INSTRUCTION OF PREALBUMIN
ASSAY KIT BY IMMUNOTURBIDIMETRY METHOD

[ PRODUCT NAME ]
Prealbumin (PA) Assay Kit by Immunoturbidimetry Method

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

[ Sample Requirements ]
The sample should be fasting serum. Samples testing should be completed at the same day after collected. Otherwise, the samples should be cryopreserved and avoid repeated freeze-thaw cycles. Prealbumin in the samples remain stable for 7 days at 2-8°C or for 3 months at cryopreservation condition.

[ Test Method ]
1. Basic parameters:
   Method: End assay
   Temperature: 37°C
   Primary wavelength: 340nm
   Secondary wavelength: 700nm
   Sample volume: 3μl
   R1: 240μl
   R2: 60μl
   Response direction: Positive
   Reaction time: 10min
   Calibration method: multi-point calibration

2. Assay Procedure:

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<tr>
<th></th>
<th>Blank(B)</th>
<th>Sample(U)</th>
<th>Calibrator(Ci)</th>
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</thead>
<tbody>
<tr>
<td>ddH2O(μl)</td>
<td>3</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sample(μl)</td>
<td>-</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>Ci (μl)</td>
<td>-</td>
<td>-</td>
<td>3</td>
</tr>
<tr>
<td>R1 (μl)</td>
<td>240</td>
<td>240</td>
<td>240</td>
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</tbody>
</table>

Mix well, incubate at 37°C for 5 min. Take blank well as zero and measure the absorbance A1 at 340nm

<table>
<thead>
<tr>
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<th>R2 (μl)</th>
<th>60</th>
<th>60</th>
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</table>

Mix well, 37°C for 5 min. Take blank well as zero and measure the absorbance A2 at 340nm.

ASSAY PROCEDURE SUMMARY
Set blank well
Time: 10min
←Detection→
Temperature: 37°C
Primary wavelength: 340nm
↑↑Secondary wavelength: 700nm
R1: 240μl R2: 60μl
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.

[ INTENDED USE ]
This product is used to determine prealbumin content in human serum.

[ PRINCIPLE ]
The PA in human serum meets the specific antibody (goat anti-human PA) in the liquid buffer, forming antigen-antibody complex, and the turbidity formed is proportional to the PA concentration in the linear range. PA concentration in the sample can be calculated by comparing the calibrator result with same processing.

[ REAGENT COMPOSITION ]
R1:
- Phosphate buffer: 20mmol/L
- PEG appropriate
- Fat-moving agent, Preservatives appropriate
R2:
- Phosphate Buffer: 30mmol/L
- Goat Anti-human PA antibody appropriate
- Preservatives
Calibrator & Control: Optional
Calibrator: 0.5ml×4; Control: 0.5ml×1

[ 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 340nm and 700nm wavelength.
[Reference Range]
Serum sample: 200mg/L-400mg/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 effect on the test result when the sample contain Ascorbic acid ≤ 0.5g/L, Hemoglobin ≤ 5.0g/L, Triglycerides ≤ 20g/L, Bilirubin ≤ 0.5g/L.

[Test Method Limitations]
Dilute with physiological saline and multiply the result by the dilution factor when the concentration of prealbumin is over 800mg/L.

[Product Performance]
1. DETECTION RANGE: 5mg/L-800mg/L, r≥0.99.
2. PRECISION: Intra-assay CV≤5%; Inter-assays≤10%.
3. ACCURACY: Inaccuracy≤10%.
4. BLANK ABSORBANCE: The absorbance values≤0.100 at 340nm wavelength and optical path 10mm.

[Precautions]
1. For in vitro diagnostic use only.
2. The reagent becomes cloudy or blank absorbance value > 0.100, 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.

[References]