Qualitative and semiquantitative determination of rheumatoid factor by agglutination to latex

TEST SUMMARY
Rheumatoid factors, contained in the serum, produce agglutination of latex particles coated with IgG.

SAMPLES
Fresh serum. Stability 7 days at 2-8°C. For longer periods of time it is recommended to freeze samples at -20°C. Frozen samples may be totally unrefrozen and stored at room temperature before using. Samples in which turbidity is observed must be cleared by centrifugation before being analysed.

REAGENTS

- Latex
  - Latex particles coated with IgG; conservative and stabilizer.

- Positive control
  - Human base stabilized solution of rheumatoid factors with a titre that gives a clear agglutination.

- Negative control
  - Proteic solution not reactive with latex.

All reagents contain 0.095% of sodium azide.

REAGENTS PREPARATION AND STORAGE
Reagents are ready for the use.

The latex suspension must be resuspended with much care. When the suspension becomes homogeneous by sweet inversion, it is necessary to fill and to empty the dosage’s pipette many times.

Stability: the components of this kit will remain stable until expiration date stated on the label, when stored at 2-8°C. Do not freeze.

MATERIAL REQUIRED BUT NOT SUPPLIED
Physiologic solution.

COD. AK00210 Slide and disposable stirrers.

PRECAUTIONS
Reagent may contain not reactive and conservative components. It is opportune to avoid contacts with the skin and do not swallow.

Perform the test according to the general “Good Laboratory Practice” (GLP) guidelines.

QUALITATIVE PROCEDURE

<table>
<thead>
<tr>
<th>Reagents</th>
<th>Sample</th>
<th>Positive control</th>
<th>Negative control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample +</td>
<td>50 µl (1 gt)</td>
<td>50 µl (1 gt)</td>
<td>..</td>
</tr>
<tr>
<td>Control -</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Latex</td>
<td>50 µl (1 gt)</td>
<td>50 µl (1 gt)</td>
<td>50 µl (1 gt)</td>
</tr>
</tbody>
</table>

Mix using disposable stirrers and spreading homogeneously the mixture on the slide, then, shake slide for 2 minutes by a sweet rotating motion or by a stirrer at 100 r.p.m., and observe eventual agglutination using artificial light.

RESULTS INTERPRETATION

POSITIVE: A clear agglutination within 2 minutes.
NEGATIVE: No agglutination within 2 minutes.
In case of positivity it is opportune to titre semi quantitatively the serum.

SEMIOQUANTITATIVE PROCEDURE
Prearrange serial dilution of the serum, pipetting in six slide areas, 50 µl of physiologic solution and 50 µl of sample in the first area. Using the same pipette (inspiring and discharging many times) mix carefully contents of first area and transfer 50 µl in the following area etc. Discharge 50 µl from last area. Dispense latex suspension, shake, and after 3 minutes observe agglutination. The titre is given by last clear agglutination. Procedure is summarized in the scheme below.

WASTE DISPOSAL
Product is intended for professional laboratories. Waste products must be handled as per relevant security cards and local regulations.

PACKAGING

- CODE AK00210 (100 TESTS)
  - Latex 1 x 5 ml
- CODE AK00211 (100 TESTS)
  - Latex 1 x 5 ml
  - Positive control 1 x 0.5 ml
  - Negative control 1 x 0.5 ml
  - Slide black spot 3
  - Stirrers 50

- CODE AK00235 (RF Controls)
  - Positive control 1 x 0.5 ml
  - Negative control 1 x 0.5 ml

REFERENCES


MANUFACTURER
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SYMBOLS

IVD Only for IVD use
LOT Lot of manufacturing
REF Code number

Storage temperature interval
Expiration date
Warning, read enclosed documents
Read the directions
Biological risk

Mod. 01.06 (ver. 3.4 - 05/12/2005)