**RHEUMATOID FACTOR**

**INTENDED USE**
Diagnostic reagent for in vitro quantitative determination of Rheumatoid Factor (RF) in human serum by turbidimetric immunoassay (Aggregated human IgM method).

**DIAGNOSTIC IMPLICATIONS**
The diagnosis of rheumatoid arthritis (RA) is based largely on clinical examination, but laboratory tests (e.g. RF Test) are useful to support the clinical diagnosis and to evaluate the severity and course of the disease in the individual patient.

RF is a term used to describe a variety of antibodies (in most cases of the IgM type) that will react with modified human IgG (e.g. IgG in circulating immune complexes, IgG adsorbed to latex, etc.) and IgG of animal origin. RF is highly associated with rheumatoid arthritis, as high as 90% of patients with RA have RF titers of more than 20 IU/ml.

**METHOD**
Measurement of antigen-antibody reaction by the end-point method.

**REAGENTS PROVIDED**
- **Buffer**
  - Good’s buffer (pH 7.4), 50 mmol/l.
  - Sodium azide (0.09%).
- **RF reagent**
  - Heat-aggregated human IgG (<0.5 mg/ml).
  - Sodium azide (0.09%).
- **Calibrator**
  - Dilution of human plasma containing high level of RF with saline. Pooled human serum, liquid and stabilized.
  - Contains 0.09% sodium azide as preservative. Concentration: see bottle label.

**PREPARATION AND STABILITY OF REAGENTS**
- **Reagent Preparation**
  - Liquid reagents, ready for use.
- **Stability and Storage**
  - The reagents are stable until expiry date when kept at 2-8°C. Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

**SAMPLE COLLECTION**
Use fresh serum. If the test can not be carried out on the same day, the serum may be stored at 2-8°C for 48 hours. If stored for a longer period, the sample should be frozen.

**STABILITY AND STORAGE**
- The reagents are stable until expiry date when kept at 2-8°C. Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

**TEST PROCEDURE**
- **Test:** Mix 50 µl samples, calibrator and control(s) with 900 µl buffer. Read optical density (OD1) of samples, calibrator and control(s) at 340 nm. Add 180 µl RF-Reagent. Mix and incubate for 5 minutes at room temperature. Read optical density (OD2) of samples, calibrator and control(s) at 340 nm.
- **Calculate \\
\[ \Delta \text{OD's}, \text{plot a calibrator curve and read the concentration of controls and samples.} \]\n
**REFERENCE VALUES**
- **0 - 20 IU/ml (WHO)**
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**PERFORMANCES**
The performance characteristics for the RF reagents were measured on a clinical chemistry analyzer (Cobas Mira and Selectra2).

**PERFORMANCE CHARACTERISTICS**
- **Measuring Range:** 0 – 500 IU/ml
- **Detection Limit:** 3 IU/ml
- **Hook Effect:** No risk
- **Sensitivity:** 0.00027 ABS units/concentration unit
- **Accuracy:**
  - Intra-Run: 2.68 ± 1.38
  - Inter-Run: 3.07 ± 1.4
- **Specificity:** Monospecific
- **Interferences:**
  - No interference for: Hemoglobin (500 mg/dl), Bilirubin (50 mg/dl), Ascorbic acid (50 mg/dl), Intrafat (3%).
- **Limitations:** None
- **Comparison with nephelometry:**
  - \[ y = 0.9486x - 0.2587 \]
  - \[ r = 0.9900 \]

**REMARKS**
- May explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.
- Each donor unit used in the preparation of the calibrators and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA.

**REFERENCES**

**AUTOMATION**
Application procedures on clinical chemistry analyzers are available upon request.

**Manual Procedure**
Sample/Control: Ready for use
- Reference curve: generate a reference curve by diluting the calibrator successively 1:2 in saline 9 g/l. Use saline 9 g/l as zero point.
- Test: Mix 50 µl samples, calibrator and control(s) with 900 µl buffer. Read optical density (OD1) of samples, calibrator and control(s) at 340 nm. Add 180 µl RF-Reagent. Mix and incubate for 5 minutes at room temperature. Read optical density (OD2) of samples, calibrator and control(s) at 340 nm.
- Calculate \[ \Delta \text{OD's}, \text{plot a calibrator curve and read the concentration of controls and samples.} \]

**REFERENCE SYMBOLS**
- **LOT** Lot Number
- **IDV** In vitro Diagnostics
- **CONT** Content
- **REF** Catalogue Number
- **IN** Manufacturer
- **DATE** Expiry Date
- **STOR** Storage Temperature

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**QUALITY SYSTEM CERTIFIED**
ISO 9001 ISO 13485