Reactivos GPL

Barcelona, España

CE

- RF TURBI -

RF
TURBILATEX

Store at: +2+8ºC.

Presentation:
Cod. TL025 CONT: R1 1 x 40 ml / R2 1 x 10 ml./ CAL 2 ml.
Cod. TL026 CONT: R1 2 x 40 ml / R2 2 x 10 ml./ CAL 2 ml.
Cod. TL027 CONT: R1 4 x 40 ml / R2 4 x 10 ml./ CAL 2 ml.

Procedure

Diagnostic reagent for qualitative measurement of RF.

Only for *in vitro use in clinical laboratory* (IVD)

TEST SUMMARY

The RF-Turbilatex is a quantitative turbidimetric test for the measurement of RF in human serum or plasma.
Latex particles coated with human gamma globulin 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.

REAGENTS COMPOSITION

Diluent (R1)	Tris buffer 20 mmol/L, pH 8.2. Preservative.
Latex (R2)	Suspension of latex particles coated with human gamma globulin, pH: 7.4. Preservative.
RF-CAL	Calibrator. Human serum. The RF concentration is stated on the vial label.
Optional	Ref.: TL012 Control ASO/CRP/RF Level L Ref.: TL022 Control ASO/CRP/RF Level H

PRECAUTIONS

Components from human origin have been tested and found to be negative for the presence of HBsAg and HCV, and of antibody to HIV (1/2). However, handle cautiously as potentially infectious.
Good laboratory safety practices should be followed when handling laboratory reagents or human samples.

REAGENT PREPARATION AND STABILITY

RF Calibrator: Reconstitute (→) with 2.0 mL of distilled water. Mix gently and incubate 10 minutes at room temperature before use.
Reconstituted calibrator: Stable for 1 month at 2-8ºC or 3 months at -20ºC.
Do not freeze; frozen latex and diluent could change the functionality of the test.

Calibration curve:
Prepare the following RF calibrator dilutions in ClNa 9 g/L as diluent. 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 RF (µL)	--	25	50	100	200	400
ClNa 9 g/L (µL)	400	375	350	300	200	--
Factor	0	0.0625	0.125	0.25	0.5	1.0

Signs of reagent deterioration:
- Presence of particles (R1, R2) and turbidity (R1).

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Reagents should not be left inside the analyzer after use, they must be stored refrigerated at 2-8ºC. Latex may sediment. Mix reagents gently before use. Do not use reagents over the expiration date.

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.
Recalibrate when control results are out of specified tolerances, when using different lot of reagent and when the instrument is adjusted.

SPECIMEN

Fresh serum. Stable 7 days at 2-8ºC or 3 months at –20ºC.
The samples with particles or fibrin should be centrifuged to eliminate them.
Do not use haemolized or lipemic samples.

Discard contaminated specimen

MATERIAL REQUIRED BUT NOT PROVIDED

- Thermostatic bath at 37º C.
- Spectrophotometer capable of accurate absorbance readings at 650 nm (600-650)

General laboratory equipment

TEST PROCEDURE

1. Bring the reagent and the photometer (cuvette holder) to 37ºC.
2. Assay conditions:
   - Wavelength: …….. 650 nm (600-650 nm)
   - Temperature: …….. 37ºC
   - Cuvette light path: …….. 1 cm.
3. Adjust the instrument to zero with distilled water.
4. Pipette into a cuvette:

	Blank	Micro Test
R.1 Diluent	800 µL	400 µL
R.2 Latex	200 µL	100 µL

5. Mix and read the absorbance (Blank reagent)
6. Add the sample/calibrator.

	Blank	Calibrator / Sample	Blank (Micro Test)	Calibrator / Sample (Micro Test)
ClNa 9 g/L	7 µL	--	3,5 µL	--
Calibrator or sample	--	7 µL	--	3,5 µL

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

Serum controls Ref.: TL012 and Ref.: TL022 are recommended to monitor the performance.
Control Sera are recommended before and after testing samples to monitor the performance of manual and automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES

Up to 20 IU/ml.

It is suggested that each laboratory establish its own reference range.

CLINICAL SIGNIFICANCE

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).

REAGENT PERFORMANCE

- *Limit detection*: Values less than 6 IU/mL give non-reproducible results.
- *Measurement range*: 6-160 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 depend 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.
- *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 dyas, using three different RF 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%
Within Run	3.3%	2.6%	3.2%
Between Run	1.7%	2.3%	3.4%
Between Day	2.5%	2.1%	3.6%

- *Accuracy:* Results obtained using this reagent (y) was compared to those obtained using a commercial reagent (x) with similar characteristics. 41 samples of different concentrations of RF 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 used analyzer.

INTERFERING SUBSTANCES

Hemoglobin (10 g/L), Bilirubin (20 mg/dL) and Lipemia (10 g/L), do not interfere. Other substances may interfere[6].

NOTE

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

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CHEMELEX, S.A.
Pol. Ind. Can Castells. C / Industria 113, Nave J
08420 Canovelles –BARCELONA-
Tel- 34 93 849 17 35 Fax- 34 93 846 78 75

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