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RHEUMATOID FACTOR (RF)

REF: K-9540M

MONOREAGENT PROCEDURE

In vitro diagnostic reagents for the quantitative determination of Rheumatoid Factor (RF) in serum by means of particle-enhanced turbidimetric immunoassay.

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) in patient's sample and latex-covalently bound human IgG. RF values are determined photometrically.

Reagents

Each RF kit contains :

A.- Buffer - 45 mL of Phosphate buffer (0,05 M) pH: 7,0 containing NaCl (0,15 M), detergent and polyethyleneglycol.

Preservative : sodium azide < 1g/L

B.- Latex reagent – 7,5 mL of a suspension of latex microparticules covalently bound human IgG in a glycin buffer (0,1 M, pH: 8,2), containing NaCL (0,15 M) and bovine serum albumin (0,5%).

Preservative: Sodium azide 0,075%

C.- Buffer Dil – 15 ml of buffer TRIS, pH: 7.0. Preservative : sodium azide < 1g/L

D.- Calibrator – 1 ml. Human - based reference fluid. Preservative: sodium azide, 0.075 %. All raw materials of human origin used in the manufacture of this product showed no reactivity when tested for HBsAg, anti-HIV-1/2 and HCV with commercially available test methods. However, this product should be handled as though capable of transmitting infectious diseases

Reagent Preparation

Working Reagent is prepared with 1 part of Latex Reagent and 6 parts of Buffer Reagent. Prepare a fresh WR based on its workload. (shake gently the reagents before pipetting).

It is recommended that each Laboratory prepares a fresh Working Reagent based on its workload.

Calibration Curve and Controls

Analytical Range up to 140 IU/mL.

Calibrator 1	100 µl of Biolatex RF Calibrator*
Calibrator 2	100 µl of Calibrator 1 + 100 µl of Buffer Dil
Calibrator 3	100 µl of Calibrator 2 + 100 µl of Buffer Dil
Calibrator 4	100 µl of Calibrator 3 + 100 µl of Buffer Dil
Calibrator 5	100 µl of Buffer Dil

(*) See values on the label or on the insert. Multiply by the appropriate factor.

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.

Storage and Stability

Reagents in the original vial is 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 vial 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. Do not freeze reagents.

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.

The RF buffer reagent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarted.

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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

Spectrophotometric analyser. Controls.

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

Wavelength		600 nm	
Temperature		37ºC	
Cuvette		1cm light path	
Measurement against distilled water blank.			
Bring the reagents at 37ºC and pipette:			
	Calibrator	Sample	Blank
Calibrator	13 µl	---	---
Sample	---	13 µl	---
Distilled Water	---	---	13 µl
Work. Reagent	500 µl	500 µl	500 µl
Mix and measure absorbance immediately (A1) incubate 2 min (37ºC), after incubation read absorbance (A2).			

Calculation

Plot the calibration curve and the sample concentration is obtained by interpolation the sample absorbance (A2-A1) in the calibration curve.

If is an one point calibration:

$$\frac{(A2-A1)_{sample} - (A2-A1)_{blank}}{(A2-A1)_{calibrator} - (A2-A1)_{blank}} x CalibratorConcentration$$

Reference Values

Values <20 IU/ml are within the normal range.

This data has to be interpreted as a guide. Each laboratory should establish its own reference intervals.

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, the data must be calculated by each instrument.

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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