RF Assay

Latex Immunoturbidimetric

CE REF C7200150SA

C7201100SA

IVD For in vitro medical device

Use

In vitro test for the quantitative determination of Rheumatoid Factor Kit in human serum on automated clinical chemistry analyzers for clinical laboratories.

Summary

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 erythematous, chronic hepatopathy, etc. This reagent has been designed to accurately and reproducibly measure blood RF using latex agglutination.

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 to 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

RF R1 Glycine buffer 100 mmol/l
Sodium azide < 0.1%
RF R2 Suspension of polystyrene latex particles coated with IgG anti-human RF. In a buffer.
Sodium azide < 0.1%
RF CAL Calibrator. Rheumatoid factor concentration is stated on the vial label.

Reagent Preparation

Reagents are liquid and ready to use. RF R2: swirl before first use. Avoid foam formation. RF Calibrator: Ready to use.

Storage and Stability

- Store the kit at 2-8°C. Do not freeze the reagents.
- After opening, the vials R1and R2 are stable until the expiration date if recapped immediately and protected from contamination, evaporation, direct light, and stored at the correct temperature.

Precaution in Use

The final concentration of the components is below the limits imposed by Regulation (EC) No. 1272/2008 - CLP (and subsequent Amendments) and Directive 88/379/CEE and subsequent amendments to the classification -packaging and labeling of dangerous substances.
The product is not classified as dangerous (DLg. N.285 art. 28 l. n. 128/1998). However the reagent should be handled with care, according to good laboratory practice.
Caution: the reagents contain Sodium Azide (0.095%) as preservative. Avoid swallowing and contacting with skin, eyes and mucous membranes.

Waste Management

Please refer to the local legal requirements.

Sample

- Serum.
- RF is stable in the samples up to 7 days at 2-8°C.

Note

- The kit, according to this method, must be used in manual procedures. About automatic using follow specific applications.
- Avoid direct light, contamination and evaporation.
- The volumes in the procedure can be changed proportionally.

Procedure

Wavelength	λ: 600 nm
Working Temperature	37°C
Optical Path	1 cm

Bring the reagents at 15-25°C before use them.

Bireagent Procedure "substrate starter"

	CALIBRATORE	CAMPIONE
Reagent R1	800 µl	800 µl
Reagent R2	200 µl	200 µl
Mix,incubate a 37°C for 30", then add:		
Sample	--	6 µl
Calibrator	6 µl	–

Mix and read the absorbance immediately (A1) and after 2 minutes (A2) of the sample addition.

Calculation

$$RF[IU/mL] = \frac{(A2\text{-}A1)\ sample}{(A2\text{-}A1)\ calibrator} \times Calibrator$$

Reference values

Normal values up to 20 IU/mL. Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

1. Limit detection: Values less than 2 IU/mL give non-reproducible results.
2. Measurement range: 2-130 IU/mL, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 In NaCl 9 g/L and retested again. The linearity limit and measurement range depends on the sample to 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.

Precision

Determined on 20 samples for each control (N-H) (Normal-High). Results:

MEAN [mg/l]	N =15.2	H = 42.9
C.V. %	N = 2.1	H = 2.5

Correlation

A study based comparing this method with a similar method on 20 samples has given a correlating factor
r = 0.998 y=1.3x + 2.7

Interferences

No interference was observed by the presence of

Bilirubin	≤ 30 mg/dl
Triglycerides	≤ 500 mg/dL
Hemoglobin	≤ 500 mg/dL

For a comprehensive review of interfering substances, refer to the publication by Young et al.

Calibration

It is recommended to use the RF Calibrators for calibration. Dissolve the RF calibrator with 1ml distilled water, and dilute to 5 calibrators as follows,

Dilute	1	2	3	4	5
CAL µl	0	25	50	100	200
Normal Saline	400	375	350	300	200
ratio	1	0.0625	0.125	0.25	0.5

Calibration Method: Non-Linear method such as Spline, Logit, Cubic, etc.

Quality Controls

It's necessary, each time the kit is used, to make the quality controls and to check that values obtained are within the acceptance range provided in the insert.

Bibliography

Kaplan, L.A., Peace, A.J.:"Clinical Chemistry", Mosby Ed. (1996).
Clinical Chemistry publication "Effects of Disease on Clinical Laboratory Tests"
Young D.S., Effects of Drugs on Clinical Laboratory Tests, AACC Press, Washington, DC 5th ed.2000.

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