Instructions for Use
For *in vitro* diagnostic use

PCR
CRP
Anvisa 80115310076

ORDER INFORMATION

Cat. No.	Kit size
4070060K	R1 2 x 25 mL + R2 1 x 10 mL + Standard 1 x 1 mL

INTENDED USE
Quantitative determination of C-Reactive Protein (CRP) in human serum by turbidimetric immunoassay.

WARRANTY
These instructions for use should be read carefully before using the product and the information contained therein should be strictly adhered to. The reliability of the test results cannot be guaranteed if the instructions are not followed.

SUMMARY
C-Reactive Protein is a non-specific acute phase-reactive protein which appears in the blood during an inflammatory process. In patients with inflammatory diseases the concentration of CRP increases and decreases more quickly than the red cells sedimentation rate (VHS).
CRP lacks diagnostic value when the patient's illness is not defined, but it is very useful for following-up inflammatory diseases, as well as for the differential diagnosis in certain cases.

METHOD
Measurement of antigen-antibody reaction by the end-point method.

COMPOSITION OF SUPPLIED REAGENTS
R1:
Phosphate buffered saline (pH 7.43)
Polyethylene glycol (40 g/L)
Sodium azide (0.95 g/L)

R2:
Phosphate buffered saline (pH 7.43)
Polyclonal goat anti-human CRP (variable)
Sodium azide (0.95 g/L)

Standard
Human serum with pre-determined CPR concentrations titled according to the standardization of the International Federation of Clinical Chemistry (IFCC) and in relation to the standardization of the College of American Pathologists.

STANDARD VALUES
The values assigned to the CRP Standard is lot-specific and valid for this lot only, which is indicated on the bottle label.
* Each laboratory must establish corrective actions in case of deviations in the recovery of the standard.
** Changes in the analyte value defined in this standard may occur due to restandardization of the reference material.

PREPARATION AND REAGENT STABILITY
The reagents and the standard are ready for use.
The reagents are stable until the expiration date, if contamination is avoided and if stored at a temperature of 2 to 8ºC.
Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

WARNINGS AND PRECAUTIONS
1. *In vitro* diagnostic use only.
2. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.
3. Take the necessary precautions when handling laboratory reagents.
4. Each donor unit used in the preparation of the standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA. Only donors with negative results were used in the manufacture. However, all products obtained from human body fluids must be handled with appropriate care in accordance with the recommended procedures for biohazardous materials since the absence of infectious agents cannot be proven.

WASTE MANAGEMENT
Follow the requirements of the current guidelines about technical regulation for the management of healthcare service waste, as well as other equivalent biosafety practices.

MATERIALS REQUIRED BUT NOT SUPPLIED
1. NaCl Solution (9 g/L)
2. General laboratory equipment
3. CPR Control from Kovalent

SPECIMEN
Use fresh serum. If the test cannot be carried out on the same day, the serum must be stored at 2 - 8°C for 48 hours. If stored for a longer period, the sample should be frozen.

ASSAY PROCEDURE
Application sheets for automated systems are available on request or at our site www.kovalent.com.br

GENERAL ASSAY PROCEDURE
- Sample/Control: No dilution.
- Reference curve: generate a reference curve by performing successive dilutions of the supplied Kovalent High PCR Standard, at 1:2 in 9 g/L NaCl Solution. Use 9 g/L NaCl Solution as the zero point.
- Test: Mix 64 µL of standards, controls or samples with 1000 µL of R1. Read the optical densities (OD1) of the standards, controls and samples at 340 nm. Add 200 µL of R2. Mix and incubate for 5 minutes at room temperature. Read the optical density (OD2) of the standards, controls and samples at 340 nm.
- Calculate ΔOD's, construct a reference curve and read the concentration of controls and samples.

PERFORMANCE CHARACTERISTICS
The performance characteristics for the CRP reagents were measured on a clinical chemistry analyzer (Hitachi 911).

Measuring Range:

Measuring range:	0 – 22 mg/dL
Limit of Detection:	0.6 mg/dL
Hook effect:	No risk
Sensitivity:	66.0 ABS units / concentration unit

Specificity / Interferences:
- Specificity: Monospecific
- Interferences: No interference for : Hemoglobin (≤250 mg/dL), Na-citrate (≤1000 mg/dL), Heparin (≤50 mg/dL), Bilirubin (≤20 mg/dL), Triglyceride (≤2500 mg/dL).
- Limitations: None

Precision [%CV]

	Low	Medium	High
Intra-Run	4.46	0.89	0.75
Inter-Run		4.29	6.60

Accuracy [mg/dL]

Control	Theorical	Measured
APTEC	1.00 (0.85 – 1.15)	0.9
Clinic 1	1.52 (1.29 – 1.75)	1.30
Clinic 2	3.39 (2.88 – 3.90)	3.15
Clinic 1	6.69 (5.69 – 7.69)	6.41

METHOD COMPARISION
Comparison of methods between Kovalent PCR and a commercial test (X) demonstrated the following result:
Comparison with nephelometry:
Y = 0.9981x – 0.0142 / r = 0.9917

REFERENCE VALUES
0.0 – 1.0 mg/dL (IFCC)
This value should be used as a guide only.
Each laboratory must establish its own reference values.

LITERATURE

1. Manack, J.R. and Richards, CB., J. Immunol. 20, 1019 (1971)
2. Ritchie, RF., J. Lab. Clin. Med. 70, 512 (1967)
3. Pepys MB. et al., Ann. NY Acad. Sci, 389, 459 (1982)

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CONSUMER INFORMATION

Symbols used:

	Manufacturer
	Temperature limit
	In vitro diagnostic device
	Caution
	Operating instructions
	Recycling material
	Do not discard directly into the environment
	Batch code
	Date of manufacture
	Use by date
	Biological hazards
	Highly toxic
	Corrosive
	Harmful

Manufacturer:

Kovalent do Brasil Ltda.
Rua Cristóvão Sardinha, 110 – Jd. Bom Retiro São Gonçalo – RJ – CEP 24722-414 www.kovalent.com.br
CNPJ: 04.842.199/0001-56

Kit sizes variations on demand:

Anvisa No.	Kit size
80115310076	R1 1 x 25 mL + R2 1 x 5 mL + Standard 1 x 1 mL

Customer Service: sac@kovalent.com.br - (21) 3907-2534 / 0800 015 1414

Expiration date and Lot no.: See label