CRP FL

RP 0090 CH 1 x 90 ml

INTENDED USE

Reagent for quantitative in vitro determination of C-reactive protein in biological fluids.

SUMMARY OF TEST

C-Reactive protein (CRP) is the acute phase protein of human serum, and is synthesized by liver hepatocytes. It is normally present in healty adults at low concentrations, but serum levels may increase over 1000-fold following stimulus. Due to the speed and magnitude of its response, CRP is a useful marker for detecting, predicting outcome of, and assessing the efficacy of treatment for various infectious, inflammatory and necrotic processes.

PRINCIPLE OF THE METHOD

C-Reactive Protein (CRP) selectively reacts with an anti-CRP antibody and forms an immunocomplex. The produced turbidity is proportional to the concentration of CRP 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.

CRP R1 **2 x 40 ml (liquid) white cap**

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

CRP R2 **1 x 10 ml (liquid) red cap**

Composition: Anti-human CRP 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

CRP R1: Danger. Causes serious eye damage (H318).

Wear protective gloves. Eye protection (P280). IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305+P351+P338). Immediately call a doctor (P310).

CRP R2: It is not classified as hazardous.

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: 340 nm
Lightpath: 1 cm
Temperature: 37°C

dispense:	blank	calibrator	sample
reagent R1	1 ml	1 ml	1 ml
water	55 µl	-	-
calibrator	-	55 µl	-
sample	-	-	55 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	125 µl	125 µl	125 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 CRP concentrations.
Successively, CRP concentration of a sample can be calculated by interpolating its absorbance value on the calibration curve.

EXPECTED VALUES

Adults < 5 mg/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.
If required, a human based calibrator is available:
CRP CALIBRATOR

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 2600 mg/l.

Sensitivity/limit of detection
The limit of detection is 1.0 mg/l.

Interferences
No interference was observed by the presence of:

hemoglobin	≤ 1000 mg/dl
bilirubin	≤ 30 mg/dl
lipids	≤ 1300 mg/dl
rheumatoid factor	≤ 415 IU/ml

Precision

intra-assay (n=10)	mean (mg/l)	SD (mg/l)	CV%
sample 1	28.6	0.44	1.54
sample 2	69.0	0.71	1.03

inter-assay (n=20)	mean (mg/l)	SD (mg/l)	CV%
sample 1	28.0	0.88	3.13
sample 2	69.2	1.87	2.70

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

CRP competitor = x
CRP FL CHEMA = y
n = 105

$y = 0.96 x + 0.07$ mg/l $r^2 = 0.998$

WASTE DISPOSAL

This product is made to be used in professional laboratories.
P501: Dispose of contents according to national/international regulations.

REFERENCES

Algarra M., Gomes D., Da Silva J.E. *Clin. Chim. Acta* 2013, 415, 1-9
Tietz Textbook of Clinical Chemistry, Fourth Edition, Burtis-Ashwood-Bruns (2006), 555-556.

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