

**DIAGNOSTIC KIT
FOR DETERMINATION OF IgG
CONCENTRATION**



OS – IgG

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 G (IgG) - the predominant serum immunoglobulin (75 % of Igs)- is of particular importance in the body's long-term defense against infection; IgG deficiency is associated with recurrent and occasionally severe pyogenic infections. IgG serum levels are increased in response to chronic or recurrent infections or autoimmune diseases.

METHOD PRINCIPLE

The IgG present in a sample form with the specific antibody an immunological complex. The increase of turbidity after the addition of antiserum is proportional to IgG concentration in the sample.

REAGENTS

Package

- 1-Reagent 1 x 44.5 ml
- 2-Reagent 1 x 18.5 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 IgG 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 though 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 2-8°C or up to 6 months at -20°C.

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: 045

Specific Test Parameters										
General		LIH	ISE	Range						
Test name:	IgG					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	76	µL	Dilution	0	µL	L	-2.0000	H	2.5000	
Wavelength: Pri.						570	Sec.	800		
Method:						END				
Reaction Slope:						+				
Measuring Point 1: First			0	Last		27				
Measuring Point 2: First			0	Last		10				
Linearity:										
No-Lag-Time:										
Reagent OD Limit:							First H	2.5000		
							Last L	-2.0000	Last H	2.5000
Dynamic Range:										
Correlation Factor:							A	1.000	B	0.000
On-board Stability Period:										

Specific Test Parameters									
General		LIH	ISE	Range					
Test name:	IgG					Type:	Serum		
Value/Flag:	#	Level L:	#	Level H:	#				
Normal Ranges:									
	Sex	Age L	Month	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:	IgG					Type:	Serum		
Calibration Type:	6AB	Formula:	Spline	Counts:	1	Process:	CONC		
Point 1:	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H				
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:	#		*	-2.0000	2.5000				
1-Point Cal.Point:		<input type="checkbox"/>	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	5.65 – 17.65 g/l
children (> 6 years)	6.50 – 16.00 g/l
children (1 month – 6 years)	2.00 – 12.40 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 analysers Olympus AU400 and Cobas Mira. Results may vary if a different instrument is used.

▪ **Measurement range:** 0.125 g/l to 35 g/l.

▪ **Interferences:**

Hemoglobin up to 0.32 g/dl, bilirubin up to 29.5 mg/dl, triglycerides up to 2000 mg/dl, heparin up to 0.5 g/l, sodium fluoride up to 4g/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	CV [%]
level 1	938.7	23.2	2.5
level 2	1539.8	10.9	0.7
level 3	1947.8	38.2	2.0

Reproducibility (day to day) n = 10	Mean [mg/dl]	SD	CV [%]
level 1	916.9	24.2	2.6
level 2	1500.7	49.7	3.3
level 3	1915.5	46.9	2.5

▪ **Method comparison**

A comparison between IgG values determined at Olympus AU400 (y) and at Advia 1650 (x) using 26 samples gave following results:

$$y = 1.0329 x - 0.7214 \text{ g/l};$$

$$R = 0.9913 \quad (R - \text{correlation coefficient})$$

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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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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