RF-Turbilatex

Latex turbidimetry

Hemezyme

GENUINE QUALITY RELIABLE RESULTS

MATERIAL PROVIDED

1. R1: Buffer solution
2. R2: Latex solution
3. Calibrators: Concentration stated on vials
4. Instructions for use (IFU)

INTENDED USE:

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

PRINCIPLE:

Latex particles are activated with human, denatured IgG, by means of a covalent bond to increase sensitivity and stability of the reagent. The suspension of coated particles agglutinates in the presence of RF, causing a degree of turbidity which can be detected photometrically and is proportional to the RF concentration in the sample. The quantitative analysis is obtained by interpolation of this photometric value with those found by testing known concentrations of RF.

CLINICAL SIGNIFICANCE:

Rheumatoid Factor (RF) is an auto-antibody which reacts with fragment Fc of human IgG and is present in particular in patients affected by rheumatoid arthritis (RA), and can be considered as an indication of the inflammatory process. High RF concentrations often indicate a marked degeneration of the disease. The classical test methods are based on the agglutination of erythrocytes or latex particles coated with human IgG. These methods are suitable for qualitative or semiquantitative evaluations, while the immunoturbidimetric technique adopted in the present test allows the reproducible, quantitative determination of the rheumatoid factor concentration. Determination of the RF is therefore of clinical importance to establish the diagnosis and prognosis, and to monitor therapeutic efficacy in rheumatoid arthritis.

MATERIAL REQUIRED BUT NOT PROVIDED:

1. any other analyzer
2. Stopwatch
3. Calibrated micropipettes
4. Disposable tips
5. Incubator
6. Hand gloves
7. 0.9% w/v NaCl solution

REAGENTS STORAGE AND STABILITY:

1. Store the reagents at 2-8°C. **DO NOT FREEZE.**
2. The shelf life of reagent and calibrators are as per the expiry date mentioned on the respective bottle/vial labels.
3.
4. Protect the reagent from light.

PRECAUTIONS:

1. In vitro diagnostic use only.
2. Reagent may contain some non-reactive and preservative components. It is recommended to handle carefully avoiding contact with skin and ingestion.
3. Specimen should be considered infectious and handled appropriately.

   Perform the test according to the general 'Good Laboratory Practice' (GLP) guidelines.
4. Do not use in case of any damage or leakage of kit.

PREPARATION OF WORKING REAGENT:

Reagents and calibrators are ready to use.

SPECIMEN COLLECTION & PRESERVATION:

1. Serum, do not use plasma.
2. Sample should be stored at 2-8°C for 7 days or -20°C for 3 months.
3. Discard the contaminated sample.

TEST PROCEDURE:

1. System Parameters:

Parameter	Rheumatoid Factor
Mode	Fixed time
Reaction slope	Increasing
Wavelength	630nm
Path length	10mm
Calibrator concentration	Stated on vial
R1 volume	300µL
Sample/calibrator volume	5µL
Incubation temperature	37°C
Incubation time	5 minutes
R2 volume	75µL
Flow cell temperature	37°C
Delay time	60 seconds
Read time	300 seconds
Linearity	160IU/mL
Sensitivity	2IU/mL

2. Manual Assay Procedure:

Perform the assay as per given below:

Wavelength : 630nm

Temperature : 37°C

R1	300µL
Sample/ calibrator	5µL
Mix well, incubate at 37°C for 5 minutes, then add	
R2	75µL
Mix, aspirate the assay mixture. The first reading should be recorded at 60 seconds (A1) followed by second reading at 300 seconds (A2) at 37°C, 630nm. (ΔA = A2-A1)	

3. Calculation:

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

QUALITY CONTROL:

For internal quality control any normal and abnormal controls should be assayed with each batch of samples.

Each laboratory should establish corrective action in case of deviations in control recovery.

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REFERENCE VALUES:

0-20IU/mL

Note: It is recommended that each laboratory should establish its own reference range based on the patient population.

PERFORMANCE CHARACTERISTICS:

1. **Measuring Range**
   The test has been developed to determine Rheumatoid factor within a measuring range from 2.0 – 160.0IU/mL.
2. **Linearity**
   The higher detection limit is up to 160.0IU/mL.
   If the concentration exceeds this value, the sample should be diluted 1:1 with 0.9% saline solution and reassayed. Multiply the result by dilution factor.
3. **Sensitivity**
   The analytical sensitivity of Rheumatoid factor assay is 2.0IU/mL.
4. **Specificity/Interference**
   No interference was observed by, Bilirubin upto 30mg/dL, Intralipid upto 0.3%, Hemoglobin upto 2g/L.
5. **Precision**

Intra-assay n = 20	Mean (IU/mL)	SD	CV (%)
Sample 1	27.10	0.69	2.53
Sample 2	71.31	1.16	1.63

Inter-assay n = 20	Mean (IU/mL)	SD	CV (%)
Sample 1	26.23	1.20	4.57
Sample 2	70.33	2.86	4.06

BIBLIOGRAPHY:

1. Robert W Dorner et al. Clinica Chimica Acta 1987;167: 1 – 21.
2. Frederick Wolfe et al. Arthritis and Rheumatism 1991; 34: 951- 960.
3. Adalbert F. Schubart et al. The New England Journal of Medicine 1959; 261: 363 – 368.
4. Robert H Shmerling et al. The American Journal of Medicine 1991; 91: 528 –
5. 534.

INDEX OF SYMBOLS:

	Consult The Manual Before Use		Product Catalog Number
	Warning		Manufacturers Identification
	For Use Within Temperature Limits		Date Of Manufacture
	In Vitro Diagnostic Medical Device		Expiry Date
	Lot Number		Tests Per Kit