INSTRUCTION OF RETINOL BINDING PROTEIN
ASSAY KIT BY LATEX ENHANCED IMMUNOTURBIDIMETRY METHOD

[ PRODUCT NAME ]
Retinol Binding Protein (RBP) Assay Kit by Latex Enhanced Immunoturbidimetry Method

[ Packing specifications ]
Basing on the bottle type, product model can be classified into 7170, 7060, 7020, Beckman, Toshiba, Mindray, DuPont, Innova, Siemens, KHB, Abbott, General type, etc.

<table>
<thead>
<tr>
<th>R1</th>
<th>R2</th>
</tr>
</thead>
<tbody>
<tr>
<td>60ml×3</td>
<td>60ml×1</td>
</tr>
<tr>
<td>60ml×1</td>
<td>60ml×1</td>
</tr>
<tr>
<td>90ml×2</td>
<td>60ml×1</td>
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<tr>
<td>50ml×3</td>
<td>50ml×1</td>
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<tr>
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<td>40ml×1</td>
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<tr>
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<tr>
<td>6×64T</td>
<td>6×64T</td>
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<tr>
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<td>12×64T</td>
</tr>
<tr>
<td>4ml×24</td>
<td>2.7ml×12</td>
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</tbody>
</table>

[ Intended Use ]
This product is used to determine RBP concentration in human serum.

[ CLINICAL SIGNIFICANCE ]
Retinol-binding protein is a low molecular weight lipophilic carrier protein. RBP has important clinical significance for early diagnosis and treatment indicated of liver and kidney disease based on its small molecular weight and a short half-life. RBP also can be used as a sensitive marker for early diagnosis of malnutrition because of it can specifically reflect the body’s nutritional status.

[ PRINCIPLE ]
The agglutination reaction occurs between RBP in sample and the corresponding anti-RBP-antibody combined with latex particles when they meet in the liquid buffer. The reaction produced turbidity is proportional to the concentration of RBP in the sample with the presence of an appropriate amount of its corresponding antibodies. At a specific wavelength, RBP concentration in the sample can be calculated by comparing the calibrator result with same processing.

[ COMPOSITION ]
R1 : Detection Reagent 1
Tris buffer 100mmol/L
Polyethylene glycol (PEG), Appropriate Preservatives
R2 : Detection Reagent 2
Phosphate buffer 100mmol/L
Latex particle suspensions, 0.15% Preservatives

[ Storage And Stability ]
Stored for up to 12 months at 2-8°C, protect from light. After opening, the reagent remains stable for 30 days at 2-8°C, protect from light.

[ Applicable Instrument ]
This assay kit is suitable for automatic or semi-automatic biochemical analyzer with 600nm wavelength.

[ Sample Requirements ]
Serum samples. Samples testing should be completed at the same day after collected. Otherwise, the samples should be cryopreserved and avoid repeated freeze-thaw cycles. RBP in the samples remain stable for 7 days at 2-8°C and for 3 months at -20°C.

[ TEST METHOD ]
1. BASIC PARAMETERS
Method: End assay Temperature: 37°C
Primary wavelength: 600nm
Secondary wavelength: none
Calibration method: multi-point calibration
Sample: 3μl R1 : 300μl
R2 : 100μl Response direction: Positive
Reaction Time: 10 min

2. Assay Procedure

<table>
<thead>
<tr>
<th>Blank ( B )</th>
<th>Sample( U )</th>
<th>Calibration ( Ci )</th>
</tr>
</thead>
<tbody>
<tr>
<td>ddH2O(μl)</td>
<td>3</td>
<td>-</td>
</tr>
</tbody>
</table>
Sample(μl) - 3 - 
Calibration (μl) - - 3 
Reagent R1 (μl) 300 300 300 
Mix well, incubate at 37°C for 5 minutes.

Reagent R2(μl) 100 100 100 
Mix and incubate for 30 seconds at 37°C. Take blank well as zero and measure the absorbance value at 600nm after 4.5 minutes. Calculate ΔA = A2 - A1

ASSAY PROCEDURE SUMMARY:
Set Blank well ← Detection → Time : 10 min 
Temperature : 37°C Primary wavelength 600nm ↑ ↑Secondary wavelength none 
R1 : 300μl R2 : 100μl Sample : 3μl

3. CALCULATIONS
Based on multi-point calibrator concentration and the corresponding absorbance change rate ΔA/min, the multi-point non-linear calibration model is used to define the working curve, sample absorbance change rate on the working curve with the corresponding concentration is concentration of sample.

【Reference Range】
25mg/L-70mg/L ;
Recommendations: Each laboratory should establish its own reference range. 

【Interpretation of Test Results】
1. The test results reflect only the status at the sampling time. Clinicians need to be combined with clinical data and other relevant test results to make judgment.
2. There is no significant effect on the test result when the sample contain Ascorbic acid ≤ 0.5g/L; Bilirubin ≤ 0.5g/L; Hemoglobin ≤ 5.0g/L; Triglycerides ≤ 10g/L.

【LIMITATIONS OF THE TEST】
Dilute with physiological saline and multiply the result by the dilution factor when the the concentration of RBP is over 110mg/L.

【PERFORMANCE】
1. DETECTION RANGE : 3mg/L -110mg/L , r≥0.990.
2. PRECISION : Intra-assay CV≤8.0%, Inter-assay CV≤10.0%.

3. ACCURACY : Inaccuracy≤10%.
4. Blank absorbance : 0.200≤the absorbance value≤1.200 at 600nm wavelength and optical path 10mm.

【PRECAUTIONS】
1. For in vitro diagnostic use only.
2. Reagents become cloudy or blank absorbance values> 1.200 or absorbance value <0.200, should be discarded.
3. The reagent and sample amount can be changed with same ratio according to needs.
4. The test equipment must be clean to avoid contamination.
5. Reagents and components of different batches are not interchangeable.
6. The waste solution generated by the test and decomposition difficulty packaging materials should be collected and sent to local waste treatment station.

【MANUFACTURER】
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[Product standards] 
YZB / E 1072-2014 
[Specification approval date] 
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