Retinol Binding Protein Assay Kit (RBP)

Method: Latex Enhanced IT

Cat.NO.	Size	Instrument
GB3360S	R1:1×45ml R2:1×15ml	For Hitachi 7060/7150 & Shimadzu CL7200/8000
GS3361S	R1:1×45ml R2:1×15ml	For Hitachi 7170 & Olympus AU640/400/600
GX3361S	R1:1×45ml R2:1×15ml	For SYNCHRON CX5/7/9/LX20
GT3361S	R1:1×45ml R2:1×15ml	For TOSHIBA

INTENDED USE

For the quantitative in vitro determination of retinol binding protein in serum or urine.

CLINICAL SIGNIFICANCE

Retinol-binding protein is a sensitive index to reflect the nutritional status of the body, especially protein - calorie malnutrition. Visceral protein is a conventional laboratory indicators of protein - energy malnutrition, but retinol-binding protein can make a faster response.

RBP is mainly synthesized in the liver. The change of serum RBP is related with liver disease and is influenced by the emergence of liver disease and severity of the impact. The concentration of RBP is significantly decreased in liver disease, cirrhosis and acute, chronic hepatitis.

RBP can be used as a indicator of the early diagnosis of renal tubular injury. Retinol-binding protein is stable in the urine, not easily broken down, and not disturbed by pH and blood pressure etc. When the renal proximal tubule is injured, urinary displacement increases significantly, so the increasing of RBP in urine can be used as a marker of therenal proximal tubule injury. When kidney filtration function is injured, the concentration of blood RBP increase. So RBP concentration in the blood or urine can be used clinically as an ideal marker of renal function.

ASSAY PRINCIPLE

Latex particles coated polyclonal anti-human RBP antibody reactes with retinol binding protein in the sample.The formation of immune complexes can be detected by changes in the turbidity at 570nm, and the RBP level is proportional to the degree of change in the sample.

REAGENT COMPOSITON

Contents	Concentration of Solutions
Reagent 1 (R1)	
Good's buffer	0.15mmol/L
Reagent 2 (R2)	
latex particles of sensitized RBP antibody	0.4w/v%

SAMPLE COLLECTION AND PREPARATION

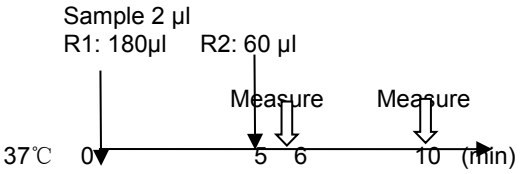
Fresh serum.Please store the sample at -20 °C.
Fresh urine.

STABILITY AND PREPARATION OF REAGENTS

The reagents and the standard are ready to use.
Stable up to the expiry date when stored at 2-8℃,protected from light and contamination is avoided. Do not freeze the reagents.

ASSAY PROCEDURE

Test Procedure for Analyzers (Hitachi7180)
Assay Mode: 2 Point End 19-34
Wave length (sub/main): 570nm



CALIBRATION

We recommend that this assay should be calibrated using Gcell calibrator GC-RBP.

CALCULATION OF RESULTS

RBP (mg/dl) = $\Delta A_{Sample}/\Delta A_{Std}$ x $Conc._{Std}$ (mg/dl)

QUALITY CONTROL

For quality control, use Gcell RBP Control as daily quality control sera and can be purchased separately. Values should fall within a specific range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

REFERENCE RANGE

Serum	male：3.6-7.2 mg/dl (36-72mg/L)
	female：2.2-5.3 mg/dl (22-53mg/L)
Urine	0-0.7mg/L

It is recommended that each laboratory should assign its own normal range as this is dependent upon geographical location.

PERFORMANCE CHARACTERISTICS

LINEARITY

The assay is linear up to 190 mg/L.
Above this concentration, dilute the sample with NaCl solution (0.9% sodium chloride in water) and repeat the assay.

PRECISION

The CV of the test should be ≤10%.

Intar assay precision		
N=20	level 1	level 2
Mean(mg/L)	52.19	88.77
SD	0.65	1.38

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CE version 2014

CV(%)	1.25	1.56

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(mg/L)	37.42	37.99	37.90
$\bar{x}$	37.77		
(Xmax-Xmin)/$\bar{x}$	(37.99-37.42)/37.77*100=1.53%		

INTERFERENCE

The following analytes were tested up to levels indicated ang found not to interfere:

Bilirubin: up to 20mg/dl
Intralipid: up to 5000mg/dl
Hemoglobin: up to 500mg/dl

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

1. Kanai M. et al: J Clin Invest,47,2025-2044 (1968).
2. Kanai M. et al: Nippon Rinsho 57.279-281 (1999).

INDEX OF SYMBOLS

	Manufacture
	Catalogue Number
	Lot number
	Date of manufacture
	Use by(Expiration date)
	For In-Vitro Diagnostic use only
	Stored at 2-8℃
	Attention:See instruction for use
	Authorized Representative in the European Company

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