COMPLEMENT C3 FL

C3 0050 CH	1 x 50 ml
C3 0100 CH	2 x 50 ml

INTENDED USE

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

SUMMARY OF TEST

Complement C3 is an acute phase reactant produced by the liver, secreted by activated macrophages at inflammation sites and by adipocytes. C3 has been associated with atherosclerosis and cardiovascular risk factors. C3 deficiency is usually linked with the development of recurrent bacterial infections and glomerulonephritis.

PRINCIPLE OF THE METHOD

Complement C3 selectively reacts with an anti-C3 antibody and forms an immunocomplex. The produced turbidity is proportional to the concentration of C3 in the sample and can be measured at the wavelenght 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.

C3 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.

C3 R2 **0050: 1 x 10 ml (liquid) red cap**
0100: 2 x 10 ml (liquid) red cap

Composition: Anti-human C3 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

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 form 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	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 C3 concentrations.
Successively, C3 concentration of a sample can be calculated by interpolating its absorbance value on the calibration curve.

EXPECTED VALUES

Adults 90-180 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 980 mg/dl.

Sensitivity/limit of detection
The limit of detection is 0.37 mg/dl.

Interferences
No interference was observed by the presence of:

hemoglobin	≤ 1000 mg/dl
bilirubin	≤ 42 mg/dl
lipids	≤ 1500 mg/dl
rheumatoid factor	≤ 530 IU/ml

Precision

intra-assay (n=10)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	89.5	0.85	0.95
sample 2	134.8	1.41	1.05

inter-assay (n=20)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	89.6	0.73	0.82
sample 2	134.7	2.06	1.53

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

COMPLEMENT C3 competitor = x
COMPLEMENTC3 FL CHEMA = y
n = 117

$y = 0.99x + 4.23$ mg/dl $r^2 = 0.98$

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.
Rawat A., Vignesh P., Sharma M., Singh S. *Clinica Chimica Acta* 2017, 465, 123-130.

MANUFACTURER

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SYMBOLS

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

CE