CRP-Q

Turbidimetry

REF. 7710 1x100 ml with calibrator
REF. 7732 1x 50 ml with calibrator
REF. 7783 1x 50 ml without calibrator
REF. 7782 1x100 ml without calibrator

CE
IVD

Azienda certificata DNV

GIESSE DIAGNOSTICS

INTENDED USE

Quantitative determination of C-Reactive Protein (CRP) in serum.

PRINCIPLE

CRP-Q is a quantitative turbidimetric test for the measurement of C-reactive Protein (CRP) in human serum or plasma.

Latex particles coated with specific anti-human CRP are agglutinated when mixed with samples containing CRP. The agglutination causes an absorbance change, dependent upon the CRP contents of the patient sample that can be quantified by comparison from a calibrator of known CRP concentration.

SAMPLE

Freash serum. Stable 7 days at 2-8°C or 3 months at -20°C.

The samples with presence of fibrin should be centrifuged before testing.

Do not use highly hemolized or lipemic samples.

KIT COMPONENTS

Reagent (A) CRP-Q Diluent Volume = 45/90 ml	Tris Buffer 20 mmol/l, pH 8.2 Preservative
Reagent (B) CRP-Q Latex Volume = 5/10 ml	Latex particles coated with goat IgG anti-human CRP, pH 7.3 Preservative
Calibrator Volume = 1 ml	Serum of human origin **Concentration on label**

The reagents are stable until the expiration date indicated on the label if stored tightly closed at 2-8°C . Once opened, the reagents are stable one month at 2-8°C , in the absence of contamination.

keep bottles closed when not in use.

REAGENTS PREPARATION

Liquid Reagents, bring to room temperature before use.

PRECAUTIONS AND WARNINGS

Biological Risk for Reagent (B) and Calibrator

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.

Use the normal precautions required in the laboratory.

Components from human origin have been tested and found to be negative for the presence of HbsAg, HCV and antibody to HIV 1/2. However handle cautiously as potentially infectious.

Dispose of waste according to local laws.

PROCEDURE

Wavelength:	540 nm (530-550)
Lightpath:	1 cm
Temperature:	37°C

Use as monoreagent:

Mix gently latex 4-5 times before use.

Prepare the necessary amount as follows:

1 ml Reagent B (Latex) + 9 ml Reagent A (Diluent)

The workin solution (A+B) is stable 30 days at 2-8°C.

Adjust the instrument to zero with distilled water:

pipette:	sample	calibrator
Working solution (A+B)	1000 µl	1000 µl
sample	5 µl	
calibrator		5 µl

Mix, read the absorbance of the sample and the calibrator immediately (A1) and after 2 minutes (A2).

Use as bireagent:

Mix gently latex 4-5 times before use.

If necessary, prepare with saline following dilutions of the calibrator: 1, ½, ¼, 1/8, 1/16.

Pipette:	Blank	Sample	Cal (5 points)
Reagent (A)	900 µl	900 µl	900 µl
water	5 µl		
sample		5 µl	
Calibrators			5 µl
Reagent (B)	100 µl	100 µl	100 µl

Mix, read immediately the absorbance of the sample and 5 points of calibration (A1).

Wait 3 minutes and make the second reading (A2).

Reaction volumes can be proportionally varied.

This method describes the manual procedure to use the kit.

For automated procedure, ask for specific applications.

RESULTS CALCULATION

In the Bireagent Procedure is obtained a nonlinear curve

Obtain manually absorbance values to report on diagram.

CRP (mg/l) = $(A2\text{-}A1)_{Sample} / (A2\text{-}A1)_{Calibrator}$ x Calibrator Value

EXPECTED VALUES

CRP: < 6 – 8 mg/l

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL

You must perform the controls at each kit's use and verify that the values obtained are within the reference range reported in the operating instructions. For this purpose we recommend the use of control serum: REF. 7771 , REF. 7770 and the Calibrator: REF. 7774.

PERFORMANCE

Sensitivity: the sensitivity of the method is: 2 mg/l. Values less than 2 mg/l give non-reproducible results.

Prozone effect: No prozone effect up to 800 mg/l.

Linearity: the method is linear up to 150 mg/l. For higher values, dilute the sample 1:5 and multiply the result by 5.

Precision intra-assay:

	Level 1	Level 2	Level 3
Mean (mg/l)	8.6	16.8	50.5
DS	0.56	0.61	0.97
CV %	6.5	3.6	1.9

Precision inter-assay:

	Level 1	Level 2	Level 3
Mean (mg/dl)	8.6	16.8	50.5
DS	0.74	1.11	3.2
CV %	7.7	6.6	6.3

Interferences: bilirubin does not interfere up to 20 mg/dl. Lipemia does not interfere up to 10 g/l. Rheumatoid factors up to 300 U/ml does not interfere. Hemoglobin ≥ 5 g/l interferes.

Correlation against a reference method: Y = 0.892x + 0.282 r = 0.98

REFERENCES

1. Lars-Olof Hanson et al. Current Opinion in Infect Diseases 1997;10:196-201
2. Chetana Vaishnavi. Immunology and Infectious Diseases 1996; 6: 139-144
3. Yoshitsugy Hokama et al. Joournal of Clinical Lab. Status 1987; 1: 15-27
4. Kari Pulki et al. Sacand J Clin Lab Invest 1986; 46: 606-607
5. Young DS. Effects of disease on Clinical Laboratory Tests, 4th ed. AACC Press (1995).
6. Werner Muller et al. Journal of Immunological Methods 1985; 80: 77-90
7. Shogo Otsuji et al Clin Chem 1982; 28/10: 2121-2124

Giesse Diagnostics srl
Via Cervinara, 45 – Colle Prenestino – Roma – Italia. Tel. +39 06 22429353 / +39 06 22429097 – Fax +39 06 22429098
e-mail: info@giessediagnostics.com – web site: www.giessediagnostics.com

771007
Ed. 2012/04 rev. 00