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RHEUMATOID FACTOR (RF)

REF: L-9540T
B-9440T

Product for In Vitro Diagnostic. The product should be used for the quantitative determination of Rheumatiod Factor (RF) in human serum by the immunoturbidimetric procedure.

Diagnostic Relevance

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.

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 microparticules covalently bound human IgG in a glycin buffer, containing NaCL and bovine serum albumin. Preservative: Sodium azide < 0.1 %

Precautions

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.

Materials required

Automatic analyzer. Saline solution. Calibrator. Controls.

Storage and Stability

The RF reagents should be stored tightly capped at +2..+8ºC 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...+8ºC. 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...+8ºC after use. The RF buffer reagent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarted.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 discarted.

Specimens

Serum specimens should be collected by venipuncture following good laboratory practices. RF remain stable for 72 hours at +2...+8ºC. 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. Heat-inactivation of the sera is not necessary since C1q complement factor do not interfere in the assay.

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/working reagent:	Volume R2/start reagent:	Volume sample:
250 µl	40 µl	3 µl
Step 1: mix R1 and R2, add sample and read 1st reading immediately after mixing.		
Step 2: 6 min after read 2nd reading.		
Wavelength: 600 nm	Incubation Time at 37º C:6 min	

** 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. Quality Control

Standardization: use Biolatex Calibrator or other suitable calibrator material. The method was standardized against the International Reference Preparation (WHO 1970).

For quality control use Biolatex Control or other suitable control material. The control intervals and limits must be adapted to the individual laboratory requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits. Control must be assayed and evaluated as for patient samples.

Calculation

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

Reference 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.

Automatic Analyzer

This product is performed for use it in turbidimetric automatic analysers or in manual procedures.

Specific Performance Characteristics*

As is well known, the analytical characteristics of a clinical chemistry reagent depend on both the reagents and the instrument used. Multicenter studies indicate important differences in analytical characteristics among similar instruments. Therefore, this data must be calculated by each instrument.

(*) Analytical characteristics obtained in a single experiment in a Cobas-Mira plus analyser could be provided under demand.

Literature

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Significados de los símbolos indicados en las etiquetas. Explanation of symbols used on labelling. Explication des symbols figurant sur les etiquettes. Spiegazione dei simboli utilizzati sull'eticheta. Significado dos símbolos indicados nas etiquetas. Erläuterung der symbole auf den etiketten.

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