

IgM (2nd generation) Turbidimetric Immunoassay

REF: 523 001 (2 X 10 ml) + 0.5 ml High calibrator (40 test)
REF: 523 002 (2 X 25 ml) + 0.5 ml High calibrator (100 test)

Intended Use

For the quantitative determination of IgM in human serum by turbidimetric immunoassay for manual and automated chemistry analyzers

Background

IgM is important in early response to infections. The measurement of IgM is important for typing immune-deficiencies and myelomas. IgM plays an important role in the humoral defence of the body. Serum levels may be increased in all kind of acute infections. Elevated levels in cord serum suggest clinical infection in the new born.

Method

Antigen-antibody reaction using endpoint method.

Reagent (R)

Polyclonal goat anti-human IgM stabilised in saline supplemented with accelerator.
Sodium azide (0.95 g/L).

Reagents required but not supplied

1. Saline (9 g/L NaCl)
2. Calibrators and Controls

Reagent Preparation, Storage and Stability

The reagent is 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.

Specimen Collection and Preservation

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.

Procedure

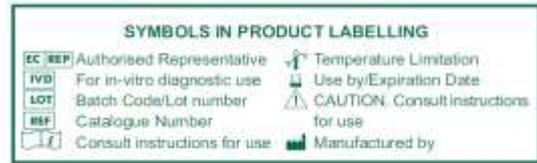
Sample/Control: dilute 1:10 in saline 9g/L

Reference curve: generate a reference curve by diluting the standard high level 1:10, 1:20, 1:40, 1:80 and 1:160 with saline (9 g/L NaCl). Use saline (9 g/L NaCl) as zero point.

Test:

	Diluted Samples	Diluted Standards	Diluted Controls
Samples	30 µl
Standards	30 µl
Controls	30 µl
Reagent	500 µl	500 µl	500 µl

Mix and incubate for 5 minutes at room temperature.
Read optical density (OD) of samples, standards and control(s) at 340 nm. Plot a standard curve and read the concentration of controls and samples.



Reference Values

Men: 34-214 mg/dL
Woman: 40-250 mg/dL

These values are for reference only. Each laboratory should establish its own reference values.

Performance Characteristics

1-Dynamic Range

0 - 452 mg/dL

2-Detection Limit

28 mg/dL

3-Hookeffect

> 4520 mg/dL

4-Sensitivity

0.00070 ABS units/concentration unit

5-Specificity

Monospecific

6-Interferences:

- No interference for Na-citrate (1000 mg/dL), Heparin (50 mg/dL), Triglyceride (2500 mg/dL), EDTA (5mg/dL).
- Haemoglobin (125 mg/dL), Turbidity (> 2.5%) and Bilirubin (> 10 mg/dL) interfere with the test

7-Precision (CV%)

	Low	Medium	High
Intra run	0.78	1.62	0.94
Inter run	2.35	3.65	3.57

8- Methods Comparison

A comparison between Spectrum Diagnostics IgM reagent and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.991 was obtained.

Precautions and warnings

1. For 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

- 1.Naito, H.K., J. Clin. Immunoassay, 9, 155 (1986)
- 2.Kottke, B.A., et. al., Mayo Clin. Proc., 61, 313 (1986)
- 3.Dati, F. et al., Lab. Med. 13, 87 (1989)

