RF-turbilatex

Latex turbidimetry

CE

Determination of Rheumatoid Factors in human serum or plasma.
Store at 2-8 °C

REF: KRF-T42B14 / KRF-T42B24

Summary:

Rheumatoid factors are a group of 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).
A study of the "American College of Rheumatology" shows that the 80,4% of RA patients were RF positive.

Principle:

Latex particles coated with human gammaglobulin are agglutinated when mixed with samples containing RF. The agglutination causes an absorbance change, dependent upon the RF contents of sample that can be quantified by comparison from a calibrator of known RF concentration.

Composition:

R1 (diluent): Tris buffer - 20 mmol/L, pH 8,2. Preservative
R1 (Latex): Latex particles coated with human gammaglobulin, pH 7,4.Preservative.
RF-CAL: Calibrator. Human serum. The RF concentration is stated on the vial label.

Precautions:

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.

Calibration:

Use RF Calibrator.
The sensitivity of the assay and the target value of the calibrator have been standardized against the International Reference Standard from NIBSC 64/002. The calibration is stable for at least 1 month.
Recalibrate when control results are out of specified tolerances, when using different lot of reagent and when the instrument is adjusted.

Calibration curve:
Prepare the following RF calibrator dilutions in NaCl 9 g/L.
Multiply the concentration of the RF calibrator by the corresponding factor stated in table bellow to obtain the RF concentration of each dilution.

Calibrator dilution	1	2	3	4	5	6
Calibrator FERR (µL) NaCl 9 g/L (µL)	- 400	25 375	50 350	100 300	200 200	400 -
Dilution Factor	0	1/16	1/8	1/4	1/2	1

Preparation:

RF Calibrator: Reconstitute (→) with 2,0 mL of distilled water. Mix gently and bring to room temperature for 10 minutes before use.

Storage and stability:

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C and contaminations are prevented during their use. Reagents should not be left inside the analyzer after use, they must be stored refrigerated at 2-8°C. Latex may sediment. Mix reagents gently before use. Do not use reagents over the expiration date.
Do not freeze; frozen latex and diluent could change the functionality of the test.
Reagent deterioration: Presence of particles and turbidity.
Reconstituted calibrator: Stable for 1 month at 2-8°C or 3 months at –20°C.

Samples:

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

Equipment:

- Thermostatic bath at 37°C.
- Spectrophotometer or photometer thermostatable at 37°C with a 650 nm filter.

Procedure:

1. Bring the reagents and the photometer (cuvette holder) to 37°C.

2. Assay conditions:
Wavelength: . . . . . 650 nm (600-650)
Cuvette: . . . . . 1 cm. light path
Temperature . . . . . .37°C

3. Adjust the instrument to zero with distilled water.

4. Pipette into a cuvette:
Diluent R1: 800 mL
Latex R2: 200 mL
5. Mix and read the absorbance (Blank reagent).

6. Add the sample/ calibrator.

	Blank	Calibrator / Sample
NaCl 9 g/L (µL)	7	-
Calibrator or sample (µL)	-	7

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

Calculations:

Calculate the absorbance difference (A_2-$A_{blank\ reagent}$) 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-$A_{blank\ reagent}$) in the calibration curve.

Quality control:

All clinical laboratories should establish an Internal Quality Control program. Check instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At pre-established intervals following the Q.C. Laboratory recommandations.

Reference values:

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

Performance characteristics:

Measuring range:
6-160 IU/mL, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 in 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.

Detection limit:
Values less than 6 IU/mL give non-reproducible results.

Prozone effect:
No prozone effect was detected upon 800 IU/mL.

Sensitivity:
Δ 3,34 mA. IU/mL.

Precision:
The reagent has been tested for 20 days, using three different FR concentrations in a EP5-based study.

EP5	%CV		
	35,8 IU/mL	78,05 IU/mL	123,26 IU/mL
Total	4.5	4.1	5.9
Intra-ssay	3.3	2.6	3.2
Inter-assay	1.7	2.3	3.4
Inter-day	2.5	2.1	3.6

Accuracy:
Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 41 samples of different concentrations of FR were assayed. The correlation coefficient (r)2 was 0,91 and the regression equation:
y = 1,2042x + 3,1344.
The results of the performance characteristics depend on the analyzer used.

Interferences:

Hemoglobin (10 g/L), bilirrubin (20 mg/dL) and lipemia (10 g/L), do not interfere. Other substances may interfere.

Notes:

Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

References:

1. Frederick Wolfe et al. Arthritis and Rheumatism 1991; 34: 951- 960.
2. Robert W Dorner et al. Clinica Chimica Acta 1987; 167: 1-21.
3. Robert H Shmerling et al. The American Journal of Medicine 1991; 91: 528 – 534.
4. Vladimir Muié et al. Scand J Rheumatology 1972; 1: 181 – 187.
5. Paul R et al. Clin Chem 1979; 25/11: 1909 – 1914.
6. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

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