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RBP (Retinol-Binding Protein)

REF: L-9515T B-9415T

For the quantitative determination of Retinol-Binding Protein (RBP) in human serum by immunoturbidimetry.

Diagnostic Relevance

Retinol-binding protein (RBP) is a protein of low relative molecular mass (Mr 21200) synthesized in the liver, isolated from plasma and urine of normal subjects. Its urinary excretion, like that β 2-microglobulin, may be a sensitive index for use in screening for tubular proteinuria; however, it is more stable than β 2-microglobulin at normal urinary pH.

RBP is the transport protein for retinol (vitamin A). The serum and plasma concentrations reflects the synthesis capacity of the liver and is markedly disminished in malnutrition and other conditions.

Due to its short half live of approximately twelve hours may be suitable for monitoring the nutritional status and efficacy of parenteral nutrition.

Principle

This RBP test is based upon the reactions RBP and latex-covalently bound between antibodies against human RBP. RBP 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 80 mg/L. The measuring temperature is 37°C. The assay can be performed on all instruments allowing turbidimetric measurements at 500 to 600 nm.

Reagents

Buffer - TRIS buffer, pH: 7,2. Containing PEG and < 0,1 % sodium azide as preservative..

Latex reagent – Polystyrene particles (0.5%) coated with antibodies anti-human-RBP in a glycine buffer (0.1 M, pH: 8.2), containing NaCL (0.15 M) and bovine serum albumin (0.5%). 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

Reagents are ready to use. Shake the latex reagent gently before dispensing its content into the appropriate plastic vials. Reagents in the original bottle are stable to the expiration date indicated on the label when capped and stored at $+2...+8^{\circ}C$. Do not freeze.

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

The RBP 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

Fresh (stored for no more than seven days at +2 to +8°C) or stored frozen samples of human serum. Samples can be stored at below -20°C for up to three months if they are frozen within 24 hours after collectioin and if repeated freeze-thaw cycles are avoided. Serum samples must be completely coagulated and, after centrifugation, must not contain any particles or traces of fibrin. Lipemic samples or frozen samples that are turbid after thawing, must be clarified by centrifigation (10 minutes at approximately 15000 x g) prior to testing.

Procedure

The reagents are ready to use as supplied. Latex reagent should be gently shaken (invert the recipient 3-4 times) before each use. Follow the instructions of the operator's manual to load the cartridge, technique programation, calibration, sample measurement and control

Volume R1/working reagent:	Volume reagent:	R2/start	Volume sample:						
250 μl	50	μl	2 µl						
Step 1: mix R1 and R2, add sample and read 1st reading immediately after mixing.									
Step 2: 5 min after read 2nd reading.									
Wavelength: 550 nm Incubation Time at 37° C: 5 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.

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 RBP concentration of each sample. Conversion: $mg/l = \mu g/ml$.

Reference Values

Each laboratory should establish an expected range for the geographical area in which it is located.

Values 30 - 60 mg/L are considered within the normal range.

Automatic Analyzer

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

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 simbolos indicados en las etiquetas. Explanation of symbols used on labelling. Explication des symbols figurant sur les etiquetas. Significado des simbolos indicados nas etiquetas. Explanation of symbols used on labelling. Explication des symbols figurant sur les etiquetas.												
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Date de Péremption	Temperature de Conservation	Número de Lot	Usage In Vitro	Numéro de catalogue	Conformité aux normes européennes	Fabriqué par	Réactif	Calibrateur	Tampon	Lyophilisé	Concentration	Contrôle élevè / Contrôle Bas
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