Rheumatoid Factor (RF) Diagnostic Reagent Kit
(Latex-enhanced immunoturbidimetry)

Product name
Generic Name: Rheumatoid Factor (RF) Diagnostic Reagent Kit (Latex-Enhanced Immunoturbidimetry)
Abbreviation: RF

Intended use
Rheumatoid factor (RF) diagnostic reagent is used for quantitative in vitro determination of rheumatoid factor in human serum on photometric systems.

Package Specifications

R1	R2
60ml×1	15ml×1
40ml×1	10ml×1
60ml×2	15ml×2

Calibrator (liquid):
Specification 1 (0.5mL×6; 6 levels);
Quality Controls (Liquid):
Specification 1 (0.5mL×2; 2 levels);

Clinical significance
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.

Principle
The assay of RF is based on turbidimetric measurement. Turbidity is caused by the formation of antigen – antibody insoluble immune complexes which can be measured turbidimetrically at 600 nm.

Main ingredient

Composition	Main ingredients
R1	PBS buffer pH7.4 100mmol/L, PEG6000 (polyethylene glycol) 5-20g/L.
R2	Human RF antigen 2.5g/L, Buffer 100mmol/L, Tween-20 1g/L
Calibration	PBS buffer 50mM, Sucrose 5%, BSA 8%, High value of rheumatoid factor
Quality control	PBS buffer 50mM, Sucrose 5%, BSA 8%, High value of rheumatoid factor

Storage and stability
This kit stays stable for 18 months when stored in a dark condition at 2-8° C (do not freeze). After being opened for the first time, the kit can be stored at 2-8° C in an anti-pollution environment and stays stable for 14 days.

Specimen preparation
Fresh serum.
-20℃ stable for 7 days.

Assay procedure
1. Reagent preparation
This reagent is liquid and can be used directly.

Main wavelength	600nm	Sample(S)	4 μl
Subwavelength	no	Reagent 1	240 μl
Reation temperature	37℃	Reagent 2	60 μl
Cuvette light path	1cm	Reaction type	Two Point End

2. Operation steps

Add to the cuvette:	
Sample(S)	4 μl
R1	240 μl
Mix well, incubate at 37℃ for 5 minutes, then add	
R2	60 μl
Mix well, incubate at 37℃ for 1 minute, absorbance A1; incubate at 37℃ for 5 minutes, absorbance A2 △A= A2-A1	

Calculations
Calculate and plot ΔA = (A2 – A1) of the calibrators versus assigned concentration values on a linear-linear graph paper. Calculate ΔA optical densities of samples and read values in IU/ml on the reference curve. Samples yielding absorbances above highest calibrator should be retested after further dilution.

Reference interval
0-20 IU/ml
It is recommended that each laboratory should establish its own reference interval.

Quality control
The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Calibration
The assay requires the use of a Multi-immunoassay Calibrator. Recalibration is recommended at anytime if one of the following events occurs:
- The Lot number of reagents changes.
- Preventative maintenance is performed or a critical component is replaced.
- Control values have shifted or are out of range and a new vial of control does not rectify the problem.

Performance characteristics
Measuring range
2 -160IU/m L
Samples above this concentration should be diluted 1+1 with 0.9% NaCl solution and the result multiplied by 2.

Sensitivity
When a control serum (15 IU/ml) is used as a sample, the range of absorbance change ⩾ 0.03ABS.

Precision

Within-Run	
n= 20	Level 1
Mean (IU/ml)	18±2
CV (%)	⩽5%

Interference
The effect of the following substances can be neglected if the concentrations of the following substances are at or below the given values.

Substances	Concentrations
Bilirubin	30mg/dl
Haemoglobin	2 g/L
Intralipid	0.3 %
VC	0.5 g/L

Automation
Special adaptations for automatic analyzers can be made on request.

General precautions
For in vitro diagnostic use only.
Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.

Precautions for measurement
Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
Reagents with different lot numbers should not be interchanged or mixed.
For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.
Material safety data sheet available for professional user on request.

Parameters for Analyzers

HITACHI	
Model	7180
Assay Code	2 Point End
Reaction Time	10
Assay Point	18-34
Wave Length Sec	/
Wave Length Prim	600
ABS. Limit	32000
Sample Volume（uL）	4
R1 Volume（uL）	240
R2 Volume（uL）	0
R3 Volume（uL）	60
Calibration Type	SPLINE
Calibration Point	5
Span Point	3
SD Limit	999
Duplicate Limit	1000 or (0%-1000Abs)
Sensitivity Limit	0
Prozone Limit	32000

OLYMPUS 400	
Sample Volume（uL）	4
Sample DIL. VOL.	/
R1 Volume（uL）	240
R2 Volume（uL）	60
Reagent DIL. VOL.	/
Measure Wave 1	600
Measure Wave 2	/
METHOD	END
SLOPE	-
Method Point	11-27
Linear Limit	-
NO LAG TIME	Yes
OD L	-
OD H	-
Reagent OD Limit	

FIRST	-2.0-+2.5
LAST	-2.0-+2.5
Correlation Factor A	1.0
Correlation Factor B	0.0
Calibration Type	6AB
Formula	spline
STD(1) Conc.#	*
Unit	IU/m L

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