Cat. No 9-435

DIAGNOSTIC KIT FOR DETERMINATION OF COMPLEMENT C4 CONCENTRATION

OS – COMPLEMENT C4

INTRODUCTION

Complement is a group of 20 immunologically distinct proteins present in blood and tissues. They are able to interact with antigen-antibody complexes, with each other and with cell membranes, in a complex way intended at destroying viruses and bacteria. They are synthesised in liver and are present in serum as functionally inactive molecules. They are activated by antigen-antibody complexes. C4 complement is a α -glycoprotein of 3 subunits. It is an acute phase reactant whose levels are increased during the acute phase. Low levels are found in immune complex diseases and in inherited angioedema, while C3 complement levels are normal.

METHOD PRINCIPLE

The complement C4 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 complement C4 concentration in the sample.

REAGENTS

Package

1-Reagent	1 x 43 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. Store closed. Protect from light and avoid contamination!

Concentrations in the test

Imidazole buffer (pH 7.0); PEG; sodium chloride; anti human complement C4 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 purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- 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.

SPECIMEN

Serum or plasma.
Serum should be separated from red blood cells as soon as possible after blood collection. If the test can not be done immediately, the sample should be stored at -70°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: **60**

Specific Test Parameters

General | LIH | ISE | Range

Test name: **C4** Type: **Serum** Operation: **Yes**

Sample: Volume	4	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: **C4** 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: **3**

Calibration Specific

General | ISE

Test name: **C4** 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 [2]

adults	0.1 – 0.4 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 an automatic analyser Cobas Mira. Results may vary if a different instrument is used.

- **Analytical range:** 0.0004 g/l – 4.0 g/l.

- **Specificity / Interferences**

Haemoglobin 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.

- **Diagnostic sensitivity:** 100%.

- **Diagnostic specificity:** 86%.

- **Precision**

Repeatability (run to run) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	13.1	0.5	3.7
level 2	26.5	0.5	1.7

Reproducibility (day to day) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	13.9	0.6	4.2
level 2	26.3	0.5	1.9

- **Method comparison**

A comparison between CORMAY reagent (y) and commercially available assay (x) using 22 samples gave following results:
y = 1.2 x + 1.2 mg/dl;
R = 0.9503 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Tietz Textbook of Clinical Chemistry, W.B. Saunders, Philadelphia, (1994).
2. Burtis C.A., Ashwood E.R., ed. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics 4th ed., PA: WB Saunders, 2262, 2006

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MANUFACTURER

PZ CORMAY S.A.
22 Wiosenna Street,
05-092 Łomianki, POLAND
tel.: +48 (0) 22 751 79 10
fax: +48 (0) 22 751 79 14
http://www.cormay.pl

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