**Rheumatoid factor FS**

**Diagnostic reagent for quantitative in vitro determination of rheumatoid factor (RF) in serum or plasma on photometric systems**

### Order Information

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Kit size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 7022 99 10 021</td>
<td>R1 5 x 25 mL + R2 1 x 25 mL</td>
</tr>
<tr>
<td>1 7022 99 10 930</td>
<td>R1 4 x 20 mL + R2 2 x 8 mL</td>
</tr>
<tr>
<td>1 7022 99 10 935</td>
<td>R1 2 x 20 mL + R2 1 x 8 mL</td>
</tr>
<tr>
<td>1 7022 99 90 309</td>
<td>R1 4 x 20 mL + R2 2 x 8 mL</td>
</tr>
<tr>
<td>1 7020 99 10 059</td>
<td>5 x 1 mL TruCal RF: Calibrator set with 5 different levels</td>
</tr>
</tbody>
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### Summary [1-4]

Rheumatoid factors (RF) are a group of autoantibodies belonging to all immunoglobulin classes directed against the Fc fragment of altered or complexed IgG. Diagnostic tests for RF determination identify mainly RF of the IgM class which are detectable in several rheumatic diseases, mainly of inflammatory origin. RF occur in approx. 70 – 80% of patients with rheumatoid arthritis (RA), but they are not specific for RA as elevated concentrations are also observed in various non-rheumatic diseases and in approx. 10% of the elderly population without clinical symptoms of RA [3]. The presence or absence of rheumatoid factors represents a valuable tool in the differential diagnosis of rheumatic diseases. Additionally, high RF concentrations in RA are often associated with a more progressive clinical course of the disease. However, a positive RF value has to be confirmed by clinical and other laboratory findings.

### Method

**Immunoturbidimetric test**

### Principle

Determination of the concentration of RF by means of photometric measurement of antigen-antibody-reaction among heat aggregated IgG and rheumatoid factors present in the sample.

### Reagents

**Components and Concentrations**

<table>
<thead>
<tr>
<th>R1:</th>
<th>Phosphate buffer pH 7.4 50 mmol/L</th>
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<tbody>
<tr>
<td>R2:</td>
<td>Heat aggregated human IgG ≤ 0.4 mg/mL</td>
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</table>

### Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8 °C and contamination is avoided. Do not freeze the reagents and keep them protected from light!

### Calculation

The concentration of RF in unknown samples is derived from a calibration curve using an appropriate mathematical model such as logit/log. The calibration curve is obtained with 5 calibrators at different levels and NaCl solution (9 g/L) for determination of the zero value.

Stability of calibration: 3 weeks

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* fluid stable
Calibrators and Controls
For the calibration of automated photometric systems, DiaSys TruCal RF calibrator set is recommended. The assigned values of the calibrators have been made traceable to the WHO reference material NIBSC W 1066. DiaSys TruLab Protein control should be assayed for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

<table>
<thead>
<tr>
<th>Cat. No.</th>
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</thead>
<tbody>
<tr>
<td>TruLab Protein 1</td>
<td>5 9500 99 10 046 3 x 1 mL</td>
</tr>
<tr>
<td>TruLab Protein 2</td>
<td>5 9510 99 10 046 3 x 1 mL</td>
</tr>
</tbody>
</table>

Performance Characteristics
Measuring Range
The test has been developed to determine concentrations of RF within a measuring range from 10 - 500 IU/mL, at least up to the concentration of the highest calibrator. When values exceed this range, samples should be diluted 1 + 2 with NaCl solution (9 g/L) and the result multiplied by 3.

Prozone Limit
No prozone effect was observed up to RF values of 3000 IU/mL.

Specificity/Interferences
No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 40 mg/dL, hemoglobin up to 500 mg/dL and lipemia up to 2000 mg/dL triglycerides. For further information on interfering substances refer to Young DS [6].

Sensitivity/Limit of Detection
The limit of detection (the minimum concentration which can be measured and distinguished from zero) is 2 IU/mL.

Method Comparison
A comparison of DiaSys Rheumatoid factor FS (y) with a commercially available immunoturbidimetric assay (x) using 73 samples gave following results:

\[ y = 1.057 x + 8.846 \text{ IU/mL}; \ r = 0.968. \]

A comparison of DiaSys Rheumatoid factor FS (y) with a commercially available nephelometric assay (x) using 47 samples gave following results:

\[ y = 0.945 x + 17.852 \text{ IU/mL}; \ r = 0.943. \]

Reference Range
In a healthy population the RF values are usually expected to be < 15 IU/mL (95th percentile). In a study, a cut-off value of 19 IU/mL was defined for optimum sensitivity (82.4%) and specificity (95.9%) for rheumatoid arthritis [7]. Each laboratory should define its own reference range for the relevant population to take into account all affecting factors.

Literature

Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany