K-ASSAY®

Alpha-1 AT

For the Quantitative Determination of Human Alpha-1 Anti-Trypsin in Human Serum

Cat. No. KAI-001

INTENDED USE

For the quantitative determination of human alpha-1 anti-trypsin (Alpha-1 AT) in human serum by immunoturbidimetric assay. Alpha-1 anti-trypsin aids in the diagnosis of several conditions including juvenile and adult cirrhosis of the liver. In addition, alpha-1 anti-trypsin deficiency has been associated with pulmonary emphysema. FOR IN VITRO DIAGNOSTIC USE.

INTRODUCTION AND SUMMARY

The K-ASSAY® Alpha-1 AT assay is intended for the quantitative determination of human alpha-1 anti-trypsin by immunoturbidimetric assay. The antiserum used in the kit was produced against purified human alpha-1 anti-trypsin. The K-ASSAY® Alpha-1 AT assay should be run using a two-reagent clinical chemistry autoanalyzer. Six calibrators are provided in the K-ASSAY® Multi-Analyte Calibrator. The calibrators are used to prepare a calibration curve for quantifying the levels of alpha-1 anti-trypsin present in the patient's serum sample.

KIT COMPOSITION

Reagents (Liquid Stable)

R1: Buffer Reagent 3 x 20 mL
Tris(hydroxymethyl)aminomethane (100 mM)

R2: Antiserum Reagent 2 x 10 mL
Anti-human alpha-1 anti-trypsin goat antiserum (75%)

WARNINGS AND PRECAUTIONS

FOR IN VITRO DIAGNOSTIC USE. Rx only.

Not to be used internally in humans or animals. Normal precautions exercised in handling laboratory reagents should be followed.

Do not mix or use reagents from one test kit with those from a different lot number.

Do not use reagents past their expiration date stated on each reagent container label.

Do not pipette by mouth. Avoid ingestion and contact with skin.

Reagents in this kit contain sodium azide as a preservative. Sodium azide may form explosive compounds in metal drain lines. When disposing of reagents through plumbing fixtures, flush with copious amounts of water. For further information, refer to “Decontamination of Laboratory Sink Drains to Remove Azide Salts,” in the Manual Guide-Safety Management No. CDC-22 issued by the Centers for Disease Control, Atlanta, Georgia.

WARNING: This product can expose you to chemicals including thiourea which is known to the State of California to cause cancer/birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov. The R-1 reagent contains 0.009% of thiourea (CAS No. 62-56-6).

REAGENT PREPARATION

The reagents are ready to use. They do not need to be reconstituted.

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 the package and bottle labels.

REAGENT STABILITY

Opened reagents can be used for 1 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

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

a) Use or function
b) Installation procedures and requirements
c) Principles of operation
d) Performance characteristics, operating instructions
e) Calibration procedures including materials and / or equipment to be used
f) Operational precautions, limitations, and hazards
g) Service and maintenance information

SPECIMEN COLLECTION AND PREPARATION

Serum is required for this assay. 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) within 2 hours. Serum should be stored refrigerated (2-8°C) and can be used within 1 week or should be stored frozen for up to 2 months.

Use plastic tubes for storing the sample, do not use glass.

AUTOMATED ANALYZER APPLICATION

Suitable for two-reagent automated analyzers that use a multi-point calibration method.
CALIBRATION

For samples with an alpha-1 anti-trypsin level less than 325 mg/dL, a multi-point calibration curve using the K-ASSAY® Multi-Analyte Calibrator should be used. It is recommended that the user determine calibration frequency as this depends on the instrument and number / type 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’s calibration curve does not fall within the stated range. Recalibrate if the value determined for the controls fall outside the stated recovery range.

LIMITATIONS OF PROCEDURE

The measurable range for alpha-1 anti-trypsin is between 30 - 325 mg/dL. Grossly lipemic samples and samples with very high triglyceride concentrations should be diluted 1 part sample with 4 part isotonic saline or filtered to decrease nonspecific light scattering. Multiply results by 2 to compensate for the dilution.

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

PERFORMANCE

Precision

The precision for the K-ASSAY® Alpha-1 AT assay was determined using packaged reagents, pooled human serum, and a Hitachi 717 analyzer.

Precision Assay: Within Run

<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>136</td>
<td>3.13</td>
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Precision Assay: Between Runs

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<td>355</td>
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Accuracy / Correlation

A comparison of the K-ASSAY® Alpha-1 AT and a Binding Site Alpha-1 AT RID Test Kit was performed using a Hitachi 717. The test results provided the following data:

\[
\begin{align*}
\text{y} &= 0.708x + 12.165 \\
\text{r} &= 0.942 \\
n &= 50 \\
\text{x} &= \text{Binding Site Alpha-1 AT RID} \\
\text{y} &= \text{K-ASSAY® Alpha-1 AT assay}
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<table>
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<tr>
<th>x min</th>
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Assay Range

30 - 325 mg/dL

INTERFERENCE

| Bilirubin C | No interference up to 20 mg/dL |
| Bilirubin F | No interference up to 20 mg/dL |
| Hemoglobin  | No interference up to 500 mg/dL |
| Intralipid  | No interference up to 500 mg/dL |

EXPECTED VALUE

The expected value as reported is between 97 - 161 mg/dL. Each laboratory should establish its own expected values using this kit.

REFERENCES


LABELING SYMBOLS

EC REP Authorized Representative in the European Community

KAMIYA BIOMEDICAL COMPANY

EU AUTHORIZED REPRESENTATIVE

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

ORDERING / PRICING / TECHNICAL INFORMATION

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

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