**Assay Procedure**

**L**

µ

temperature. Mix all reagents gently before using. An example of automated application (Hitachi 717):

↓

37° C, 5 min.

- Opened reagents can be used for one month if stored at 2-8° C.

Cloudiness or particulate material in solution is cause to discard.

**Automated Method (Example)**

**K**

**ASSAY**

**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

**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.
LIMITATIONS OF PROCEDURE
The measurable range for alpha-1 acid glycoprotein is between 10 to 200 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 alpha-1 acid glycoprotein 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.

The absorbance of isotonic saline should be below 0.2 and the absorbance of the 80 mg/dL calibrator should be between 0.05 and 0.30 after allowing for the reagent blank.

PERFORMANCE

Precision
The precision for the K-ASSAY® Alpha-1 AG 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>32.5</td>
<td>0.53</td>
<td>1.6%</td>
</tr>
<tr>
<td>II</td>
<td>20</td>
<td>92.3</td>
<td>0.6</td>
<td>0.7%</td>
</tr>
<tr>
<td>III</td>
<td>20</td>
<td>233.7</td>
<td>2.17</td>
<td>0.9%</td>
</tr>
</tbody>
</table>

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

\[ y = 1.016x + 3.547 \]
\[ r = 0.995 \]
\[ n = 37 \]

x = Binding Site Alpha-1 AG RID
y = K-ASSAY® Alpha-1 AG assay

Assay Range
10-200 mg/dL

INTERFERENCE
Ascorbic Acid: No interference up to 200 mg/dL
Bilirubin: No interference up to 20 mg/dL
Hemoglobin: No interference up to 500 mg/dL
Lipemia: No interference up to 4%

EXPECTED VALUES
The expected value as reported is between 42 to 101 mg/dL. Each laboratory should establish its own expected values using this kit.

REFERENCES

LABELING SYMBOLS

EU AUTHORIZED REPRESENTATIVE

Advena Ltd.
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ORDERING / PRICING / TECHNICAL INFORMATION

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