TURBITEST AA LINE

FR

látex

For rheumatoid factor determination

SUMMARY

Rheumatoid Factors (RF) are a heterogeneous antibodies group aimed against the Fc fragment of the IgG. They generally belong to the IgM type although RF have also been found in all types of immunoglobulins (IgG, IgA, IgD and IgE). A 70-80% of the RF are found in adult patients with rheumatoid arthritis, and a 10% are found in young persons with juvenile rheumatoid arthritis. They are also found in a variety of other connective tissue diseases, such as LES, Sjögrems syndrome, systemic sclerosis, polymyositis, etc.

Rheumatoid factors (RF) are the most frequently found antibodies in patients with rheumatoid arthritis, so they represent the most requested serological determination for the diagnosis of the disease.

Their isolated detection does not determine the presence of the disease, it is only one of the needed criteria (clinical, radiological and laboratory) for the diagnosis of rheumatoid arthritis.

PRINCIPLE

The rheumatoid factors present in the sample are capable of agglutinating latex particles coated with human γ-globulin. The turbidity produced by the latex particles agglutination is proportional to the RF concentration in the sample and can be measured with a spectrophotometer.

PROVIDED REAGENTS

A. Reagent A: glycine buffer solution, pH 8.2.
B. Reagent B: suspension of evenly sized latex particles, coated with human γ-globulin.

NON-PROVIDED REAGENTS

- Wiener lab.'s **FR Calibrador Turbitest AA**.
- Saline solution
- Distilled water

INSTRUCTIONS FOR USE

Provided Reagents: ready to use.
The Reagent B must be homogenized by gentle inversion several times before use.

WARNINGS

Reagents are for “in vitro” diagnostic use.
Reagent B has been tested and found non-reactive to HIV, HCV and HBV. However, it should be handled as infectious material.
Use the reagents according to the working procedures for clinical laboratories.
The reagents and samples should be discarded according to the local regulations in force.

STABILITY AND STORAGE INSTRUCTIONS

Provided Reagents: stable in refrigerator (2-10ºC) until the expiration date shown on the box. Do not freeze.

SAMPLE

Serum or plasma
a) Collection: obtain in the usual way.
b) Additives: if plasma is used as sample, the use of heparin as anticoagulant is recommended.
c) Known interfering substances: do not use hemolyzed, lipemic or contaminated sera. No interferences are observed from bilirubin up to 20 mg/dl, nor hemoglobin up to 5 g/l. See Young, D.S. in References for effect of drugs on the present method.
d) Stability and storage instructions: the sample should be preferably fresh. In case it cannot be processed immediately, the sample can be kept for 2 or 3 days refrigerated at 2-10ºC or up to 3 months at -20ºC. Avoid repeated freezing and thawing.

REQUIRED MATERIAL (non-provided)

- Spectrophotometer.
- Spectrophotometric cuvettes.
- Micropipettes and pipettes for measuring the stated volumes
- Kahn or hemolysis tubes.
- Stopwatch.

ASSAY CONDITIONS

- Wavelength: 600 nm
- Reaction temperature: room temperature (<25ºC). Temperature control is not critical, it can range between 22 and 30ºC.
- Reaction time: 5 minutes

PROCEDURE

CALIBRATION CURVE
Using saline solution as diluent, perform the following dilutions of the FR Calibrador:

	1	2	3	4	5	6
FR Calibrador (ul)	100	80	60	40	20	0
Saline solution (ul)	-	20	40	60	80	100
Dilution factor	1	0.8	0.6	0.4	0.2	0

The RF concentration of each dilution is obtained multiplying de FR Calibrador concentration by the corresponding dilution factor of each dilution.
In Kahn tubes labeled from 1 to 6, place:

Diluted FR Calibrador (1 to 6)	20 ul
Reagent A	600 ul
Reagent B	200 ul

Homogenize and simultaneously start the stopwatch. At 600 nm, read the absorbance of each tube (1 to 6), at 30 seconds (OD_1), and then at 5 minutes (OD_2), setting the instrument to zero with distilled water for each reading. Calculate the absorbance difference ($\Delta A = OD_2 - OD_1$) for each FR Calibrador dilution. Draw on graph paper the ΔA differences based on the FR Calibrador concentration in IU/ml.

