RHEUMATOID FACTORS (RF)

Reagents for measurement of RF concentration

- Liquid, two reagents
- Store at 2°C - 8°C
- For In Vitro Diagnostic Use
- Do not freeze

**TEST PRINCIPLE**

Rheumatoid factors (RF) cause agglutination of the latex particles coated with human gamma-globulin. The agglutination of the latex particles is proportional to the RF concentration and can be measured by turbidimetry1-3.

**REAGENT COMPOSITION**

A. Reagent: Tris buffer 20 mmol/L, sodium azide 0.95 g/L, pH 8.2.
B. Reagent: Suspension of latex particles coated with human gamma-globulin, sodium azide 0.95 g/L.

**REAGENT STABILITY AND STORAGE**

Store at 2-8°C. Reagents and Standards are stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during their use.

**SAMPLES**

Serum collected by standard procedures. RF in serum is stable for 2 days at 2-8°C.

**TEST PROCEDURE**

1. Bring the Working Reagent and the instrument to 37°C.
2. Zero the instrument with distilled water (Note 2).
3. Pipette into a cuvette:
   - Working Reagent: 0.8 mL
   - Water (Blank): Standard (S) or Sample: 10 µL
   - Reagent B (Note 3): 0.2 mL
   - Mix and insert cuvette into the instrument. Start stopwatch.
5. Read the absorbance at 650 nm after 2 minutes of the Reagent B addition.

**CALCULATIONS**

Calibration curve: Calculate the absorbance difference (ASample − ABlank) of each point of the calibration curve and plot the values found against the RF concentration. Rheumatoid factors concentration in the sample is calculated by interpolation of its absorbance (ASample − ABlank) on the calibration curve.

**EXPECTED VALUES**

- Serum, adults: Up to 30 IU/mL
- This range is given for orientation only; each laboratory should establish its own reference range.

**QUALITY CONTROL**

It is recommended to use the Rheumatoid Control Serum level I (Cod. TARHII) and II (Cod. TARIII) to verify the performance of the measurement procedure. Calibrator: We recommend: ARCHEM Standard Cat. No. TA121S.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

**METROLOGICAL CHARACTERISTICS**

Detection limit: 2 IU/mL
Measurement interval: (approximate value dependent on the highest standard concentration):
- 2-160 IU/mL: For higher values dilute sample 1/5 with distilled water and repeat measurement (Note 4).
- Repeatibility (within run):
  - Mean concentration CV n 24 IU/mL 5.3 % 20
  - 24 IU/mL 5.6 % 20
- Reproducibility (run to run):
  - Mean concentration CV n 24 IU/mL 6.6 % 25
  - 39 IU/mL 6.1 % 25
- Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents.

Details of the comparison experiments are available on request.
- Zone effect: This method has not zone effect up to 800 IU/mL.
- Interferences: Hemoglobin (10 g/L), bilirubin (20 mg/dL) and lipemia (triglycerides10 g/L) do not interfere. Other drugs and substances may interfere.

These metrolological characteristics have been obtained using an analyzer. Results may vary if a different instrument or manual procedure are used.

**DIAGNOSTIC CHARACTERISTICS**

Rheumatoid Factors (RF) are a group of IgM antibodies (although IgG and IgA have been also described) directed against the Fc fragment of the IgG molecules.

RF is mainly present in the serum of patients with rheumatoid arthritis but other diseases may also produce RF: chronic inflammatory processes, infectious diseases such as subacute bacterial endocarditis, malaria, syphilis, leprosy, leishmaniasis, tuberculosis and a variety of autoimmune diseases such as systemic lupus erythematosus.

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

**NOTES**

1. The calibration curve is linear up to 120 IU/mL in some instruments. In these cases, calibration may be performed with a single point (40 IU/mL). If better accuracy is required, it is recommended to use the multipoint calibration method.
2. These reagents may be used in several automatic analysers.
3. Shake the Reagent B vial gently before using.
4. The measurement interval depends on the sample to reagent ratio. The interval will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

**AUTOMATION**

Special adaptions for automatic analyzers can be made on request.

**REFERENCES**