RHEUMATOID FACTOR (RF)
Turbo Latex

REF: 561 001 100 test
R1 Buffer 2 x 20 ml
R2 Latex 1 x 10 ml

Intended Use
In vitro diagnostic reagents for the quantitative determination of Rheumatoid Factor (RF) in human serum by means of particle-enhanced turbidimetric immunoassay.

Background
The most consistent serological feature of rheumatoid arthritis is the increased concentration of autoantibodies directed against antigenic sites in the Fc region of human and animal IgG namely rheumatoid factors (RFs) in the blood and joint fluid. The potential role of these factors in the pathogenesis of this disease has been studied extensively, with the finding that both environmental and genetic factors affect production of RF. RF determinations are clinically important for the diagnosis, prognosis, and assessment of therapeutic efficacy of rheumatoid arthritis. Although RFs may be found in all immunoglobulin classes, the RF most frequently detected in the laboratory is IgM type, present in about 75 - 80 % of adult patients with rheumatoid arthritis but in about 10 % of children with juvenile rheumatoid arthritis.

Test Principle
This RF test is based upon the reactions between IgM-anti-IgG (RF) in patient’s sample and latex-covalently bound human IgG. RF values are determined photometrically.

Reagents
Buffer
Phosphate buffer (0.05 M) pH: 8.0 containing NaCl (0.15M), detergent and polyethylene glycol.
Preservative: sodium azide < 1g/L

Latex reagent
A suspension of latex micro particles covalently bound human IgG in a glycine buffer (0.1 M, pH: 8.2), containing NaCL (0.15 M) and bovine serum albumin (0.5%).
Preservative: Sodium azide 0.075 %

Calibrator
Human - based reference fluid. Preservative: sodium azide, 0.075 %.
All raw materials of human origin used in the manufacture of this product showed no reactivity when tested for HBsAg, anti-HIV-1/2 and HCV with commercially available test methods. However, this product should be handled as though transmitting infectious diseases.

preparation
RF Calibrator: Reconstitute with 2 ml of distilled water: Mix gently and bring to room temperature for about 10 minutes before use

Calibration Curve:
Prepare the following RF Calibrator dilutions in NaCl 9 g/L Multiply the concentration of the RF Calibrator by the corresponding factor stated in the table below to obtain the RF concentration of each dilution.

<table>
<thead>
<tr>
<th>Calibrator dilution</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calibrator RF</td>
<td>---</td>
<td>25</td>
<td>50</td>
<td>100</td>
<td>200</td>
<td>400</td>
</tr>
<tr>
<td>NaCl 9 g/L</td>
<td>400</td>
<td>375</td>
<td>350</td>
<td>300</td>
<td>200</td>
<td>---</td>
</tr>
<tr>
<td>Factor</td>
<td>0</td>
<td>0.0625</td>
<td>0.125</td>
<td>0.25</td>
<td>0.5</td>
<td>1</td>
</tr>
<tr>
<td>Concentration (IU/ml) (for example: the undiluted C = 200 IU/ml)</td>
<td>0</td>
<td>12.5</td>
<td>25</td>
<td>50</td>
<td>100</td>
<td>200</td>
</tr>
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</table>

Storage and Stability
All the components of the kit are stable until the expiration date on the label when stored tightly closed at (2 - 8 °C) and contaminations prevented during their use. Do not use reagents over the expiration date.

Reagent deterioration: presence of particles and turbidity
Reconstituted calibrator: stable for 1 month at 2 - 8 °C or 3 months at 20 °C

Do not freeze; frozen Latex or Diluent could change the functionality of the test.

Samples
Fresh serum or plasma. Stable 7 days at 2 - 8 °C or 3 months at 20 °C the samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or icteric samples.

Procedure
1 - Bring the reagents and the photometer to 37°C
2 - Assay conditions:
Wavelength: 650 nm (600 - 650 nm)
Temperature: 37°C
Cuvette: 1cm light path
3 - Adjust the instrument to zero with distilled water.
4 - Pipette into a cuvette:

| Diluent (ml) | 0.4 |
| Latex (ml) | 0.1 |

5 - Mix and read the absorbance (blank reagent)
6 - add the sample / Calibrator

<table>
<thead>
<tr>
<th>Blank</th>
<th>Sample / Calibrator</th>
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<tbody>
<tr>
<td>NaCl 9 g/L</td>
<td>4 μl</td>
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<tr>
<td>Sample / Calibrator</td>
<td>--</td>
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</table>

7 - Mix and read the absorbance after 2 minutes (A2) of the sample addition.

Calculation
Calculate the absorbance difference (A2-A blank) of each point of the calibrator dilution and plot the values obtained against the RF concentration of each calibrator dilution. Rheumatoid factor concentration in the sample is calculated by interpolation of its (A2-A blank) in the calibration curve.

Quality Control
Control sera are recommended to monitor the performance of manual and automated assay procedures. Each laboratory should establish its own Quality Control Scheme and corrective actions if controls do not meet the acceptable tolerances.

Expected Values
Up to 20 IU/mL. Each laboratory should establish its own reference range.
Senstivity
6 IU/mL

Linearity
160 IU/mL specimens showing higher concentration should be diluted 1+4 using physiological saline and repeat the assay (result×5).

Interferences
Hemoglobin (10 g/L), bilirubin (20 mg/dL) and lipemia (10 g/L) do not interfere. Other substances may interfere.

References


Passing H. Bablok W. A new biometrical procedure for testing the equality of measurements from two analytical methods.


Sonderdruck aus DG Klinische Chemie Mitteilungen 1995; 26: 207 – 224

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