Rheumatoid Factor Assay Kit (RF)

Method: Immunoturbidimetric

Cat . No.	Size	Instrument
GB610M	3×20 ml 1×20 ml	For Hitachi 717 &ShimadzuCL7200/8000
GS611M	3×20 ml 1×20 ml	For Hitachi917 &OlympusAU640/400/600
GT611M	3×20 ml 1×20 ml	For TOSHIBA
GX611M	1×60 ml 1×20 ml	For Beckman CX5/7/9/LX20

INTENDED USE
Immunoturbidimetric assay for the in vitro quantitative determination of rheumatoid factor in human serum.

CLINICAL SIGNIFICANCE
Rheumatoid factor (RF) is an autoantibody against human IgG commonly seen in sera at a high concentration in some conditions, particularly in patients with rheumatoid arthritis.The measurement of RF value is useful in evaluating the diagnosis, effects of therapy and prognosis of RA, systemic lupus erythematosus, chronic hepatopathy, etc. This reagent has been disigned to accurately and reproducibly measure blood RF using latex agglutination.

ASSAY PRINCIPLE
When an antigen-antibody reaction occurs between RF in a sample and denatured human IgG which has been adsorbed to latex particles,agglutination results.This agglutination is detected as an absobance change (550-660 nm), with the magnitude of the change being proportional to the quantity of RF in the sample.The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration.

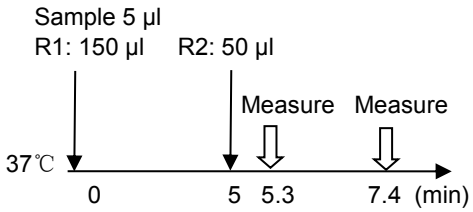
REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
Glycine buffer	130mmol/L
NaCl	320mmol/L
Reagent 2 (R2)	
Tris/HCl buffer	60mmol/L
Suspension of latex particles sensitizend with denatured human IgG	0.17%

SAMPLE COLLECTION AND PREPARATION
Samples collected using standard collecting tubes. Analyse serum samples fresh or store for up to 72 hours at 2-8℃, or 6 months at -20℃.

STABILITY AND PREPARATION OF REAGENTS
All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.
Once opened contents are stable for 1 month at 2-8℃.

Assay Procedure
Test Procedure for Analyzers (OlympusAU640/400)
Wavelength: 600 nm
Assay mode:Fixed



CALIBRATION
Use the specific RF calibrator(Cat. No.GC-RF).

CALCULATIONS OF RESULTS
Plot calibrator concentrations against the corresponding ΔA values using graph paper. The concentration of RF in the sample is obtained by reading of a value from the calibration curve. Do not attempt to extrapolate above or below the range of the calibrators.

QUALITY CONTROL
For quality control, use GQ-RF as daily quality control sera and can be purchased separately. Values should fall within a specific range. If these values fall outside the range and repetition excludes error, the following steps should be taken:
1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.
4. Check the quality of the water used for reagents reconstitution.

NORMAL RANGES
serum: 0-18 IU/ml
Each laboratory should establish an expected range with a set of standards.

MAIN PERFORMANCE CHARACTERISTICS

LINEARITY
The method is linear up to 120 IU/ml. Sample above this concentration should be diluted with 0.9% NaCl and reassay. Multiply the result by dilution factor.

PRECISION
The CV of the test should be CV<10%

Intar assay precision			
N=20	level 1	level 2	level 3
Mean(IU/ml)	17.7	31.2	44.6
SD	0.09	0.34	0.36
CV(%)	0.53	1.08	0.80

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(IU/ml)	18.4	18.4	18.3
$\bar{x}$	18.4		
(Xmax-Xmin)/$\bar{x}$	(18.4-18.3)/18.4*100=0.87%		

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INTERFERENCE

Serum analytes other than RF were added to normal serum spiked with RF. The following analytes were tested up to the following levels and found not to interfere:

Direct bilirubin	up to 30mg/dl
Hemoglobin	up to 500mg/dl
TG	up to 2000mg/dl

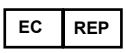
SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

1. Anderson, S.G., Bentzon, M.W., Houba, V. and Krag, P. Bull. Wld. Hlth. Org. 42: 311-318 (1970).
2. Galvin, J.P. et al., Clin. Lab. Assays 4: 73-95(1983).

INDEX OF SYMBOLS

	Manufacture
	Catalogue Number
	Lot number
	Date of manufacture
	Use by(Expiration date)
	For In-Vitro Diagnostic use only
	Stored at 2-8℃
	Attention:See instruction for use
	Authorized Representative in the European Company

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