ROBONIK®

prieturb™ ...Latex Turbidimetric Immunoassay

RF

In vitro diagnostic test kit, for professional use only

INTENDED USE : Quantitative determination of Rheumatoid Factor in serum.

ORDERING INFORMATION :	**Pack Size**	**Cat. No.**
	50 ml	PTL RF 01 50

CLINICAL SIGNIFICANCE :

Rheumatoid factors are a group of antibodies directed to determinants in the Fc portion of the immunoglobin G molecule. Although rheumatoid factors are found in number of rheumatoid disorders, such as Systemic Lupus Erythematosus (SLE) and Sjogren's syndrome as well as in nonrheumatic conditions, its central role in clinic lies in its utility as an aid to the diagnosis of rheumatoid arthritis (RA).

METHOD :

Particle Enhanced Turbidimetric immuno Assay (PETIA), where inert latex particles are used to increase the sensitivity of the reaction.

PRINCIPLE :

Prieturb RF – Latex is a particle based immunoassay for quantitative determination of Rheumatoid Factors (RF) in human serum. Latex particles coated with purified Human Immunoglobulin, when allowed to react with samples containing RF agglutinate causing a change in absorbance. This change depends on the concentration of RF and is determined by comparing it with a calibrator (standard) of known concentration.

REAGENTS

COMPONENTS AND CONCENTRATIONS :

1. R1 : Activation buffer (40 ml)
Buffer Solution

2. R2 : Latex Reagent (10 ml)
Suspension of Latex Particles coated with Human Immunoglobulin
(Preservative : Sodium Azide 0.95 g/L)

3. Calibrator 120 IU/ml (0.2 ml)
Human serum Containing known concentration of RF
(Preservative : Sodium Azide 0.95 g/L)

STORAGE INSTRUCTIONS AND REAGENT STABILITY :

1) Store the reagents at 2 to 8°C. DO NOT FREEZE.
2) The shelf life of the reagent, activation buffer and the calibrator is as per the expiry date mentioned on the respective vial label.

WARNINGS AND PRECAUTIONS :

1. To avoid contamination. Use clean laboratory materials. Use clean dry disposable pipette tips for dispensing. Close reagent bottle immediately after use. Avoid direct exposure of reagent to light.
2. Components of human origin have been tested & found to be negative for the presence of HBsAg, HCV & antibody to HIV (1/2). However specimen should be treated as potentially infectious & handled with appropriate caution.

WASTE MANAGEMENT :

Please refer to local regulation requirements.

REAGENT PREPARATION :

1. All reagents are ready to use no special preparation is required.
2. RF Calibrator : Ready to use.

MATERIALS REQUIRED BUT NOT PROVIDED :

Photometer, stopwatch, well calibrated micropipettes, disposable tips, isotonic saline, particulate free distilled water, test - tube rack, incubator / waterbath set at 37°C, optically clean disposable cuvettes such as Semi micro cuvettes / glass cuvettes.

SPECIMEN :

No special preparation of the patient is required prior to specimen collection by approved techniques and precaution for collection & handling.
Only serum should be used for testing. Should a delay in testing occur, store the samples at 2 to 8°C. Samples can be stored for up to two days at 2 to 8°C, provided they are not contaminated. Do not use hemolysed, icteric, or highly turbid sera. Turbid or particulate serum samples must be clarified by centrifugation at 2000 rpm for 15 minutes prior to testing. Use the clear supernatant for testing.

ASSAY PROCEDURE :

Application sheets for automated systems are available on request.

Wavelength	:	Hg 630 nm
Temperature	:	37°C
Cuvette	:	1 cm light path
Read Against	:	Distilled Water
Mode	:	Fixed Time / Initial Rate

Bring reagents & samples to room temperatures before use.

For preparation of Calibration Curve and assays follow the following procedure:

Calibration curve: *Prepare dilutions of the calibrator as mentioned below :*

Concentration of RF in IU/ml	80	40	20	10
Normal Saline	25 µl	50 µl	50 µl	50 µl
Calibrator 120 IU/ml	50 µl	50 µl	50 µl	50 µl

Transfer 5 µl of the Normal saline in the test-tube labelled as ***'0'***
Transfer 5 µl of the calibrator from the vial directly in the test-tube labelled as ***'120'***

TEST PROCEDURE :

A) With multi-point calibration and read time 2 min(120 Sec) :

Label the test tubes as: Standard, 1 to 6(0, 5, 20, 40, 80, 120 IU/ml)& Sample , Control. Piepette 400µl R1, Calibrator/Sample 5µl & 100µl R2, mix well & Read Delta A, as per the procedure A or B. Repeat the Procedure for all the Standards and for sample.

Pipette out following reagents and sample / calibrator in a clean dry test tubes.

	Calibrator	Sample
R1 Buffer	400 µl	400 µl
Calibrator	5 µl	–
Sample	–	5 µl
R2 Latex	100 µl	100 µl

Mix well and read the variation of absorbance (Δ A) between **5 seconds** and **120 seconds** for all dilutions of calibrator (0 to 120 IU/ml) and Samples.

