**Prealbumin**

**For the Quantitative Determination of Human Prealbumin in Serum**

**Cat. No. KAI-053**

**INTENDED USE**

For the quantitative determination of human prealbumin in serum by immunoturbidimetric assay. For IN VITRO DIAGNOSTIC USE.

**INTRODUCTION AND SUMMARY**

Prealbumin (thyroxin-binding prealbumin) transports thyroid hormones thyroxin (T4) and triiodothyronine (T3). It also transports vitamin A in association with retinol binding globulin.

Prealbumin levels are useful in the evaluation of several clinical conditions. Levels are decreased in most forms of acute and chronic hepatic disease. Prealbumin is a negative acute phase reactant with decreased levels associated with diseases involving inflammation or tissue necrosis.

Prealbumin has a circulation life of less than 2 days and is therefore a sensitive indicator of protein-calorie malnutrition.

Prealbumin has been measured using a variety of methods, including radioimmunocassay (RIA), radial diffusion, nephelometric, and enzyme-linked immunosorbent assay. The K-ASSAY® Prealbumin assay uses an immunoturbidimetric format.

**PRINCIPLE OF TEST**

The K-ASSAY® Prealbumin assay quantifies prealbumin based on immunoturbidimetric assay. The reagent uses a goat polyclonal antibody specific for human prealbumin.

The antibody binds to the prealbumin in the serum forming light scattering immune complexes which increase the turbidity of the sample. Since the increase in turbidity is proportional to the amount of prealbumin in the sample, the prealbumin concentration can be determined by measuring this increase in turbidity. The increase in turbidity is measured at 340 nm.

Prealbumin in the sample is quantitatively determined. The K-ASSAY® Prealbumin can be run using a two reagent clinical chemistry analyzer. Six calibrators are prepared using the K-ASSAY® Prealbumin Calibrator. These calibrators are used for quantifying the levels of prealbumin present in the patient's serum sample.

**ASSAY PROCEDURE**

Measurement of absorbance is to be made with an instrument able to accurately read absorbance at 340 and 700 nm. Refer to the instrument manual from the manufacturer regarding the following:

- **Use or function**
- **Installation procedures and requirements**
- **Principles of operation**
- **Performance characteristics, operating instructions**
- **Calibration procedures including materials and / or equipment**
- **Operational precautions, limitations, and hazards**
- **Service and maintenance information**

**SPECIMEN COLLECTION AND PREPARATION**

It is recommended that specimen collection be carried out in accordance with NCCLS document M29-T2. No method can offer complete assurance that human blood samples will not transmit infection. Therefore, all blood samples should be considered potentially infectious.

Serum is required for this assay. Do not use plasma or patient samples contaminated with heparin. Blood should be collected and the serum collected as soon as possible. Soon after the blood is drawn, it should be allowed to clot, centrifuged, and the serum separated from the clot to a plastic tube (not glass). Samples not tested within 72 hours should be frozen at -20°C. Avoid multiple freeze-thaws.

The instrument and type/number of other assays being performed.

**STORAGE AND HANDLING**

All reagents should be stored refrigerated (2-8°C). Return all reagents to 2-8°C promptly after use. Unopened reagents can be used for up to 18 months from the date of manufacture, as indicated by the expiration date on package and bottle labels.

**REAGENT STABILITY**

Opened reagents can be used for one month if stored at 2-8°C. Discard reagents if they become contaminated. Evidence of cloudiness or particulate material in solution is cause to discard.

**INSTRUMENT**

**ASSAY CODE**

(2 POINT)

WAVELENGTH

STD.(1) Conc. 
STD.(2) Conc. - POS. (*2) - (2) STD.(3) Conc. - POS. (*3) - (3) STD.(4) Conc. - POS. (*4) - (4) STD.(5) Conc. - POS. (*5) - (5) STD.(6) Conc. - POS. (*6) - (6) SD LIMIT (999) DUPLICATE LIMIT (10000)

Sensitivity Limit (0)

ABS. LIMIT (SLOPE) (32000) (INCREASE)

PROZONE LIMIT (-32000) (LOWER)

EXPECTED VALUE (-99999) (99999)

PANIC VALUE (-99999) (99999)

INSTRUMENT FACTOR (1.00)

* 1:6 Input concentration of calibrators

**Note:** Allow all reagents and specimens to warm to room temperature. Mix all reagents gently before using.

An example of automated application (Hitachi 717):

- **Sample**
  - 5 µL

- **R1 (Buffer Reagent)**
  - 250 µL

- **R2 (Antiserum Reagent)**
  - 50 µL

- **Wavelength**
  - 37°C, 5 min.