SAMPLES PROCEDURE
Samples should be processed without dilution. See PROCEDURE LIMITATIONS

Sample	20 ul
Reagent A	600 ul
Reagent B	200 ul

Homogenize and simultaneously start the stopwatch. Measure at 600 nm the absorbance of each sample, at 30 seconds (OD_1), and then at 5 minutes (OD_2), setting the instrument to zero with distilled water for each reading.

CALCULATIONS
Calculate de absorbance difference ($\Delta A = OD_2 - OD_1$) for each sample tested. Interpolate this ΔA in the calibration curve to determine the concentration in IU/ml corresponding to the sample under study. Samples with an absorbance above the FR Calibrador highest absorbance, must be diluted 1:2 or 1:4 with saline solution and processed again. Multiply the obtained result by 2 or by 4 accordingly.

QUALITY CONTROL METHOD
Wiener lab.`**s Control Inmunológico Turbitest AA**.
The Control should be assayed in the same manner as the samples.

REFERENCE VALUES
0-20 IU/ml
Each laboratory should set its own reference values.

SI SYSTEM UNITS CONVERSION
FR (UI/ml) x 1 = FR (kUI/l)

PROCEDURE LIMITATIONS
Turbidity and particles in the sample may interfere with the test. Therefore, the particles that may be the result of an incomplete coagulation or protein denaturalization must be removed by centrifugation before performing the test.
It is recommended to dilute, with saline solution, those samples with excess quantities of RF and process them again.

PERFORMANCE
a) Reproducibility: simultaneously processing 20 replicates of one sample, the following results were obtained:

Level	S.D.	C.V.
23.3 IU/ml	± 0.24 IU/ml	1.01 %
55.3 IU/ml	± 0.81 IU/ml	1.47 %

b) Dynamic range: up to 120 IU/ml for the described assay conditions in this insert.

PARAMETERS FOR AUTOANALYZERS
Refer to the specific applications of each autoanalyzer.

WIENER LAB. PROVIDES
- 1 x 30 ml Reagent A
  1 x 10 ml Reagent B
(Cat. Nº 1103261)

- 1 x 30 ml Reagent A
  1 x 10 ml Reagent B
(Cat. Nº 1009302)

- 1 x 30 ml Reagent A
  1 x 10 ml Reagent B
(Cat. Nº 1009222)

- 1 x 30 ml Reagent A
  1 x 10 ml Reagent B
(Cat. Nº 1009648)

REFERENCES

- Moore, T. - Clin. Biochem. 26:75, 1993.
- Henkel, E. - J. Clin. Chem. Clin. Biochem. 22:919, 1984.
- Young, D.S. - "Effects of Drugs on Clinical Laboratory Tests", AACC Press, 4th ed., 2001.

Symbols

The following symbols are used in packaging for Wiener lab. diagnostic reagent kits.

CE — This product fulfills the requirements of the European Directive 98/79 EC for "in vitro" diagnostic medical devices

EC REP — Authorized representative in the European Community

IVD — "In vitro" diagnostic medical device

Σ — Conteins sufficient for <n> tests

Use by

Temperature limitation (store at)

Do not freeze

Biological risks

Volume after reconstitution

Cont. — Contents

LOT — Batch code

Manufactured by:

Xn — Harmful

Corrosive / Caustic

Xi — Irritant

Consult instructions for use

Calibr. — Calibrator

CONTROL — Control

CONTROL + — Positive Control

CONTROL − — Negative Control

REF — Catalog number

Wiener Laboratorios S.A.I.C.
Riobamba 2944
2000 - Rosario - Argentina
http://www.wiener-lab.com.ar
Dir. Téc.: Viviana E. Cétola
Biochemist
A.N.M.A.T. Registered product
Cert. Nº: 3230/99

Wiener lab.

2000 Rosario - Argentina