

COMPLEMENT C4 FL

C4 0050 CH	1 x 50 ml
C4 0100 CH	2 x 50 ml

INTENDED USE

Reagent for quantitative in vitro determination of Complement C3 in biological fluids.

SUMMARY OF TEST

The C4 is the fourth complement component. It is one of a group of serum proteins that are active in the body's immune response to destroy infectious agents. The C4 is utilized only by the classical complement pathway, so that it is decreased only when this pathway is activated. In the case of diseases activating alternative pathways only, C4 levels will be normal. Measurements of this protein help in the diagnosis of immunologic disorders, especially those associated with deficiencies of complement components.

PRINCIPLE OF THE METHOD

Complement C4 selectively reacts with an anti-C4 antibody and forms an immunocomplex. The produced turbidity is proportional to the concentration of C4 in the sample and can be measured at the wavelength 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.

C4 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.

C4 R2 **0050: 1 x 10 ml (liquid) red cap**
0100: 2 x 10 ml (liquid) red cap

Composition: Anti-human C4 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:	340 nm		
Lightpath:	1 cm		
Temperature:	37°C		
dispense:	blank	calibrator	sample
reagent R1	1.2 ml	1.2 ml	1.2 ml
water	20 μ l	-	-
calibrator	-	20 μ l	-
sample	-	-	20 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 C4 concentrations.

Successively, C4 concentration of a sample can be calculated by interpolating its absorbance value on the calibration curve.

EXPECTED VALUES

Adults 10 - 40 mg/dl

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:

MULTINORM CHEMA

with normal or close to normal control values,

MULTIPATH CHEMA

with pathological control values.

If required, a multiparametric, human based calibrator is available:

REFERENCE P MULTICALIBRATOR

Please contact Customer Care for further information.

TEST PERFORMANCE

Measuring range

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 230 mg/dl.

Sensitivity/limit of detection

The limit of detection is 0.271 mg/dl.

Interferences

No interference was observed by the presence of:

hemoglobin	\leq 1000 mg/dl
bilirubin	\leq 60 mg/dl
lipids	\leq 1600 mg/dl
rheumatoid factor	\leq 1100 IU/ml

Precision

intra-assay (n=10)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	18.07	0.22	1.23
sample 2	27.01	0.30	1.11

inter-assay (n=20)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	17.99	0.42	2.31
sample 2	27.00	0.43	1.60

Methods comparison

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

$$\begin{aligned} \text{COMPLEMENT C4 competitor} &= x \\ \text{COMPLEMENT C4 FL CHEMA} &= y \\ n &= 30 \end{aligned}$$

$$y = 0.909x - 0.267 \text{ mg/dl} \quad r^2 = 0.99$$

WASTE DISPOSAL

This product is made to be used in professional laboratories.

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








REFERENCES

Tietz Textbook of Clinical Chemistry, Fourth Edition, Burtis-Ashwood-Bruns(2006).

MANUFACTURER

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SYMBOLS

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