

IgA FL

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

INTENDED USE

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

SUMMARY OF TEST

Immunoglobulins are proteins of immune system involved in the defense against microorganisms. IgAs account for 10-15% of total immunoglobulins, these are mainly produced by mucosa-associated lymphoid tissue (MALT) and play two important functions: mucosal immunity and neonatal immunity.

PRINCIPLE OF THE METHOD

Immunoglobulins A (IgA) selectively react with an anti-IgA antibody and form an immunocomplex. The produced turbidity is proportional to the concentration of IgA in the sample, and can be measured at the wavelength of 600 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.

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

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

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

Composition: Anti-human IgA antibody \geq 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

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.

Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

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 from direct light sources.

Samples are stable 7 days when stored at 2-8°C and 1 month at -20°C.

TEST PROCEDURE

Wavelength:	600 nm		
Lightpath:	1 cm		
Temperature:	37°C		
dispense:	blank	calibrator	sample
reagent R1	1.2 ml	1.2 ml	1.2 ml
water	10 μ l	-	-
calibrator	-	10 μ l	-
sample	-	-	10 μ l
Mix, incubate at 37°C for 5 minutes. Read against reagent blank the absorbances of calibrator (A_{c1}) and sample (A_{x1}).			
dispense:	blank	calibrator	sample
reagent R2	300 μ l	300 μ l	300 μ l
Mix, incubate at 37°C for 5 minutes. Read against reagent blank the absorbances of calibrator (A_{c2}) and sample (A_{x2}).			

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 IgA concentrations.

Successively, IgA concentration of a sample can be calculated by interpolating its absorbance value on the calibration curve.

EXPECTED VALUES

Newborns	0-0.02 g/l
Adults	0.7-4.0 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 38 g/l.

Sensitivity/limit of detection

The limit of detection is 0.01 g/l.

Interferences

No interference was observed by the presence of:

hemoglobin	\leq 1000 mg/dl
bilirubin	\leq 27 mg/dl
lipids	\leq 1290 mg/dl
rheumatoid factor	\leq 630 IU/ml

Precision

intra-assay (n=10)	mean (g/l)	SD (g/l)	CV%
sample 1	1.46	0.02	1.04
sample 2	2.38	0.02	0.94

inter-assay (n=20)	mean (g/l)	SD (g/l)	CV%
sample 1	1.46	0.07	4.99
sample 2	2.40	0.10	4.16

Methods comparison

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

$$\begin{aligned} \text{IgA competitor} &= x \\ \text{IgA FL CHEMA} &= y \\ n &= 21 \end{aligned}$$

$$y = 0.97x + 0.04 \text{ g/l} \quad r^2 = 0.99$$

WASTE DISPOSAL

This product is made to be used in professional laboratories.

P501: Dispose of contents according to national/international regulations.

REFERENCES

Ledue T.B., Collins M.F. and Ritchie R.F., *Clin. Chem. Lab. Med.* 2002, 40(5), 520-528
Tietz Textbook of Clinical Chemistry, Fourth Edition, Burtis-Ashwood-Bruns (2006), 569-574.

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SYMBOLS

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