RF Latex L

Quantitative turbidimetric latex assay for the measurement of rheumatoid factor (RF) in human serum

CE IVD

ORDER INFORMATION

REF	Kit size
GD8432 00	1x40 + 1x10 ml
KL8432 00	1x40 + 1x10 ml
BK8432 00	2x(40+10 ml)

CLINICAL SIGNIFICANCE[1-7]

Rheumatoid factors are a group of IgM antibodies directed to determinants in the Fc portion of the immunoglobulin G molecule. Although rheumatoid factors are found in a number of rheumatoid disorders, such as systemic lupus erythematosus (SLE) and Sjögren's syndrome, as well as in nonrheumatic conditions, its central role in clinic lies its utility as an aid in the diagnosis of rheumatoid arthritis (RA).
The rheumatoid factors are found in 70-100% of cases of definite rheumatoid arthritis depending on the test procedure used to detect them.

METHOD PRINCIPLE

The latex particles coated with human gammaglobulin are agglutinated when they react with samples that contain rheumatoid factors (RF). The latex particles agglutination is proportional to the concentration of the RF in the sample and can be measured by turbidimetry[8,9].

COMPOSITION

Reagent A-Diluent
Tris buffer 20 mmol/l, pH 8.2.
Reagent B-Latex
Latex particles coated with human gammaglobulin, pH 8.2.

PREPARATION OF THE REAGENTS

The reagents are liquids ready to use.

Calibration curve
Prepare dilutions of the Calibrator using NaCl 9 g/l as diluent. Multiply the concentration of the Calibrator by the corresponding factor indicated in the table below to obtain the RF concentration of each point of the curve.

Dilutions	1	2	3	4	5	6
RF Calibrator(µl)	-	10	20	40	60	80
NaCl 9 g/l (µl)	80	70	60	40	20	-
Factor	0.0	0.125	0.25	0.5	0.75	1.0

STORAGE AND STABILITY

The reagents will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8 ºC and contaminations are prevented during their use. Do not use the reagents after the expiration date.

Reagent deterioration: presence of particles and turbidity.

ANCILLARY EQUIPMENT

- Automatic pipette to measure reagent and sample
- Thermostatic bath at 37 °C
- Spectrophotometer or photometer thermostatable at 37 °C capable to read 650 ± 20 nm
- Analysis cuvettes (optical path = 1 cm)
- NaCl (9 g/l) solution
- RF Calibrator L (Ref. GD8433 00)
- Plasmaprotein Normal Control L (Ref. GD8461 00)
- Plasmaprotein Pathological Control L (Ref. GD8464 00)
- Plasmaprotein Normal and Pathological Control L (Ref. GD8466 00)

SAMPLES

Fresh serum.
Samples with presence of fibrin should be centrifuged before testing. Hemolyzed or contaminated samples are not suitable for testing.
Stable for 7 days at 2-8 ºC or 3 months at –20 ºC.

ANALYTICAL PROCEDURE

1. Prewarm the reagents and the photometer (cuvette holder) to 37 ºC.
2. Using distilled water zero the instrument at 650 nm.
3. Pipette into a cuvette:

RA (Diluent)	800 µl
Sample/Calibrator/Water (Blank)	7 µl
RB (Latex)	200 µl

4. Mix well and record the absorbance at 650 nm after 2 minutes (A_2) of the reagent RB addition.

CALCULATION OF RESULTS

Calculate the absorbance difference (A_2 - A_{Blank}) of each point of the calibration curve and plot the values obtained against the RF concentration of each calibrator dilution. Rheumatoid factor concentration in the sample is calculated by interpolation of its (A_2 - A_{Blank}) in the calibration curve.

REFERENCE VALUES [10]

Adults: up to 30 IU/ml

It is recommended that each laboratory establishes its own reference range according to the examined population.

INTERNAL QUALITY CONTROL

To ensure adequate quality control (QC), each run should include a set of controls (normal and abnormal) with assayed values handled as unknowns.
Each laboratory should establish its own quality control scheme and corrective actions if controls do not meet the acceptable tolerances.

ANALYTICAL PERFORMANCES

Linearity
The method is linear up to 160 IU/ml, under the described assay conditions. Samples with higher concentrations should be diluted 1:5 with NaCl 9 g/l and retested again.

Detection limit
Values less than 5 IU/ml give non-reproducible results.

Analytical sensitivity
3.0 mA/IU RF/ml

Prozone effect
Prozone effect is not observed up to 800 IU/ml.

Precision

	Mean (IU/ml)	%CV
Intra-assay	27.1	5.5
n = 10	65.1	3.8
Inter-assay	27.1	7.7
n = 10	65.1	6.7

Accuracy
Results obtained with this reagent did not show systematic differences when compared with commercial reagents of similar characteristics. Details of comparison are available on request.

Interferences
Bilirubin (40 mg/dl), hemoglobin (4 g/l), lipemia (5 g/l) do not interfere.
Other substances may interfere[11].

Note:
1. This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meet the performance characteristics of the method. It is recommended to validate periodically the instrument. Contact to the distributor for any question on the application method.
2. The linearity limit depends on the sample/reagent ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
3. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

PRECAUTIONS IN USE
The reagents contain inactive components such as preservatives (Sodium azide or others), surfactants etc. The total concentration of these components is lower than the limits reported by 67/548/ECC and 88/379/EEC directives about classification, packaging and labelling of dangerous substances. However, the reagents should be handled with caution, avoiding swallowing and contact with skin, eyes and mucous membranes.

The reagents from human donors have given negative results to anti-HIV 1/2, anti-HCV and HBsAg, anyhow handle with caution.

The use of the laboratory reagents according to good laboratory practice is recommended[12].

Waste Management
Please refer to local legal requirements.

REFERENCES
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