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A Division of Orchard Medical

Rheumatoid Factor (RF)

IVD

Order Information

Cat. No.
OMR1149

Kit Configuration
Reagent 1: 1x40mL
Reagent 2: 1x10mL
Calibrator: 1 x 2 mL

Summary

Rheumatoid factors are a group of antibodies directed to determinants in the Fc portion of the immunoglobulin G molecule. Although rheumatoid factors are found in a number of rheumatoid disorders, such as systemic lupus erythematosus (SLE) and Sjögren's syndrome, as well as in nonrheumatic conditions, its central role in clinic lies its utility as an aid in the diagnosis of rheumatoid arthritis (RA). A study of the "American College of Rheumatology" shows that the 80.4% of RA patients were RF positive.

Method

Immunoturbidimetric test

Principle

The RF-Turbilatex is a quantitative turbidimetric test for the measurement of RF in human serum or plasma. Latex particles coated with human gammaglobulin are agglutinated when mixed with samples containing RF. The agglutination causes an absorbance change, dependent upon the RF contents of sample that can be quantified by comparison from a calibrator of known RF concentration.

Reagent Storage Instruction And Stability

The reagent is stable until the expiration date on the label when stored tightly closed at 2^0-8^0C.
If found Particles and Turbidity means Reagent deterioration.
Do not freeze; frozen Latex or Diluent could change the functionality of the test.
All the components of the kit are stable until the expiration date on the label when stored tightly.
Reagent 1: Diluent Reagent
2: Latex Solution
Calibrator: Lyophilized serum – Separate Pack

Composition

Reagent contained: Tris buffer 20 mmol/L, Latex particles coated with human gammaglobulin and Preservative.
Calibrator: Lyophilized Serum (RF Value on Label)

Warnings and Precautions

1. Keep out of reach of children. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
2. Take off immediately all contaminated clothing.
3. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow. Avoid contact with skin and mucous membranes.
4. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

Reagent 1 and 2 ready to use.
RF Calibrator: Reconstitute with 2 mL of distilled water. Mix gently and incubate 10 minutes at room temperature before use. Calibrator Stable for 1 month at 2^0-8^0C or 3 months at –20^0C (Freeze only once).

Calibrator dilution	1	2	3	4	5	6
Calibrator RF (µL)	--	25	50	100	200	400
NaCl 9g/L(µL)	0	375	350	300	200	-
Factor	0	0.0625	0.125	0.250	0.50	1.00

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum, heparin, plasma or EDTA plasma separate at the latest 1h after blood collection from cellular contents.
7 days at 2° –8°C
60 days at –20°C
Only freeze once! Discard contaminated specimens.

Assay Procedure

Wavelength: 650 nm (600-650) Temperature: 37^0C
Light path: 10 mm

	Sample / Calibrator
Reagent 1 Diluent	800 µL
Latex Reagent 2	200 µL
Sample /Calibrator	7 µL
Mix and read the absorbance immediately (A1) and after 2 minutes (A2) of the sample addition.	

CALCULATIONS:

$$RF(IU/mL) = \frac{(A2\text{-}A1)\ sample}{(A2\text{-}A1)\ calibrator} \times Calibrator\ concentration$$

Quality Controls

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.

Performance Characteristics Measuring Range

The test has been developed determine RF activities within a measuring range from 5- 180 IU/mL. If such value is exceeded the sample should be diluted 1 + 4 with double distilled water and results multiplied by 5.

Interferences

No interference was observed by, Bilirubin up to 20 mg/dL and Triglycerides up to 1000 mg/dL.

Sensitivity / Limit of Detection
The lower limit of detection is 5 IU / mL.

Linearity
The higher limit of detection is 180 IU / mL.

Precision

Intra-assay n = 20	Mean (IU/mL)	SD (IU/mL)	CV (%)
Sample 1	23.96	1.19	4.97
Sample 2	65.36	1.54	2.35

Inter-assay n = 20	Mean (IU/mL)	SD (IU/mL)	CV (%)
Sample 1	53.75	1.13	2.10
Sample 2	13.51	0.79	5.87

Method Comparison
A comparison of Nucleus Diagnosys RF (y) with a commercially available test (x) using 20 samples gave following results:
$y = 0.941x + 2.054$; $r^2 = 0.995$

Reference Range
Normal value upto 20 IU/mL.

Each laboratory should check if reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

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MANUFACTURED BY: NUCLEUS DIAGNOSYS LLP, INDIA

Marketed By: ORCHARD MEDICAL,

DIAMOND ARCADE, 68 JESSORE ROAD,

1st FLOOR, UNIT No. 110 & 112, KOLKATA – 700 055

CUSTOMER CARE No: 84200 69980

CUSTOMER CARE E-MAIL: sales.orchardmedical@gmail.com