

COD 31083 1 x 20 mL	COD 31072 1 x 50 mL	COD 31078 1 x 250 mL
STORE AT 2-8°C		
Reagents for measurement of IgM concentration Only for <i>in vitro</i> use in the clinical laboratory		

IMMUNOGLOBULIN M (IgM)



IMMUNOGLOBULIN M (IgM) Turbidimetry

PRINCIPLE OF THE METHOD

Immunoglobulin M in the sample precipitates in the presence of anti-human immunoglobulin M antibodies. The light scattering of the antigen-antibody complexes is proportional to the immunoglobulin M concentration and can be measured by turbidimetry^{1,2}.

CONTENTS

	COD 31083	COD 31072	COD 31078
A. Reagent	1 x 20 mL	1 x 50 mL	1 x 250 mL

COMPOSITION

A. Reagent: Imidazole buffer 0.1 mol/L, goat anti-human IgM antibodies, sodium azide 0.95 g/L, pH 7.5.

STORAGE

Store at 2-8°C.

The Reagent is stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during its use.

Indications of deterioration: Presence of particulate material, turbidity, absorbance of the blank over 0.200 at 340 nm.

ADDITIONAL REAGENTS

– Protein Calibrators (BioSystems cod. 31075). The set contains 5 different levels of IgM concentration and it should be used to prepare the calibration curve. The calibrators are supplied ready to use.

REAGENT PREPARATION

Reagent is provided ready to use.

ADDITIONAL EQUIPMENT

- Thermostatic water bath at 37°C.
- Analyzer, spectrophotometer or photometer with cell holder thermostatable at 37°C and able to read at 340 ± 20 nm.

SAMPLES

Serum or plasma collected by standard procedures. Use heparin or EDTA as anticoagulants. Lipemic samples are not suitable for testing.

Serum or plasma IgM is stable for 7 days at 2-8°C.

PROCEDURE

1. Bring the Reagent and the instrument to 37°C.
2. Pipette into a cuvette (Note 1):

Reagent (A)	1.0 mL
Distilled water (Blank), Calibrator or Sample	15 µL

3. Mix and insert cuvette into the instrument. Start stopwatch.
4. Read the absorbance of the Blank, Calibrators and Sample at 340 nm after exactly 10 minutes of sample addition.

CALIBRATION

Calibration curve: Plot the absorbance values of each calibrator against its IgM concentration. Use the Blank as the calibrator of 0 concentration. IgM concentration in the sample is calculated by interpolation of its absorbance on the calibration curve.

A calibration is recommended at least every 2 months, after reagent lot change or as required by quality control procedures.

REFERENCE VALUES

Serum, adults³: 40 - 230 mg/dL = 0.40 - 2.30 g/L.

This range is given for orientation only; each laboratory should establish its own reference range.

QUALITY CONTROL

It is recommended to use the Protein Control Serum level I (Cod. 31211) and II (Cod. 31212) to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

METROLOGICAL CHARACTERISTICS

- Detection limit: 2.1 mg/dL = 0.021 g/L.
- Measurement interval (approximate value dependent on the highest standard concentration): 2.1 - 300 mg/dL = 0.021 - 3.00 g/L. For higher values dilute sample 1/5 with distilled water and repeat measurement.

- Repeatability (within run):

Mean concentration	CV	n
83 mg/dL = 0.83 g/L	1.4 %	20
205 mg/dL = 2.05 g/L	1.4 %	20

- Reproducibility (run to run):

Mean concentration	CV	n
83 mg/dL = 0.83 g/L	4.5 %	25
205 mg/dL = 2.05 g/L	1.9 %	25

- Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

- Zone effect: > 1400 mg/dL = 14.00 g/L.

- Interferences: Bilirubin (20 mg/dL) and rheumatoid factor (150 IU/mL) do not interfere. Lipemia (triglycerides 4.4 g/L) and hemoglobin (2.0 g/L) may affect the results. Other drugs and substances may interfere⁴.

These metrological characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure are used.

DIAGNOSTIC CHARACTERISTICS

Immunoglobulins M account for 5 to 10% of the total circulating immunoglobulins in adult serum. Most of the serum IgM is a pentamer.

Plasma IgM concentration is decreased in inherited or acquired deficiencies of immunoglobulin production.

Diffuse (polyclonal) hyperimmunoglobulinemia is the normal response to infections. IgM is often increased in primary viral infections and blood-stream infections such as malaria, as well as in primary biliary cirrhosis. Increases in serum monoclonal IgM (paraprotein) are found in Waldenström's macroglobulinemia and other proliferative disorders of plasma cells.

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

NOTES

1. These reagents may be used in several automatic analysers. Instructions for many of them are available on request.

BIBLIOGRAPHY

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4. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.
5. Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press, 2001.