard solutions should be measured at least twice.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using an automatic analyser HITACHI 917. Results may vary if a different instrument is used.

- Analytical range:** 3 - 120 U/ml.
- Antigen excess:** up to 770 U/ml.
- Specificity / Interferences**
Haemoglobin up to 500 mg/dl, bilirubin up to 30 mg/dl, intralipid up to 5%, do not interfere with the test.

Precision

Repeatability (within run) n = 21	Mean [U/ml]	SD [U/ml]	CV [%]
level 1	17.18	0.25	1.44
level 2	39.64	0.21	0.52

Reproducibility (run to run) n = 21	Mean [U/ml]	SD [U/ml]	CV [%]
level 1	17.68	0.79	4.47
level 2	40.40	1.10	2.72

Method comparison

A comparison between CORMAY reagent (y) and commercially available assay (x) using 107 samples gave following results:

$$y = 1.006x - 7.492 \text{ U/ml};$$

$$R = 0.996 \quad (R - \text{correlation coefficient})$$

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Galvin J.P. et al.: Particle enhanced photometric immunoassay systems., Clin Lab. Assay (Pap.Annu.Clin.Lab.Assays Conf.), 4th,73 (1983).
2. Singer J.M. et al.: The latex fixation test. I. Application to the serologic diagnosis of rheumatoid arthritis, Amer. J. Med., 888 (1956)

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MANUFACTURER

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