ACCUTURB-100

# RF-Turbilatex

Latex-Enhanced Turbidimetry Assay.

## INTENDED USE

**For the Quantitative determination of RF in serum**
**Only for *In Vitro* Diagnostic use**

## ORDER INFORMATION

| REF | CONT |
|---|---|
| TRF 25T | 1 x 7.5 ML |
| TRF 50T | 1 x 15 ML |

## CLINICAL SIGNIFICANCE

Rheumatoid Factor is 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 Sjogrens syndrome as well as in nonrheumatic conditions its central role in clinic lies its utility as an aid in the diagnosis of rheumatoid arthritis.As the study of the American college of Rheumatology shows that the 80.4% of RA patients were RF positive.

## PRINCIPLE

RF turbilatex is a quantitative turbidimetric test for the measurement of RF in human serum. 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 samples that can be quantified by comparison from a calibrator of known RF concentration.

## KIT CONTENT

| Reagent | 25 tests/kit | 50 tests/kit | Major ingredients |
|---|---|---|---|
| Reaction buffer (R1 reagent) | 1×6 ml | 1×12 ml | Phosphate Reaction buffer |
| RF latex combo (R2 reagent) | 1×1.5ml | 1×3 ml | Latex particles coated with human gamma-globulin |
| Cuvette & Bead | 25 no's | 50 no's | / |
| Specification | 1 copy | 1 copy | / |
| Magnetic card | 1 piece | 1 piece | / |

## SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only.
2. DO NOT pipette by mouth. Avoid contact with skin and eyes. If spilt, thoroughly, wash affected areas with water. For further information, consult the RF Reagent Material Safety Data Sheet.
3. Reagent contains Sodium Azide as a preservative. This may react with copper or lead plumbing to form explosive metal azides. Upon disposal, flush with large amounts of water to prevent azide build up.
4. Do not use the reagent after the expiration date printed on the kit.
5. Components from human origin have been tested and found to be negative for the presence of HBsAg,HCV and antibody to HIV(1/2).However handle the calibrator cautiously as potentially infectious material.

## SAMPLE COLLECTION AND PRESERVATION

Fresh serum: Stable for 7 days at 2-8°C or 3 months at -20°C.
Samples with presence of fibrin should be centrifuged before testing.
Do not use highly hemolysed or lipemic sample.

## REAGENT STABILITY

All the component of the kit are stable until the expiry date on the label when stored tightly closed at 2-8°C and contaminants prevented during there use, Do not use expired reagents.

## ASSAY PROCEDURE

**1.THE REAGENT DOSE DISPENSING IN THE CUVETTE**

| Reagent | Dose |
|---|---|
| Reaction Buffer (R1 Reagent) | 240µl |
| Sample | 5 µl |
| Mix and incubate for 3 minutes at 37°C in incubator slot (A,B,C,D). | |
| RF antibody latex combo (R2 Reagent) | 60 µl |

## 2. OPERATING STEP

**(1).** When starting it shows "Read card", Put the corresponding lot magnetic card in the reader slot, reading the card correctly, the screening displays the reagent name and lot number, the instrument status indication light is working (yellow-green). Please check carefully.
**(2).** After confirm the lot number, dispense 240µl reaction buffer (R1) to a colorimetric cuvette and 5µl sample and mixing sticker. Do not produce bubbles when dispensing the sample. Mix and incubate for 3 minutes at 37°C in incubator slot (A,B,C,D).
**(3).** Put the colorimetric cuvette in the detection well, gently press the cuvette until it contacts the bottom. The status indication light will be off when the analyzer detects the colorimetric cuvette successfully.
**(4).** When the analyzer shows "Add [R2]", dispense 60µl RF antibody latex combo (R2) in the cuvette. The analyzer will mix automatically and start to detect, it shows: "Testing…" it shows the result automatically and record the value.
**(5).** After detecting, move the cuvette. The status indication light will be working (yellow- green). Return to step (2) to detect next sample.
**(6).** If moving the cuvette out in the process of detecting, the screen shows "Give up testing".
**(7).** If the result shows >161.00 IU/ml, may use Normal saline to dilute the sample 1:5 (add 400µl Normal saline in 100µl sample), input dilution multiply 5, the analyser can calculate the sample concentration automatically.

## LINEARITY

The method is linear to a concentration of 0 -160 IU/ml.
If the concentration exceeds this value, the sample should be diluted 1:5 with 0.9% saline solution and re-assayed.

## REFERENCE INTERVAL

| | |
|---|---|
| Serum plasma | upto 20 IU/ml. |

## QUALITY CONTROL

To ensure adequate quality control, Normal and abnormal control with assayed values should be run as unknown samples.

## INTERFERENCES

Hemoglobin 10 g/dL, Bilirubin 20 mg/dL and Lipemia 10 g/dL do not interfere. Other substances may interfere.

## BIBLIOGRAPHY


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2. Robert W Dorner et al. Clinica Chemica Acta 1987;167;1-21.
3. Robert H Shmerling et al The American Journal of medicine 1991;
4. Vladimir Mule at al Scand J Rheumatalogy 1972;1;181-187.


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