Rheumatoid Factor (RF)
A rapid latex slide test for the detection of Rheumatoid Factor in serum

**Intended Use**
Rapid latex agglutination test for the qualitative screening and semi-quantitative determination of rheumatoid factor (RF) in human serum.

**Background**
Rheumatoid factors are immunoglobulins which are directed against the Fc portion of IgG. Rheumatoid arthritis is a chronic systemic disease of unknown etiology. Its diagnosis is based on combined clinical and radiographic analysis. The determination of RF is the laboratory test that is most commonly used not only for the diagnosis of rheumatoid arthritis but also assists in the prognosis of the disease and in the monitoring of therapeutic response.

**Test Principle**
Spectrum RF latex reagent is a suspension of polystyrene particles sensitized with human gamma globulin. When the latex reagent is mixed with a serum containing rheumatoid factor, visible agglutination occurs. The latex reagent has been produced so that agglutination will take place only when the level of RF is greater than 10 IU/ml.

**Reagents**
Spectrum RF latex kit contains the following reagents:
- Latex Reagent (bottle with green cap):
  A suspension of polystyrene latex particles in glycine-saline buffer pH: 8.6 ± 0.1, coated with human gama globulin.
- Positive Control Serum (bottle with red cap):
  Is prepared from a stabilized human serum pool containing RF. Both reagents contain 0.9 g/L Sodium azide as a preservative.
- Negative Control Serum (bottle with white cap):
  Reagent contain 0.9 g/L Na azide as a preservative.

**Slides and Stirrers**
NOTE: Negative Control Serum, Slides and Stirrers are only included in Complete Kits REF: 518 001 (50 test) & REF: 518 002 (100 test)

**Storage & Stability**
The reagents are stable up to the expiration date specified when stored at 2 – 8°C.

**Precautions and Warnings**
All human blood components used to prepare controls have been tested for Hepatitis B surface antigen (HBsAg) and HTLV-III antibodies by FDA approved procedure and found to be non-reactive. No known test method for HBsAg or HTLV-III antibodies offers total assurance that a human derived product will not transmit hepatitis or HTLV-III virus. The user is therefore cautioned to handle reagents as if being capable of transmitting these diseases.

**Specimen Collection and Preservation**
Use only serum specimens, plasma samples are not suitable for the test. Serum samples can be stored for 24 hrs at 2 – 8°C, for longer storage it is recommended to store the samples at -20°C.

**Results and Interpretation**
- **Negative result:** No agglutination of the latex particles suspension within two minutes.
- **Positive result:** An agglutination of the latex particles suspension will occur within two minutes, indicating a RF level of more than 10 IU/ml.

**Semi-Quantitative Test**
1. Serum to be titrated is serially diluted (1:2, 1:4, 1:8 etc) in 0.9 g/L saline solution.
2. Place one drop (50 μl) of the positive control and 50 μl of the patient serum into separate circles on the glass slide.
3. Shake the RF latex reagent gently and add one drop (45 μl) on each circle next to the sample to be tested and control.
4. Mix well using disposable stirrer spreading the mixture over the whole test area and tilt the slide gently. Agitate for about 2 minutes with rotator or by hand and observe for the presence or absence of agglutination.

**Expected Value**
Not clearly specified. However, it has been found that the existence of significantly high titre (more than 30 IU/ml) are present in more than 70 % of patients with rheumatoid arthritis.

**Performance characteristics**
1. **Prozone effect:** No detected prozone effect up to 1500 IU/ml
2. **Analytical Sensitivity:** 10 IU/ml
3. **Diagnostic Sensitivity:** 100 %
4. **Diagnostic Specificity:** 99 %
The diagnostic sensitivity and specificity were obtained by comparing 150 samples with one commercial kit.

**Interferences**
Lipids (10g/L), hemoglobin (10g/L) and Bilirubin (20mg/dL) do not interfere.
Limitations of the Procedure

Occasional agglutinations observed after 4 minutes have no diagnostic significance. Highly haemolyzed and lipemic serum as well as plasma interfere with the test.

References


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