Cat. No 9-431

DIAGNOSTIC KIT FOR DETERMINATION OF IgM CONCENTRATION

OS – IgM

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 43.5 ml
2-Reagent	1 x 11 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. 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.
- Products from human source have been tested for the 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.

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
These reagents may be used in automatic analysers Olympus AU400/AU640.
1-Reagent and 2-Reagent are ready to use.
For reagent blank 0.9% NaCl is recommended.

APPLICATION
Reagent ID: **046**

Specific Test Parameters — General | LIH | ISE | Range

Test name: **IgM** Type: **Serum** Operation: **Yes**

Sample:	Volume	2.5 µL	Dilution	0 µL	Pre-Dilution Rate:	1		
Reagents:	R1 Volume	200 µL	Dilution	0 µL	Min OD		Max OD	
	R2 Volume	40 µL	Dilution	0 µL	L	-2.0000	H	2.5000
					Reagent OD Limit:			
Wavelength:	Pri.	340	Sec.	700	First L	-2.0000	First H	2.5000
Method:		END			Last L	-2.0000	Last H	2.5000
Reaction Slope:		+			Dynamic Range:			
Measuring Point 1:	First	0	Last	27	L		H	
Measuring Point 2:	First	0	Last	10	Correlation Factor:			
Linearity:		%			A	1.000	B	0.000
No-Lag-Time:					On-board Stability Period:			

Specific Test Parameters — General | LIH | ISE | Range

Test name: **IgM** Type: **Serum**

Value/Flag: # Level L: # Level H: #

Normal Ranges:

	Sex	Age L Year	Age L Month	Age H Year	Age H Month	L	H
1.	#	#	#	#	#	#	#
2.	#	#	#	#	#	#	#
3.	#	#	#	#	#	#	#
4.	#	#	#	#	#	#	#
5.	#	#	#	#	#	#	#
6.	#	#	#	#	#	#	#
7. None Selected						#	#
8 Out of Range						#	#

Panic Value: L # H # Unit: g/l Decimal Places: 2

Calibration Specific — General | ISE

Test name: **IgM** Type: **Serum**

Calibration Type: 6AB Formula: Spline Counts: 1 Process: CONC

	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1:	#		**	-2.0000	2.5000
Point 2:	#		*	-2.0000	2.5000
Point 3:	#		*	-2.0000	2.5000
Point 4:	#		*	-2.0000	2.5000
Point 5:	#		*	-2.0000	2.5000
Point 6:	#		*	-2.0000	2.5000
Point 7:					

1-Point Cal.Point: with CONC-0 Slope Check: None Advanced Calibration: #

MB Type Factor: Calibration Stability Period:

\# User defined
* Calibrator value
** Saline should be used as calibrator 1

REFERENCE VALUES [4]

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.
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 the 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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