Rheumatoid Factor (RF) Quantitative immunoturbidimetric test on ASL(O)

<table>
<thead>
<tr>
<th>Cat.No</th>
<th>Package Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF1355103</td>
<td>5 x 25 mL R1(Buffer) / 1 x 10 mL R2 (Antiserum)</td>
</tr>
</tbody>
</table>

Diagnostic Implications
Diagnosis of rheumatoid arthritis (RA) is based largely on clinical examination, but laboratory tests (e.g. RF Test) do support the clinical diagnosis.
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: About 90% of patients with RA have RF titers of more than 40 IU/mL.

Method
Photometric measurement of an immunoturbidimetric antigen-antibody endpoint reaction

Reagents
R1 (Buffer)
Phosphate buffered saline (pH 7.43)
Sodium azide (0.95 g/L)

R2 (Antiserum)
Glycine buffer (pH 8.2)
Heat-aggregated human IgG (variable)
Sodium azide (0.95 g/L)

Preparation and Stability
Reagent Preparation
Liquid reagents, ready for use

Stability and Storage
The reagents are stable until expiry date when kept at 2-8°C.
On board stability is at least 4 weeks if contamination is avoided.
Do not freeze!

Reagents required but not supplied
1. 0.9 g % sodium chloride
2. Calibrators (“Cal”) and Controls (“Con”)

Warnings and precautions
Reagents contain Sodiumazide (0.95 g/l) as conservative. Do not swallow! Do not touch skin and / or mucous membranes!

Samples
Use fresh serum.
If the test cannot 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.

Assay Procedure
Wavelength 340 nm
Cuvette 1 cm lightpath
Temperature 37°C
Measure Against Reagent Blank (RB)

<table>
<thead>
<tr>
<th>Sample / Cal/Contr</th>
<th>Reagent-Blank</th>
<th>Sample/Cal/Contr</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1</td>
<td>100 µl</td>
<td>1000 µl</td>
</tr>
<tr>
<td>R2</td>
<td>200 µl</td>
<td>200 µl</td>
</tr>
<tr>
<td>Mix, incubate for 3 min , read absorbance A1, then add :</td>
<td>Mix, incubate for 5 min , read absorbance A2 .</td>
<td></td>
</tr>
</tbody>
</table>

\[ \Delta A = [(A_2 - A_1) \text{ Sample/Cal/Con}] \]

Calculation
The concentration is calculated through a calibration curve using a suitable mathematical procedure e.g. logit/log. The calibration curve is established by 5 calibrators of different concentrations and NaCl-solution (9 g/l) for the determination of zero. Stability of the calibration is at least 4 weeks.

Applications for automated systems are available on request

Calibration /Controls
For the calibration of automated photometric systems we recommend Inmesco RF calibrators. These values are traceable on the WHO-reference material.
For internal QC use Inmesco RF- or Protein-controls.

Reference Values
Normal: 0 - 20 IU/mL (WHO)

(This range is given for orientation only. Each laboratory should establish its own reference values)
Performance Data

- **Range / Linearity**
The test can measure RF-concentrations up to the concentration of 500 IU/mL.
At higher concentrations dilute the samples 1+1 with NaCl-solution (9 g/l). Multiply result by 2.
- **Hookeffect**
Not observed.
- **Specificity / Interferences**
Inmesco RF is specific on human RF.
There is no interference with ascorbic acid up to 50 mg/dl, bilirubine up to 30 mg/dl, hemoglobin up to 500 mg/dl, lipämia up to 1000 mg/dl triglycerides.
No interference from anticoagulants in the normal concentrations.
- **Sensitivity / Detection Limit**
Low detection limit = 2.5 IU/mL

- **Precision (n = 20)**

<table>
<thead>
<tr>
<th>Intra run</th>
<th>mean (IU/mL)</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>low</td>
<td>11.3</td>
</tr>
<tr>
<td>Sample 2</td>
<td>medium</td>
<td>3.39</td>
</tr>
<tr>
<td>Sample 3</td>
<td>high</td>
<td>3.69</td>
</tr>
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</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>low</td>
<td>9.51</td>
</tr>
<tr>
<td>Sample 2</td>
<td>medium</td>
<td>3.48</td>
</tr>
<tr>
<td>Sample 3</td>
<td>high</td>
<td>4.66</td>
</tr>
</tbody>
</table>

- **Correlation**
A comparative study has been performed between the Inmesco method and another commercial reagent on 20 human serum samples. The parameters of linear regression are as follows:

\[ y = 0.603x + 32.5 \text{ IU/mL} \quad ; \quad r = 0.878 \]

**Literature**

**SYMBOLS USED**

- IVD
  - For in vitro diagnostic medical use
- LOT
  - Batch Code
- Use by
  - Temperature limitation