RHEUMATOID FACTOR

Cat. No.	Pack name	Packaging (Content)
BLT20036	RF	5 x 25 ml RF Buffer 1 x 25 ml RF Reagent 1 x 1 ml RF Calibrator
BLT20037	RF	1 x 25 ml RF Buffer 1 x 5 ml RF Reagent 1 x 1 ml RF Calibrator

EN

CE IVD

INTENDED USE
Diagnostic reagent for *in vitro* quantitative determination of Rheumatoid Factor (RF) in human serum by turbidimetric immunoassay.(Aggregated human IgG method).

DIAGNOSTIC IMPLICATIONS
The diagnosis of rheumatoid arthritis (RA) is based largely on clinical examination, but laboratory tests (e.g. RF Test) are useful to support the clinical diagnosis and to evaluate the severity and course of the disease in the individual patient.
RF is a term used to describe a variety of antibodies (in most cases of the IgM type) that will react with modified human IgG (e.g. IgG in circulating immune complexes, IgG adsorbed to latex, etc.) and IgG of animal origin.
RF is highly associated with rheumatoid arthritis, as high as 90 % of patients with RA have RF titers of more than 20 IU/ml.

METHOD
Measurement of antigen-antibody reaction by the end-point method.

REAGENTS PROVIDED

Buffer
Good's buffer (pH 7.4). 50 mmol/l.
Sodium azide (0.09 %).

RF reagent
Heat-aggregated human IgG (<0.5 mg/ml).
Sodium azide (0.09 %).

Calibrator
Dilution of human plasma containing high level of RF with saline. Pooled human serum, liquid and stabilized.
Contains 0.09% sodium azide as preservative. Concentration : see bottle label

PREPARATION AND STABILITY OF REAGENTS

Reagent Preparation
Liquid reagents, ready for use.

Stability and Storage
The reagents are stable until expiry date when kept at 2-8°C. Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

REAGENTS REQUIRED BUT NOT SUPPLIED
Saline (9 g/l NaCl)

SAMPLE COLLECTION
Use fresh serum. If the test can not be carried out on the same day, the serum may be stored at 2-8°C for 48 hours. If stored for a longer period, the sample should be frozen.

AUTOMATION
Application procedures on clinical chemistry analyzers are available upon request.

Manual Procedure
Sample/Control: Ready for use

Reference curve: generate a reference curve by diluting the calibrator successively 1:2 in saline 9 g/l. Use saline 9 g/l as zero point.

Test: Mix 50 µl samples, calibrator and control(s) with 900 µl buffer. Read optical density (OD1) of samples, calibrator and control(s) at 340 nm. Add 180 µl RF Reagent. Mix and incubate for 5 minutes at room temperature. Read optical density (OD2) of samples, calibrator and control(s) at 340 nm.

Calculate ΔOD's, plot a calibrator curve and read the concentration of controls and samples.

Reference Values
0 - 20 IU/ml (WHO)
This range is given for orientation only. Each laboratory should establish its own reference values.

PERFORMANCES
The performance characteristics for the RF reagents were measured on a clinical chemistry analyzer (Cobas Mira and Selectra2).

Measuring Range: 0 – 500 IU/ml
Detection Limit: 3 IU/ml
Hook Effect: No risk
Sensitivity: 0.00027 ABS units/concentration unit
Precision:
[%CV]

	Low	Medium	High
Intra-Run	2.68	1.38	1.55
Inter-Run	3.07	1.4	1.78

Accuracy:
[IU/ml)]

Control	Assigned	Measured
ERBA	111 (94-128)	105
Biorad	19.6 (16.6-22.5)	18.0

Specificity: Monospecific

Interferences: No interference for : Hemoglobin (500 mg/dl), Bilirubin (50 mg/dl), Ascorbic acid (50 mg/dl), Intrafat (3%).
Limitations: None

Comparison with nephelometry: y = 0.9486x – 0.2587
r = 0.9900

PRECAUTIONS AND WARNINGS
1.*In vitro* diagnostic use only.
2.Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.
3.Each donor unit used in the preparation of the calibrators and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA.

Also available Calibrators and Controls

Cat. No.	Product name	Pack name	Content
BLT20038	RF CALIBRATOR	RF CAL	1 x 1 ml
BLT20039	RF CONTROL	RF CON	1 x 1 ml
BLT20034	MULTICONTROL LEVEL 1	MULTICON L1	1 x 1 ml
BLT20035	MULTICONTROL LEVEL 2	MULTICON L2	1 x 1 ml

REFERENCES

1. Waaler, e., Acta Path. Microb. Scan., 17 (1940)
2. Bandilla, K. I., and Mc Duffie, F. C., Arthritis Rheum., 12, 74 (1969)
3. Müller, W., The Serology of Rheumatoid Arthritis. Berlin - Göttingen - Heidelberg 97 (1962)

USED SYMBOLS

LOT Lot Number
IVD In vitro Diagnostics
See Instruction for Use
REF Catalogue Number
Manufacturer
CONT Content
Expiry Date
Storage Temperature

12000131
12000132

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

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