**IMMUNOGLOBULIN M**

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

**Diagnostic Implications**
IgM is important in early response to infections. The measurement of IgM is important for typing immunodeficiencies and myelomas. IgM plays an important role in the humoral defense of the body. Serum levels may be increased in all kind of acute infections. Elevated levels in cord serum suggest clinical infection in the newborn.

**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 IgM (variable).
  - Sodium azide (0.95 g/l).
- **Calibrator**
  - 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.

**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 130 µl of IgM 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:** 34 – 214 mg/dl (IFCC)
- **Woman:** 40 – 250 mg/dl
This range is given for orientation only. Each Laboratory should establish his own reference values.

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

**Measuring Range:** 0 – 500 mg/dl
**Detection Limit:** 6 mg/dl
**Hook Effect:** no risk
**Sensitivity:** 6.7 ABS units / concentration unit

**Quality System Certified**

**ISO 9001**
**ISO 13485**

**Comparison with Behring Nephelometry:**
\[ y = 0.9875x - 8.2224 \]
\[ r = 0.9966 \]

**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.
References