Determination of the Apolipoprotein B protein, by radial immunodiffusion plate

PROCEDURE

1. Construct a curve that plots the square of the precipitating ring versus the concentrations of the controls. A straight line, with an intercept in the range 10-11 mm, should be obtained. Sample values are determined by interpolation.

2. Construct a curve that plots the square of the precipitating ring versus the logarithm concentration of the controls. The graph will be a straight line only for low values. Sample values are determined by interpolation.

3. Read on enclosed reference table the concentration value corresponding to the precipitating ring diameter. The ring value is obtained from the control serum (that has to be used every time) which should have a confidence limit of 0.2 mm (from the reference table).

NOTE

The diffusion time and the reading time depend on the concentration and the specific diffusion protein. After 72 h the diffusion of the protein at any concentration is completed. For lower concentrations it is possible to read in lower times (i.e. 36 h), however in such cases it is advisable to read again after 3/5 hours. If the diameter is still the same it is possible to set the concentration, on the contrary, if the diameter is different, ring should be remeasured after a further 3/5 hours.

CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:

**IC00300** 1 x 1 ml
(for Apolipoprotein A1 and Apolipoprotein B)

TEST PERFORMANCE

**Precision**

<table>
<thead>
<tr>
<th>Intra-assay (n = 10)</th>
<th>mean (mg/dl)</th>
<th>SD (mg/dl)</th>
<th>CV %</th>
</tr>
</thead>
<tbody>
<tr>
<td>sample 1</td>
<td>83.81</td>
<td>1.86</td>
<td>2.22</td>
</tr>
<tr>
<td>sample 2</td>
<td>186.98</td>
<td>2.27</td>
<td>1.22</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Inter-assay (n = 20)</th>
<th>mean (mg/dl)</th>
<th>SD (mg/dl)</th>
<th>CV %</th>
</tr>
</thead>
<tbody>
<tr>
<td>sample 1</td>
<td>84.8</td>
<td>1.77</td>
<td>2.10</td>
</tr>
<tr>
<td>sample 2</td>
<td>186.98</td>
<td>2.21</td>
<td>1.19</td>
</tr>
</tbody>
</table>

Methods comparison

A comparison between LTA and a commercially available product gave the following results on 70 samples:

Apolipoprotein B LTA = x
Apolipoprotein B competitor = y
n = 70

y = 1.0019x + 0.522  r = 0.99968

EXPECTED VALUES

Apolipoprotein B  60 – 145 mg/dl

MANUFACTURER

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SYMBOLS

[ ] Only for IVD use
[ ] Lot of manufacturing
[ ] Code number
[ ] Storage temperature interval
[ ] Expiration date
[ ] Warning, read enclosed documents
[ ] Read the directions
[ ] Biological risk

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