Assay Procedure

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**
- R1 (Buffer Reagent) 250 µL
- R2 (Antiserum Reagent) 50 µL
- Serum 37°C, 5 min.
- Serum 37°C, 5 min.

**2-point endpoint, 340/700 nm**

**Automated Method (Example)**

**Chemistry Parameters for Automatic Analyzer**

**INSTUMENT**

**Hitachi 717**

**TEMPERATURE**

37°C

**TEST (PALB)**

ASSAY CODE

(2 POINT) : (24) - (50)

**SAMPLE VOLUME**

(5) (µL)

**R1 VOLUME**

(250) (µL)

**R2 VOLUME**

(50) (µL)

**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**

(1000)

**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

Parameters for other automated analyzers are available.

**CALIBRATION**

It is recommended that prealbumin levels be determined using a multi-point calibration curve prepared using the K-ASSAY Prealbumin Calibrator. It is recommended that the user determine calibration curve frequency as this depends on the instrument and type/number of other assays being performed. Initially, calibration should be performed each day.

**QUALITY CONTROL**

Normal and abnormal controls of known concentration should be included in each assay performed. These controls should fall within the stated values assigned to the controls. The validity of the assay is in question if the value for the controls generated by the assay/calibration curve does not fall within the stated range. Recalibrate if the value determined for the controls falls outside the stated recovery range.
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.

Precision Assay: Within Run

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

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

\[ x = \text{Similar Prealbumin assay} \]
\[ y = \text{K-ASSAY® Prealbumin assay} \]

<table>
<thead>
<tr>
<th>x min</th>
<th>x max</th>
<th>y min</th>
<th>y max</th>
<th>mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.7</td>
<td>43.2</td>
<td>4.2</td>
<td>38.4</td>
<td>22.89</td>
</tr>
</tbody>
</table>

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 Number
- Expiration or Use By Date
- Catalog Number
- For In Vitro Diagnostic Use
- 2-8°C Temperature Limitation. Store between 2 and 8 degrees C
- Potential Human Biohazard
- Manufacturer
- Consult Package Insert for Instructions for Use
- Authorized Representative in the European Community

EU AUTHORIZED REPRESENTATIVE

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