CORMAY IgM

DIAGNOSTIC KIT FOR DETERMINATION OF IgM CONCENTRATION

Kit name	Kit size	Cat. No
CORMAY IgM	1 x 58.5 ml	4-582

INTRODUCTION

Immunoglobulins (Igs) are the instrumental proteins of immunity. Immunity is a property of the lymphoid system which is made of organs (spleen, thymus, bone marrow) and of cells (lymphocytes). Circulating immunoglobulins are secreted in the blood by B lymphocytes and they thereby export far-away the specific biological functions of humoral immunity. Immunoglobulin M (IgM) is the first Ig to appear in response to an antigenic stimulus such as an infectious agent. In many cases, the antigen-specific IgM level subsequently falls and remains low as the IgG response appears.

METHOD PRINCIPLE

The IgM present in a sample form with the specific antibody an immunological complex. The increase of turbidity after the addition of antiserum measured at λ=340 nm is proportional to IgM concentration in the sample.

REAGENTS

Package

1-Reagent	1 x 48.5 ml
2-Reagent	1 x 10 ml

Buffer (1-Reagent) stored at 2-25°C and antiserum (2-Reagent) stored at 2-8°C are stable until expiry date printed on the package. The reagents are stable for 8 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

Concentrations in the test

Tricine buffer (pH 8.0); PEG; sodium chloride; anti human IgM antiserum; HEPES buffer (pH 7.4); stabilizers.

Warnings and notes

- Products for in vitro diagnostic use only.
- The reagents must be used only for the intended purpose, by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Do not use after expiry date.
- Do not interchange caps.
- Products from human source have been tested for HBsAg and antibodies to HIV and HCV and found to be non-reactive. However this material should be handled as thought capable of transmitting infectious disease.
- Products contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

ADDITIONAL EQUIPMENT

- automated clinical chemistry analyser capable of accommodating two-reagent assays;
- general laboratory equipment;

SPECIMEN

Serum.
Specimen without lipemia or hemolysis is recommended.
Specimen can be stored up to 3 days at 2-8ºC or up to 6 months at -20ºC.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

The reagents are ready to use.
These reagents may be used in automatic analysers according to their user manual. Applications for analysers are available on request.
These reagents may be used directly in Hitachi 911/912 analysers.
Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:

1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

REFERENCE VALUES [2]

adults	0.50 – 3.00 g/l
children (1 year – 12 years)	0.45 – 2.50 g/l
children (1 month – 12 months)	0.20 – 1.50 g/l

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY IMMUNO-CONTROL III (Cat. No 4-291) with each batch of samples.
For the calibration of automatic analysers systems the CORMAY IMMUNO-MULTICAL (Cat. No 4-287) is recommended. Calibrators and 0.9% NaCl should be used for calibration.
The calibration curve should be prepared every 4 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using an automatic analyser Cobas Mira. Results may vary if a different instrument is used.

- **Measurement range:** 0.005 g/l to 7 g/l.

- **Interferences:**

Hemoglobin up to 0.32 g/dl, bilirubin up to 29.5 mg/dl, triglycerides up to 1000 mg/dl, heparin up to 0.5 g/l, sodium fluoride up to 4 g/l, EDTA up to 5 g/l, sodium citrate up to 5 g/l do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	61.9	0.9	1.5
level 2	122.1	1.8	1.5
level 3	123.8	1.1	0.9

Reproducibility (day to day) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	56.5	2.8	5.0
level 2	122.3	6.4	5.3
level 3	123.5	6.7	5.4

- **Method comparison**

A comparison between CORMAY reagent (y) and another commercially available assay (x) using 31 samples gave following results:
y = 1.1 x + 1.8 mg/dl;
R = 0.9797 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

1. Bergstrom, K. & Lefvert, A.K. Scand.J.clin.Lab.Invest. 40 (1980) 637.
2. Norberd W. Tietz, ed.: Tietz Clinical Guide to Laboratory Tests, sd. ed. W.B. Saunders Company., (1990).
3. Burtis C.A., Ashwood E.R., Bruns D.E., ed. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics 4th ed., PA: WB Saunders., (2006).
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