INSTRUMENT APPLICATION
prietest TOUCH

```
Name : RF  , Mod : FIX_T
Pri.: 630    , Sec.: 0
Temp: 37C   , KF : 1.000
Vol : 400ul  , Unit : IU/ml
Lag : 5      , Read : 120
Blk : N, QC : Y, Norm : Y
Std :  6     , Concen :
Std.:  1  =  0,  Std.:  2  =  10
Std.:  3  =  20, Std.:  4  =  40
Std.:  5  =  80, Std.:  6  = 120
Normal HI = 18
Normal LO = 0
QCNH : *
QCNL :  *
QCABH = *
QCABL =  *
Init. OD :       =  0.5   H
Max Delta :      =  0.48
Rgnt. Linearity : 120
NOTE :
* Indicates user definable parameter.
NA Implies Not Applicable
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PARAMETERS FOR INSTRUMENT SETTING	
TEST NAME	RF
Reaction	Fixed Time
Reaction Slope	Increasing
Wavelength 1	630 nm
Temperature	37°C
Zero Setting	Distilled Water
Lag Time	5 seconds
Read Time	120 seconds
Standard Conc.	0,10, 20, 40, 80, 120
Units	IU/ml
Sample Volume	5 µl
Reagent Volume	500 µl
Reference Range	0 to 18
Reagent Linearity	120
Initial OD	< 0.5
Max Delta	0.48

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B)With single point calibration and read time 2 min (120 Sec) :
(Recommended for screening purpose only)

Prepare calibrator of concentration 40 IU/ml as mentioned below:

Concentration of RF IU/ml	40
Normal Saline	100 µl
Calibrator 120 IU/ml	50 µl

Label the test tube as calibrator, sample/control and pipette into respective test tube the reagent, calibrator, sample/control as per the following procedure.

Pipette out following reagents & sample/ calibrator in a clean dry test tubes.

	Calibrator	Sample
R1 Buffer	400 µl	400 µl
Calibrator	5 µl	–
Sample	–	5 µl
R2 Latex	100 µl	100 µl

Mix well and read the variation of absorbance (Δ A) between **5 seconds** and **120 seconds** for calibrator (40 IU/ml) and Samples.

INSTRUMENT APPLICATION ***prietest TOUCH***
Name : RF , Mod : FIX_T
Pri.: 630 , Sec.: 0
Temp: 37C , KF : 1.000
Vol : 400ul , Unit : IU/ml
Lag : 5 , Read : 120
Blk : N, QC : Y, Norm : Y
Std : 1 , Concen :
Std.: 1 = 40
Normal HI = 18
Normal LO = 0
QCNH : *
QCNL : *
QCABH = *
QCABL = *
Init. OD : = 0.43
Max Delta : = 0.23
Rgnt. Linearity : 40
NOTE :
* Indicates user definable parameter.
NA Implies Not Applicable

PARAMETERS FOR INSTRUMENT SETTING	
TEST NAME	RF
Reaction	Fixed Time
Reaction Slope	Increasing
Wavelength 1	630 nm
Temperature	37°C
Zero Setting	Distilled Water
Lag Time	5 seconds
Read Time	120 seconds
Standard Conc.	40
Units	IU/ml
Sample Volume	5 µl
Reagent Volume	500 µl
Reference Range	0 to 18
Reagent Linearity	40
Initial OD	< 0.43
Max Delta	0.23

CAUTION :

Kindly adhere to the duration strictly in case of calibrator as well as Test sample since variations may give erroneous results.

CALCULATIONS:

1. Samples which contains RF in excess of linearity limits should be diluted with normal saline.
2. Interpolate Δ A of the diluted test specimen on the calibration curve and obtain the RF concentration 'C' of the diluted test specimen.
3. Multiply the RF concentration 'C' with the dilution factor (F) of the test specimen for obtaining the concentration of RF in the neat test specimen.

   Concentration of RF in the neat test specimen in IU/ml = C x F

   (Where 'F' is the dilution factor of the test specimen, for e.g. 2 for 1:1 dilution of test specimen and so on, when diluted with normal saline).

QUALITY CONTROL :

To ensure adequate quality, use of the commercially available control sera is recommended.

PERFORMANCE CHARACTERISTICS :

MEASURING RANGE :

1. The prieturb RF reagent is linear from 3 to 120 IU/ml. If the concentration is greater than linearity, dilute the sample with normal saline and repeat the assay.
   Multiply the result with dilution factor.
2. The linearity is 40 IU/ml for the assay procedure (C) based on single point calibration and 120 sec read time.

SPECIFICITY / INTERFERENCES :

No interference was observed by Bilirubin up to 20 mg/dl, Lipemia up to 1000 mg/dl.

SENSITIVITY / LIMIT OF DETECTION :

Detection limit : 3 IU/ml

The detection limit represents the lowest measurable RF concentrations that can be distinguished from zero.

REFERENCE RANGE :

The interim reference values for RF in normal population are under 18 IU/ml.

The reference values are related to age, geographical and methodological differences and vary widely.

It is recommended that each laboratory should assign its own reference range.

LITERATURE :

1. Frederick Wolfe et al - Arthritis and Rheumatism 1991 : 34 : 951-960
2. Data on file.

ROBONIK®

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