# Reactivos GPL

**Barcelona, España**

CE

**- RF TURBI -**

RF
TURBILATEX

*Store at: +2+8ºC.*

*Presentatión:*
*Cod. TL020 CONT: R1 45 ml / R2 5 ml./ CAL 1 ml.*
*Cod. TL020-2 CONT: R1 2 x 45 ml / R2 2 x 5 ml./ CAL 1 ml*

## Procedure

***Diagnostic reagent for qualitative measurement of RF.***

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

### *TEST SUMMARY*

Latex particles coated with human anti-RF are mixed with a serum sample. Agglutination is formed when a sample containing RF is combined with the reagent. The degree of agglutination is directly proportional to the concentration of RF in the sample.

### *REAGENTS COMPOSITION*

| | |
|---|---|
| **Diluent (R1)** | Phosphate buffer 50 mmol/L, sodium azide 0.95 g/L. pH 8.2 |
| **Latex (R2)** | Suspension of latex particles coated with human gamma globulin, sodium azide 0.95 g/L, pH: 7.4 |
| **Calibrator (R3)** | Human serum: RF<br>Concentration is stated on the vial label. |
| **Optional** | Ref.: TL012 Control ASO/CRP/RF Level L<br>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*

**Working reagent (WR):** Shake gently the latex vial gently before use. Prepare the necessary amount as follow: 1 mL Latex Reagent + 9 mL Diluent. **Prepare a fresh Working Reagent based on its workload.**
**RF Calibrator:** Ready to use and stable up to the end of the indicated month and year of expiry. Store at tightly closed at 2-8º C. Carefully invert the bottles before use.
Do not freeze; frozen reagents could change the functionality of the test.
Signs of reagent deterioration:

- Particles and turbidity indicates contamination or reagents deterioration.

**All the reagents of the kit are stable up to the end of the indicated month and year of expiry. Store at tightly closed at 2-8º C. Do not use reagents over the expiration date.**

### *CALIBRATION*

The assay is calibrated against the international reference (Rheumatoid Arthritis Serum) WHO (1970). The use of other commercially available RF calibrators is not recommended.

### *SPECIMEN*

Fresh serum. Stable: 7 days at 2-8º C or 3 months at –20º C.
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 600 nm (600-650)
- Cuvettes with 1 cm light path.

**General laboratory equipment**

### *TEST PROCEDURE*

**Calibration Curve (range up to 200 IU/mL):**
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.
The Standard dilutions must be sued for measurement within 4 hours.

| | |
|---|---|
| Calibrator 1 | 100 µL Calibrator RF* |
| Calibrator 2 | 100 µL Calibrator 1 + 100 µL ClNa 9 g/L |
| Calibrator 3 | 100 µL Calibrator 2 + 100 µL ClNa 9 g/L |
| Calibrator 4 | 100 µL Calibrator 3 + 100 µL ClNa 9 g/L |
| Calibrator 5 | 100 µL ClNa 9 g/L |
| *See the values on the label. Multiply by the appropriate factor | |

**MANUAL PROCEDURE**

1. Bring the working reagent and the photometer to 37º C.
2. Set spectrophotometer wavelength to 600 nm and adjust to zero absorbance against water.
3. Pipette into a Cuvette:

| | Calibrator | Sample | Blank |
|---|---|---|---|
| Working reagent (µL) | 500 | 500 | 500 |
| Calibrator (µL) | 15 | -- | -- |
| Sample (µL) | -- | 15 | -- |
| ClNa 9 g/L (µL) | -- | -- | 15 |

4. Mix and read the absorbance immediately ($A_1$) and after 2.5 minutes ($A_2$) of the sample addition.

### *CALCULATIONS*

**Multipoint Calibration:**

1- Calculation of sample concentration is against interpolation of the absorbance ($A_2 - A_1$) in the calibration curve.
2- Calibration Curves are stable for 10 days, after which a new curve must be generated. Additionally, recalibration must be performed whenever reagent lots are changed or QC so indicate.

**One point calibration:**

$$\frac{(A_2 - A_1)_{\text{Sample}} - (A_2 - A_1)_{\text{Blank}}}{(A_2 - A_1)_{\text{Calibrator}} - (A_2 - A_1)_{\text{Blank}}} \times \text{calibrator concentration} = \text{IU/mL RF}$$

### *QUALITY CONTROL*

Serum controls Ref.: TL012 and Ref.: TL022 are recommended to monitor the performance.

**Serum Controls are recommended for internal quality control. 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).

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

### *REAGENT PERFORMANCE*

1. *Linearity*: Up to 200 IU/mL[(note2)] (calibration curve) (under the described assay conditions)n and Up to 90 IU/mL[(note2)] (one point calibration).
2. *Measurement range* (calibration curve): 6-200 IU/mL. Under the described assay conditions.
3. *Limit detection*: Values less than 6 IU/mL give non-reproducible results.
4. *Prozone effect*: No prozone effect was detected upon 1500 IU/mL.
5. *Precision:*

| | Intra-assay n = 10 | | Inter-assay n= 10 | |
|---|---|---|---|---|
| Mean (IU/mL) | 14.9 | 45.8 | 14.9 | 45.8 |
| SD | 0.96 | 1.32 | 1.2 | 2.54 |
| CV | 6.5 | 2.9 | 8.0 | 5.6 |

6. *Accuracy:* Results obtained using this reagent (y) was compared to those obtained using a commercial reagent (x) with similar characteristics. 29 samples ranging from 1 to 160 IU/mL of RF were assayed. The correlation coefficient (r) was 0.95 and the regression equation y = 0.90x – 0.54.

The results of the performance characteristics depend on the used analyzer.

### *INTERFERING SUBSTANCES*

- Do not interfere: Haemoglobin (10 g/L), Bilirubin (20 mg/dL), Lipemia (10 g/L).
- May interfere: Other substances may interfere[6].

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

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