CORMAY RF 500

DIAGNOSTIC KIT FOR DETERMINATION OF RHEUMATOID FACTOR LEVELS

Kit name	Kit size	Cat. No
CORMAY RF 500	1 x 667 ml	6-328

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 (572 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 know concentration.

REAGENTS

Package

1-Reagent	1 x 500 ml
2-Reagent	1 x 167 ml

The reagents are stable up to the kit expiry date printed on the package when stored at 2-10°C. On board stability of the reagents depends on type of analyser used for analysis. Protect from light and avoid contamination!

Concentrations in the test

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

Warnings and notes

- Product for in vitro diagnostic use only.
- After measurements are taken, reagent bottles should 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.

SPECIMEN

Serum or plasma (Na-EDTA, K-EDTA, Na-Heparin, Li-Heparin, citric acid).
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.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

1-Reagent and 2-Reagent are ready to use.
These reagents may be used in automatic analysers according to their service manual. Applications for analysers are available on request.

REFERENCE VALUES [4]

serum, plasma	< 18 IU/ml

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.
Calibration stability depends on type of analyser used for analysis. The calibration curve should be prepared with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using automatic analysers Biolis 24i Premium and Hitachi 917. Results may vary if a different instrument is used.

- **Sensitivity:** 11.3 IU/ml.
- **Linearity:** up to 120 IU/ml.
  For higher concentration of RF dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.
- **Specificity / Interferences**
  Haemoglobin up to 1.0 g/l, bilirubin up to 0.66 g/l, intralipid up to 20 g/l do not interfere with the test.
- **Precision**

Repeatability (run to run) n = 21	Mean [IU/ml]	SD [IU/ml]	CV [%]
level 1	22.0	0.19	0.85
level 2	49.3	0.26	0.52

Reproducibility (day to day) n = 63	Mean [IU/ml]	SD [IU/ml]	CV [%]
level 1	20.0	1.03	5.12
level 2	48.0	0.89	1.86

- **Method comparison**

A comparison between CORMAY reagent (y) and commercially available assay (x) using 60 samples gave following results:
y = 0.946 x - 0.87 IU/ml;
R = 0.993 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Galvin J.P. et all.: 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 arhritis, Amer. J. Med., 888 (1956)
3. Alan H.B. Wu: Tietz Clinical Guide to Laboratory Tests, 4th ed. WB Saunders, 960, (2006).
4. Internal reference range studies.

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