IMMUNOGLOBULIN G

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

**Diagnostic Implications**
IgG is a predominant serum immunoglobulin. The measurement of IgG is important for typing immunodeficiencies and myelomas. Increased levels are found in chronic infections and chronic inflammation. IgG is the only immunoglobulin which crosses the placenta and is therefore of special importance in the infant's defense against infection.

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

**Reagents Provided**

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Product name</th>
<th>Pack name</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>BLT20024</td>
<td>IgG CALIBRATOR</td>
<td>IgG 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>

**Sample collection**
Use fresh serum. If the test cannot 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 chemistry analyzers are available upon request.

**Manual Procedure**
Sample/Control: dilute 1:10 in saline 9 g/l
Reference curve: generate a reference curve by diluting the standard high level 1:10, 1:20, 1:40, 1:80, 1:160 in saline 9 g/l. Use saline 9 g/l as zero point.
Test: Mix 20 µl diluted standards, controls and samples with 900 µl buffer. Read optical density (OD1) of samples, controls and standards at 340 nm. Add 100 µl of IgG Antiserum. Mix and incubate for 5 minutes at room temperature. Read optical densities (OD2) of samples, controls and standards at 340 nm.
Calculate ∆OD’s, plot a standard curve and read the concentration of controls and samples.

**Reference Values**
680 - 1445 mg/dl (IFCC)
This range is given for orientation only. Each laboratory should establish its own reference values.

**Performances**
The performance characteristics for the IgG reagents were measured on a clinical chemistry analyzer.

| Measuring Range | 0 - 2700 mg/dl |
| Detection Limit | 90 mg/dl |
| Hook effect | > 10000 mg/dl |
| Sensitivity | 0.00014 ABS units/concentration unit |

**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>2.50</td>
<td>3.25</td>
<td>4.18</td>
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<tr>
<td>Inter-Run</td>
<td>4.08</td>
<td>1.83</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>909(727-1091)</td>
<td>948</td>
<td></td>
</tr>
<tr>
<td>BIO-RAD 2</td>
<td>2695(2156-3234)</td>
<td>2732</td>
<td></td>
</tr>
</tbody>
</table>

**Specificity:**
Monospecific
Interferences: No interference for: Hemoglobin (1000 mg/dl), Na-citrate (1000 mg/dl), Heparin (50 mg/dl), Bilirubin (20 mg/dl), Triglyceride (2500 mg/dl)
Limitations: None

**Comparison with nephelometry:**
y = 0.987x – 0.2018
r = 0.9636

**Stability at 4°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. Polyethylene glycol is not biohazardous
4. 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