# Rheumatoid Factor (RF) Test Kit

## (Immunoturbidimetry)

### 【NAME】

Rheumatoid Factor (RF) Test Kit (Immunoturbidimetry)

### 【INTEND USE】

This reagent is intended for the in vitro quantitative determination of Rheumatoid Factor (RF) in human serum or plasma. It makes sense for the diagnosis of rheumatoid arthritis. Rheumatoid factor is an autoantibody, include all types of immunoglobulins, they are resistant to denaturation or polymeric molecules FC lgG antibody fragments, for the detection of RF differential diagnosis of rheumatic diseases provide important information.

### 【METHODOLOGY】

Rheumatoid Factor (RF) and thermal polymerization IgG is reaction, and generate immune complex.Detection of the turbidity of change at 600nm, the degree of change is proportional to the RF levels in the samples.

### 【STABILITY AND STORAGE】

Unopened, avoid light preservation in 2 ~ 8 ℃, valid for 12 months;
Opened, avoid contamination preservation in 2 ~ 8 ℃, valid for 1 month.
Reagent is not allowed frozen.

### 【SPECIMEN COLLECTION AND HANDLING】

It is best to fresh Serum, heparin anticoagulant blood plasma.
Don't use the blood sample collection bottle containing sodium fluoride.
Sample stability:20～25℃preservation stability in 1 days.
2～8℃ preservation stability in 3 days .
Do not use the contaminated samples.

### 【APPLICABLE INSTRUMENT】

Fully automatic biochemical analyzer.

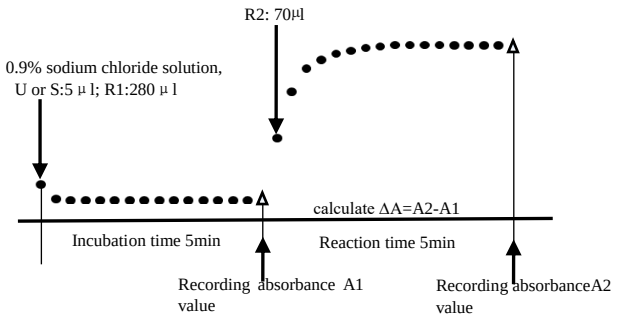
### 【SYSTEM PARAMETERS】

The following system parameters are recommended. Individual instrument applications are available upon request from the Technical Support Group

| | |
|---|---|
| Temperature | 37° C |
| Cuvette light path | 1.0cm |
| Primary Wavelength | 600nm |
| Assay Type | Two Point End |
| Direction | Increase |
| Sample : Reagent 1: Reagent 2 Ratio | 5:280:70 |
| eg : Sample Vol | 5 μL |
| Reagent1 Vol | 280 μL |
| Reagent2 Vol | 70 μL |
| Linearity | 0～80IU/mL |
| Testing | Deducting the reagent blank |

### 【OPERATION STEPS】

R1: Reagent 1 R2: Reagent 2 S: Calibrator U: Sample




### 【CALCULATION】

ΔAbs = [（A2- A1）Calibrator or Sample] － [（A2- A1）Blank]
According to the calibration requirements, with different levels of calibration solution, together with 9 g/L sodium chloride solution as the blank. After measurement,the instrument automatic synthesize calibration curve for the calibration response quantity through the appropriate mathematical model (such as Logit/ Spline).Using RF calibration values to calibrate instrument ,within the scope of the reportable results,the instrument directly report reliable test results.

### 【REFERENCE RANGE】

＜20IU/mL
By clinical trials, choose no less than 100 newborn or adults blood specimens, tested by automatic biochemical analyzer, and then processing the testing value with statistical method, calculating out the reference range.
**Recommendation: The laboratory set up its own reference range!**

### 【THE LIMITATION OF TEST RESULTS】

Rheumatoid Factor (RF) testing is just one of the standard that clinicist diagnose the patient. Clinical physicians should according to patients' bodies, history and other diagnostic program, to get comprehensive judgment.

### 【THE INTERPRETATION OF TEST RESULTS】

Human error, the processing of specimen, analysis instrument deviation, etc. all can affect the measurement result；When one sample deviates from the expected value too far, need to be tested again.

### 【PERFORMANCE INDEX】

1.Reagent blank absorbance ≤1.0,(600nm,lcm optical path).
2.Precision: repeatability CV≤5%;batch variations R≤8%.
3.Accuracy: relative deviation ≤10%.
4.Linearity range: 0～80IU/mL,r≥0.990.

### 【ATTENTION】

1.Reagent contains sodium azide (toxic) preservatives, avoid contact with skin and mucous membrane.If necessary preventive measures should be taken use of reagents, reagent contact with skin and mucous membrane, please rinse with water, please go to a doctor if necessary.
2.The maximum linearity is 80IU/mL.If testing results is upper limit,dilute with 0.9% sodium chloride solution before test, results multiplied by the dilution ratio.
3.Liquid waste disposal: Suggest follow local regulations.
4.This specification is applied to the double reagent.
5.Different batches reagents cannot mix, when replacing reagents batch number, please calibration again.

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