2-point endpoint, 340/700 nm

**Automated Method (Example)**

Chemistry Parameters for Automatic Analyzer

**INSTRUMENT** Hitachi 717

**TEMPERATURE** 37°C

**TEST** (PALB)

**ASSAY CODE** (2 POINT) : (24) - (50)

**SAMPLE VOLUME** (5) (

**R1 VOLUME** (250) () (NO)

**R2 VOLUME** (50) () (NO)

**WAVELENGTH** (700) (340)

**CALIB. METHOD** (NONLINEAR) (1) (6)

**STD.(1) Conc. POS.** (*1) - (1)

**STD.(2) Conc. POS.** (*2) - (2)

**STD.(3) Conc. POS.** (*3) - (3)

**STD.(4) Conc. POS.** (*4) - (4)

**STD.(5) Conc. POS.** (*5) - (5)

**STD.(6) Conc. POS.** (*6) - (6)

**SD LIMIT** (999)

**DUPLICATE LIMIT** (10000)

**SENSITIVITY LIMIT** (0)

**ABS. LIMIT (SLOPE)** (32000) (INCREASE)

**PROZONE LIMIT** (-32000) (LOWER)

**EXPECTED VALUE** (-99999) (99999)

**PANIC VALUE** (-99999) (99999)

**INSTRUMENT FACTOR** (1.00)
LIMITATIONS OF PROCEDURE

The measurable range for prealbumin is between 0 to 60 mg/dL. Grossly lipemic samples and samples with very high triglyceride concentrations should be diluted 1 part sample with 1 part isotonic saline or filtered to decrease nonspecific light scattering. Multiply results by 2 to compensate for the dilution.

If the prealbumin concentration of a patient sample is greater than the highest calibrator value, dilute 1 part sample with 4 parts isotonic saline and reassay. Multiply results by 5 to compensate for the dilution.

This assay should not be used with plasma samples or with patient samples contaminated with heparin.

PERFORMANCE

Precision

The precision for the K-ASSAY® Prealbumin assay was determined using packaged reagents, pooled human serum, and a Hitachi 717 analyzer.

<table>
<thead>
<tr>
<th>Sample</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>20</td>
<td>11.2</td>
<td>0.145</td>
<td>1.29%</td>
</tr>
<tr>
<td>II</td>
<td>20</td>
<td>24.9</td>
<td>0.289</td>
<td>1.16%</td>
</tr>
<tr>
<td>III</td>
<td>20</td>
<td>57.0</td>
<td>0.767</td>
<td>1.35%</td>
</tr>
</tbody>
</table>

Accuracy / Correlation

A comparison of the K-ASSAY® Prealbumin assay and a similar Prealbumin assay was performed using a Hitachi 717. The test results provided the following data:

\[ y = 0.9164x - 0.332 \]
\[ r = 0.9924 \]
\[ n = 50 \]

\[ x \text{ min} = 5.7 \]
\[ y \text{ min} = 4.2 \]
\[ x \text{ max} = 43.2 \]
\[ y \text{ max} = 38.4 \]
\[ x \text{ mean} = 22.89 \]
\[ y \text{ mean} = 20.64 \]

Linearity

Linearity tests were performed with dilutions of normal human serum spiked with prealbumin. Testing was linear from 0 to 60 mg/dL of prealbumin.

INTERFERENCE

- Bilirubin F and C: No interference up to 20 mg/dL
- Hemoglobin: No interference up to 470 mg/dL
- Lipemia: No interference up to 5%

EXPECTED VALUES

The expected value as reported in the scientific literature is between 16 to 40 mg/dL. Each laboratory should establish its own expected values using this kit.

REFERENCES


LABELING SYMBOLS

LOT Lot Number
REF Reagent
REV Expiration or ‘Use By’ Date
IVD For In Vitro Diagnostic Use
°C Temperature Limitation. Store between 2 and 8 degrees C
H Potential Human Biohazard
CR Manufacturer
PB Consult Package Insert for Instructions for Use
ECREP Authorized Representative in the European Community

EU AUTHORIZED REPRESENTATIVE

Advena Ltd.
Tower Business Centre, 2nd Flr.,
Tower Street, Swatar, BKR 4013 Malta

ORDERING / PRICING / TECHNICAL INFORMATION

KAMIYA BIOMEDICAL COMPANY
12779 Gateway Drive
Seattle, WA 98168 USA
TEL: (206) 575-8068 / (800) 526-4925
FAX: (206) 575-8094