**RHEUMATOID FACTOR (RF)**

**REF:** 546 001   **100 test**

**R1 Buffer :**  25 ml

**R2 Latex :**  5 ml

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**Intended Use**

In vitro diagnostic reagents for the quantitative determination of Rheumatoid Factor (RF) in human serum by immunoturbidimetric procedure.

**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) and latex-covalently bound human IgG. RF values are determined turbidimetrically using fixed-time measurement with sample blank correction. The relationship between absorbance and concentration permits a multipoint calibration with a measuring range between 0 and 140 IU/ml. The measuring temperature is 37ºC. The assay can be performed on all instruments allowing turbidimetric measurements at 500 to 600 nm.

**Reagents**

**Buffer**

Phosphate buffer pH 7.0. Containing NaCl, detergent and PEG. Preservative : sodium azide < 0.1 %.

**Latex reagent**

Suspension of latex microparticles covalently bound human IgG in a glycine buffer, containing NaCl and bovine serum albumin. Preservative: Sodium azide < 0.1 %

**Precautions and Warnings**

For in vitro diagnostic use only. Do not pipette by mouth. Reagents containing sodium azide must be handled with precaution. Sodium azide can form explosive azides with lead and copper plumbing. Since absence of infectious agents cannot be proven, all specimens and reagents obtained from human blood should always be handled with precaution using established good laboratory practices.

Disposal of all waste material should be in accordance with local guidelines.

As with other diagnostic tests, results should be interpreted considering all other test results and the clinical situation of the patient.

**Material Required**


**Storage and Stability**

The RF reagents should be stored tightly capped at (2 - 8 ºC) when not in use. Do not freeze. Reagents in the original vials are stable to the expiration date on the vial label when capped and stored at (2 - 8 ºC). Immediately following the completion of an assay run, the reagent vials should be capped until next use in order to maximize curve stability. Once opened the reagent can be used within 1 month if stored tightly closed at +2...+8º C after use.

The RF buffer reagent should be clear and colourless. Any turbidity may be a sign of deterioration and reagent should be discarded. The RF latex reagent should have a white, turbid appearance free of granular particulate. Visible agglutination or precipitation may be a sign of deterioration, and the reagent should be discarded.

**Specimen Collection and Preparation**

Serum specimens should be collected by venipuncture following good laboratory practices. RF remain stable for 72 hours at (2 - 8 ºC). If the test should be performed later, it is recommended to freeze the serum. Heavily lipemic specimens, or turbid frozen specimens after thawing, must be clarified before the assay with a delipidating agent or by a high-speed centrifugation. Delipidation of samples do not affect the results of RF in serum samples. The cleared patient serum sample must be used on the same day, as turbidity may reoccur. Heatactivation of the sera is not necessary since C1q complement factor do not interfere in the assay.

**System Parameter**

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<tr>
<th>Parameter</th>
<th>Value</th>
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<tbody>
<tr>
<td>Wavelength</td>
<td>600 nm</td>
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<tr>
<td>Optical path</td>
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<tr>
<td>Assay type</td>
<td>Turbidimetric</td>
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<tr>
<td>Temperature</td>
<td>37 ºC</td>
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<tr>
<td>Incubation time</td>
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**Procedure**

The reagents are ready to use as supplied. Latex reagent should be gently shaken (invert the recipient 3-4 times) before each use.

Volume R1/Buffer reagent: 250 µl

Volume R2/Latex reagent: 40 µl

Volume sample: 3 µl

**Step 1:** mix R1 and R2, add sample and read 1st reading immediately after mixing.

**Step 2:** after 6 min read 2nd reading.

**Note:** Volume, time and wavelength are recommended. Adjust them depending of analyser features.

This reagent is intended to be used in clinical chemistry analysers. Adaptations for some of them are available.

**Calibration and Quality Control**

Standardization: use Spectrum Calibrator or other suitable calibrator material. The method was standardized against international reference preparation (WHO 1970).

For quality control use Spectrum Control or other suitable control material.
**Calculation**

The turbidimetric analysers automatically calculate the RF concentration of each sample.

**Expected Values**

Values <20 UI/ml are within the normal range. This data has to be interpreted as a guide. Each laboratory should establish its own reference intervals.

**References**


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

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