BIOLABO
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MANUFACTURER:
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Rheumatoid Factor Turbidimetric Immunoassay

Reagent for quantitative determination
of Rheumatoid Factor (RF) in human serum

REF RF050E	**R1** 1 x 50 mL	**R2** 1 x 10 mL
REF RF520E	**R1** 5 x 20 mL	**R2** 1 x 20 mL

TECHNICAL SUPPORT AND ORDERS
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Latest revision: www.biolabo.fr

CE

IVD

Made in France

I: corresponds to significant modifications

INTENDED USE

This reagent is designated for professional use in laboratory (manual or automated method).
It allows to detect and measure rheumatoid factors in human serum to assess the status of rheumatoid factors in the body.

GENERALITIES (2) (4) (5)

RF is found in Rheumatoid Arthritis (RA), Sjogren's syndrome, scleroderma, sarcoidosis and other pathologies.

RF consists in a variety of antibodies that are usually of IgM class and will react with modified human IgG or IgG of animal origin.

About 75% of patients with RA have detectable RF of IgM class. The highest titres are seen in severe active chronic disease with vasculitis, and subcutaneous nodules.
80-90% of patients with Sjogren's syndrome will have high titre of RF.

PRINCIPLE (3)

Turbidimetric Immunoassay (TIA): Photometric measurement of antigen-antibody reaction between aggregated human IgG and RF, by the end-point method at 340 nm.

REAGENTS

R1	**RF TIA**	Buffer	
Good's buffer (pH 7,4)		50	mM
Sodium azide		0.95	g/L
R2	**RF TIA**	Anti-RF	
Heat-aggregated human IgG		≤ 0,5	mg/mL)
Sodium azide		0.95	g/L

According to 1272/2008 regulation, these reagents are not classified as dangerous.

SAFETY CAUTIONS

- BIOLABO reagents are designated for professional use in laboratory
- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Liquid Reagents, ready for use.

STABILITY AND STORAGE

Stored away from light, well cap in the original vial at 2-8°C, reagent is stable when stored and used as described in the insert:

Unopened,
- Until the expiry date stated on the label of the Kit.

Once opened:
- When free from contamination, Reagents R1 and R2 are stable for:
  - 3 months at 2-8° C

SPECIMEN COLLECTION AND HANDLING (1) (2)

Use fresh serum.

If the test cannot be carried out on the same day, the serum may be stored at 2-8°C for 24 hours.

If stored for a longer period, the sample should be frozen at -20°C.

LIMITS (6)

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

1. Medical analysis laboratory equipment.
2. Spectrophotometer or Biochemistry Clinical Analyzer
3. Saline (NaCl 9 g/L)
4. REF CO4000: Solution for cleaning measuring system of analysers

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with

CALIBRATION

- REF RF CALSET51: RF Standard Set (WHO Standardization)
- Batch specific value is indicated in the certificate of analysis and on the label of each vial.
- Use saline as zero point
- Construct the standard curve measuring each vial of RF CALSET51 (§ Procedure)

The calibration frequency depends on proper instrument functions and on the preservation of the reagent.

REFERENCE INTERVALS (1)

WHO Values: < 20 IU/mL

This range is given as a guide only.

Each laboratory should establish its own normal ranges for the population that it serves.

I PERFORMANCES

On a clinical chemistry analyser Selectra PRO M, 340 nm , at 37°C

Detection limit: 3 IU/mL

Linearity range**:** from 15 (LOQ) to 500 IU/mL.

Above 500 IU/mL, dilute the specimen with saline and re-assay considering the dilution factor to calculate the result. Linearity limit depends on specimen/reagent ratio.

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High level*
Mean (IU/mL)	29.2	105.7	204
S.D. IU/mL	1.06	2.85	3.13
C.V. %	3.7%	2.7%	1.5%

Between run N = 20	*Low level*	*Normal level*	*High level*
Mean (IU/mL)	24.6	102.2	190.2
S.D. IU/mL	0.88	1.37	3.63
C.V. %	3.6%	1.3%	1.9%

Sensitivity: 0.00021 Abs/concentration unit

Specificity: Monospecific

Hook effect: No Risk

Comparison study on Cobas Mira with Nephelometry (27 samples between 0 to 569 IU/mL):

y = 0.6026x + 32.5 r = 0.8776

Interferences:

No interference for: Haemoglobin (500 mg/dL), Ascorbic acid (50 mg/dL), Bilirubin (50 mg/dL), Intralipid (3%)

Other substances may interfere (see § Limitations)

On-board stability:

Reagents R1 and R2 are stable 30 days.

Calibration Frequency:

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations

QUALITY CONTROL

- REF RF CONT1: RF Control
- External quality control program.

It is recommended to control in the following cases:

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test.
2. If control is still out of range, use a new vial of calibrator or a fresh calibrator and repeat the test.
3. If control is still out of range, repeat the tests with a new vial of reagent.

If control is still out of range, please contact BIOLABO technical support or your local Agent.

PROCEDURE

Let stand reagents, standards, control and specimens at room temperature.

Before use, mix reagent R2 by gentle swirling.

Manual Procedure:

Realise calibration curve (§ Calibration)

Pipette into well identified test tubes:	Blank	Calibration	**Assays**
Buffer (R1)	900 µL	900 µL	900 µL
Saline	50 µL		
Standards		50 µL	
Specimen			50 µL
Mix well. Record absorbance A1 against Blank at 340 nm.			
Anti-RF (R2)	180 µL	180 µL	180 µL
Mix and let stand for 5 minutes at room temperature. Record absorbance A2 against Blank at 340 nm.			

Note: With Manual Procedure on Spectrophotometer, performances and stability data should be validated by user

Automatic Biochemistry analyzer:

Refer to User's manual

Specific applications are available on request

CALCULATION

Manual procedure:

Calculate ΔAbs (Abs A2 – Abs A1) for standards, controls and assays.

Plot a Standard Curve "Concentration = f(ΔAbs)".

Read the concentration (IU/mL) of controls and samples on the graph.

Automatic Biochemistry analyzer:

The analyser provides directly final result (IU/mL).

Refer to User's manual and specific application.

REFERENCES

(1) TIETZ N.W. Textbook of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p.1833.

(2) Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p.958-961.

(3) Klauss K., Bandilla M. D., and Mc Duffie M. D., Arthritis and Rheumatism, vol.12, n°2, p.74-81 (1969)

(4) Waaler E., Acta Path. Microb. Scan., 17 (1940)

(5) Müller W., The serology of Rheumatoid Arthritis. Berlin-Göttingen-Heidelberg 97 (1962)

(6) YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p. 3-511 to 3-512