IMMUNOGLOBULIN A

<table>
<thead>
<tr>
<th>Cat.No.</th>
<th>Product name</th>
<th>Pack name</th>
<th>Content</th>
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</thead>
<tbody>
<tr>
<td>BLT20023</td>
<td>IgA CALIBRATOR</td>
<td>IgA CAL H</td>
<td>1 x 1 ml</td>
</tr>
<tr>
<td>BLT20034</td>
<td>MULTICONTROL LEVEL 1</td>
<td>MULTICON L1</td>
<td>1 x 1 ml</td>
</tr>
<tr>
<td>BLT20035</td>
<td>MULTICONTROL LEVEL 2</td>
<td>MULTICON L1</td>
<td>1 x 1 ml</td>
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</tbody>
</table>

Reagents required but not supplied
1. Sodium Chloride (9 g/l)
2. Calibrators and Controls

Sample collection
Use fresh serum. If the test can not be carried out on the same day, the serum may be stored at 2 - 8°C for 48 hours. If stored for a longer period, the sample should be frozen.

Automation
Application procedures on clinical chemical analyzers are available upon request.

Manual Procedure
Sample/Control: Ready for use
Reference curve: generate a reference curve by diluting the standard high level successively 1:2 in saline 9 g/l. Use saline 9 g/l as zero point.
Test: Mix 5 µl standards, controls and samples with 900 µl buffer. Read optical density (OD1) of samples, controls and standards at 340 nm. Add 150 µl of IgA Antiserum. Mix and incubate for 5 minutes at room temperature. Read optical densities (OD2) of samples, controls and standards at 340 nm. Calculate ΔOD’s, plot a standard curve and read the concentration of controls and samples.

Reference Values
Men: 83 - 406 mg/dl (IFCC)
Women: 70 - 374 mg/dl
This range is given for orientation only. Each Laboratory should establish its own reference values.

Performances
The performance characteristics for the Immunoglobulin IgA reagents were measured on a clinical chemistry analyzer.

Measuring Range: 0 - 600 mg/dl
Detection Limit: 1 mg/dl
Hook effect: > 6000 mg/dl
Sensitivity: 15.2 ABS units / concentration unit

Intended Use
Quantitative determination of IgA in human serum by turbidimetric immunoassay.

Diagnostic Implications
The measurement of IgA is important for typing immuno-deficiencies and myelomas. Furthermore it plays a role in acute and chronic infections as first line of defence. Increased levels may be found in acute infectious hepatitis, chronic aggressive hepatitis, posthepatic/cryptogenic cirrhosis, active alcoholic cirrhosis, chronic infection, rheumatoid arthritis, polydermatomyositis, mixed connective tissue disease.

Method
Measurement of antigen-antibody reaction by the end-point method.

Reagents Provided
Buffer
Saline (9 g/l).
Accelerator.
Sodium azide (0.95 g/l).

Antiserum
Phosphate buffered saline (pH 7.43).
Polyclonal goat anti-human IgA (variable).
Sodium azide (0.95 g/l).

Calibrator
Dilution of pooled human serum, liquid and stabilized. Contains 0.09% sodium azide as preservative.
Concentration: See bottle label

Preparation and Stability of Reagents
Reagent Preparation
Liquid reagents, ready for use.

Stability and Storage
The reagents are stable until expiry date when kept at 2-8°C. Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

Precision:

<table>
<thead>
<tr>
<th>[%CV]</th>
<th>Low</th>
<th>Medium</th>
<th>High</th>
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<tbody>
<tr>
<td>Intra-Run</td>
<td>0.84</td>
<td>0.94</td>
<td>1.20</td>
</tr>
<tr>
<td>Inter-Run</td>
<td>1.70</td>
<td>1.41</td>
<td>1.07</td>
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</table>

Accuracy:

<table>
<thead>
<tr>
<th>[mg/dl]</th>
<th>Control</th>
<th>Assigned</th>
<th>Measured</th>
</tr>
</thead>
<tbody>
<tr>
<td>BIO-RAD 1</td>
<td>135 (108 – 162)</td>
<td>140</td>
<td></td>
</tr>
<tr>
<td>BIO-RAD 2</td>
<td>251 (201 – 301)</td>
<td>245</td>
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</tr>
</tbody>
</table>

Specificity:
Monospecific

Interferences:
No interference for Haemoglobin (1000 mg/dl), Na-citrate (1000 mg/dl), Heparin (50 mg/dl), Bilirubin (20 mg/dl), Triglyceride (2500 mg/dl), EDTA (5 mg/dl) and Turbidity (5%)

Limitations:
None

Comparison with Behring Nephelometry:
y = 0.9623x – 1.3803
r = 0.9964

Stability at 2 - 8°C: at least 3 years after production

Precautions and warnings
1. In vitro diagnostic use only.
2. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.
3. Each donor unit used in the preparation of the standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA.

QUALITY SYSTEM CERTIFIED
ISO 9001  ISO 13485
References