RF - Turbidimetric CE

REF 3130025	REF 3130030	REF 3130035
1 x 50 mL	2 x 50 mL	2 x 200 mL
CONTENTS	**CONTENTS**	**CONTENTS**
R1.Reagent 1x 40 mL	R1.Reagent 2 x 40 mL	R1.Reagent 2 x 160 mL
R2. Reagent 1 x 10 mL	R2. Reagent 2 x 10 mL	R2. Reagent 4 x 20 mL
CAL. 1 x 2 mL	CAL. 1 x 2 mL	CAL. 1 x 2 mL
For *in vitro* diagnostic use only		

RF - Turbidimetric

Latex Turbidimetry

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]

REAGENTS COMPOSITION

R1 **Diluent**. Tris buffer, 20 mmol/L, pH 8.2.

R2 **Latex**. Latex particles coated with human gammaglobulin, pH 8.2.

CAL **Calibrator.** Ref 3931305 1x2 mL. Human serum. RF concentration is stated on the label vial and it is trazable to the "Rheumatoid Arthritis Serum" 64/002 from WHO (NIBSC).

Precautions: The reagents contain sodium azide 0.95 g/L. Avoid any contact with skin or mucous.
The reagents from human donors have been given negative results to anti-HIV 1/2, HBsAg and anti-HCV. Handle cautiously is recommended.

REAGENT PREPARATION

R1 Ready to use.

R2 Ready to use. Mix gently the vial by inversion before use (Note 4).

CAL 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.

Dilución	1	2	3	4	5	6
RF-CAL (µL)	--	10	20	40	60	80
ClNa 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

1. The reagents will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not use the reagents after the expiration date.
2. Reagent deterioration: Presence of particles, turbidity and increment of blank reagent.

SAMPLES

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

MATERIAL REQUIRED

- Thermostatic bath at 37ºC.
- Spectrophotometer or photometer thermostatable at 37ºC with a 650 ± 20 nm filter.

PROCEDURE

Preliminary Procedure

Prewarm the reagents and the photometer (cuvette holder) to 37ºC.

Analytic Procedure

1. Using distilled water zero the instrument at 650 nm.
2. Pipette into a cuvette:

Diluent: R1	0.8 mL
Sample/ Calibrator/ Water (Blank)	7 µL
Latex: R2	0.2 mL

3. Mix well and record the absorbance after 2 minutes (A_2) of the reagent R2 addition.

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Calculation

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.

QUALITY CONTROLS

Control sera are recommended to monitor the performance of manual and automated assay procedures. It is recommended to use Plasma Protein Control N-I (ref: 3915010) and N-II (ref: 3915015).
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES[10]

Adults: Up to 30 IU/mL
Each laboratory should establish its own reference range.

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.

ANALYTICAL PERFORMANCE

- ***Linearity limit:*** Up to 160 IU/mL, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 en ClNa 9 g/L and retested again.
- ***Detection limit:*** Values less than 5 IU/mL give non-reproducible results.
- ***Analytical sensitivity:*** 3.0 mA / UI/mL.
- ***Prozone effect:*** Up to 800 IU/mL.
- ***Precision:***

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

- ***Accuracy:*** Results obtained with this reagents did not show systematic differences when compared with commercial reagents of similar characteristics. Studies 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].

NOTES

1. This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meets 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.
4. For automatic instruments, avoid the presence of bubbles in the reagents that may interfere with the assay results.

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