IgM FL

GM 0050 CH	1 x 50 ml
GM 0100 CH	2 x 50 ml

INTENDED USE

Reagent for quantitative in vitro determination of IgM in biological fluids.

SUMMARY OF TEST

Immunoglobulins are proteins of immune system involved in the defense against microrganisms. Immunoglobulins M, which represent 5-10% of total immunoglobulins in human serum, deal with primary immune response, indeed these are first synthesized after the exposure to external agent.

PRINCIPLE OF THE METHOD

Immunoglobulins M (IgM) selectively react with an anti-IgM antibody and form an immunocomplex. The produced turbidity is proportional to the concentration of IgM in the sample, and can be measured at the wavelenght of 340 nm.

KIT COMPONENTS

For in vitro diagnostic use only.
The components of the kit are stable until expiration date on the label.
Keep away from direct light sources.

IGM R1 **0050: 1 x 40 ml (liquid) white cap**
0100: 2 x 40 ml (liquid) white cap

Composition: Buffer pH 7.50, PEG ≥ 2%, stabilizers and preservatives.

IGM R2 **0050: 1 x 10 ml (liquid) red cap**
0100: 2 x 10 ml (liquid) red cap

Composition: Anti-human IgM antibody ≥ 2%, stabilizers and preservatives.

Store all components at 2-8°C.

REAGENT PREPARATION

Use separate reagents ready to use.
Stability: up to expiration date on labels at 2-8°C;
Stability since first opening of vials: use preferably within 60 days at 2-8°C.

PRECAUTIONS

IGM R1: Danger. Causes serious eye damage (H318).

Wear protective gloves. Eye protection (P280). IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305+P351+P338). Immediately call a doctor (P310).

IGM R2: It is not classified as hazardous.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

SPECIMEN

Serum, plasma.
Keep specimens away form direct light sources.
Samples are stable 7 days when stored at 2-8°C and 1 month at -20°C.

TEST PROCEDURE

Wavelength:	340 nm
Lightpath:	1 cm
Temperature:	37°C

dispense:	blank	calibrator	sample
reagent R1	1.2 ml	1.2 ml	1.2 ml
water	15 µl	-	-
calibrator	-	15 µl	-
sample	-	-	15 µl

Mix, incubate at 37°C for 5 minutes.
Read against reagent blank the absorbances of calibrator (Ac_1) and sample (Ax_1).

dispense:	blank	calibrator	sample
reagent R2	300 µl	300 µl	300 µl

Mix, incubate at 37°C for 5 minutes.
Read against reagent blank the absorbances of calibrator (Ac_2) and sample (Ax_2).

RESULTS CALCULATION

For calibrators and samples, calculate $\Delta A=A_2-A_1$.
A calibration curve is plotted by the use of a set of standards with increasing IgM concentrations.
Successively, IgM concentration of a sample can be calculated by interpolating its absorbance value on the calibration curve.

EXPECTED VALUES

Newborns	0.05-0.3 g/l
Adults	0.4-2.3 g/l

Each laboratory should establish appropriate reference intervals related to its population

QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control serum is available:

QUANTINORM CHEMA
with normal or close to normal control values.

If required, a multiparametric, human based calibrator is available:
REFERENCE P MULTICALIBRATOR

Please contact Customer Care for further information.

TEST PERFORMANCE

Measure interval
Measure interval depends on the concentration of the highest standard used for calibration.
If such a limit value is exceeded, it is suggested to dilute sample 1+4 with distilled water and to repeat the test, multiplying the result by 5.

Hook effect
No Hook effect is observed with concentrations lower than 30 g/l.

Sensitivity/limit of detection
The limit of detection is 0.016 g/l.

Interferences
No interference was observed by the presence of:

hemoglobin	≤ 1000 mg/dl
bilirubin	≤ 45 mg/dl
lipids	≤ 770 mg/dl
rheumatoid factor	≤ 630 IU/ml

Precision

intra-assay (n=10)	mean (g/l)	SD (g/l)	CV%
sample 1	0.70	0.005	0.69
sample 2	1.40	0.009	0.66

inter-assay (n=20)	mean (g/l)	SD (g/l)	CV%
sample 1	0.70	0.024	3.38
sample 2	1.40	0.061	4.32

Methods comparison
A comparison between CHEMA and a commercially available product gave the following results:

IgM competitor = x
IgM FL CHEMA = y
n = 20

$y = 1.186x - 0.058$ g/l $r^2 = 0.99$

WASTE DISPOSAL

This product is made to be used in professional laboratories.
P501: Dispose of contents according to national/international regulations.

REFERENCES

Blirup-Jensen S. *Clin. Chem. Lab. Med.* 2001, 39(11), 1098-1109
Tietz Textbook of Clinical Chemistry, Fourth Edition, Burtis-Ashwood-Bruns (2006), pagg. 569-574.

MANUFACTURER

Chema Diagnostica
Via Campania 2/4
60030 Monsano (AN) - ITALY - EU
phone +39 0731 605064
fax +39 0731 605672
e-mail: mail@chema.com
website: http://www.chema.com

SYMBOLS

IVD	*in vitro* diagnostic medical device
LOT	batch code
REF	catalogue number
	temperature limit
	use by date
	caution
	consult instructions for use

CE