C- Reactive Protein (CRP)
(Immunoturbidimetric Method)

- **Kit Specifications:**

	Reagent/Quantity	Storage
Cat. No.: **CP0011**	R.1: 1x 50 ml R.2 1x10ml total 60 ml	2-8°C
Cat. No.: **CP0111**	R.1: 4x 50 ml R.2 2x20ml total 240 ml	2-8°C
Cat. No.: **CP0017**	R.1: 1 x 50 ml R.2 1x 10ml total 60 ml	2-8°C
Cat. No.: **CP0117**	R.1: 4x 50 ml R.2 2x20ml total 240 ml	2-8°C

- **Intended Use:**

In Vitro Diagnostic reagent pack for the quantitative determination of C- reactive protein CRP, in human serum on automated and semi-automated photometric systems.

- **Summary and Explanation:**

CRP is cyclic pentameric non glycogenic serum acute protein with contain the five identical subunits. The total weight is 105 kDal. This protein is mainly produce in liver and the cell wall of artery. In the present of calcium ion can attached to the most phosphorylcholin phospho lipids. The main reason of this name is the ability of this protein which can bind to capsular C-polysaccharides in the pneumococcus infection. CRP has some different roles such as attached to chromatins and histones but the essential physiological roles of CRP is clean up the cellular wastage. Meanwhile, CRP conductivity to phagocytic cells to increase the phagocytose anti genes. Also, attach to some classic complement and stimulate macrophage of phagocytose, connect to LDL in plaque of atherosclerotic which remove LDL from plaque, connect to T lymphocytes increased the cytotoxic T cell response and modified of the stick platelets together. The amount of the CRP will have increased after myocardial infarction, stress, trauma, infection, inflammation, surgery and neoplastic cell proliferation. The evaluation concentration of CRP is critical in inflammation disease, infection diagnostic in leukemia, treatment management of septicemia and meningitis in children which is difficult to get bacteria logical samples. The measurement of CRP compare to ESR is more sensitive. The key point is the concentration of CRP in early and pre early stage of diseases rise rapidly and after well treatment and recovery reduction speedy.

Principle of the Method:

The principle of this assay is measurement the level of CRP, C reactive protein. The complex is make turbidity and measurable on ۲40 Nano meter. The intensity of turbidity is related to amount of CRP in the sample. The base of this assay is reaction between antigen and antibody. The CRP in the sample get sensitive by anti-body against CRP in human

CRP antigen + anti-CRP antibody ⟶ antigen/antibody complex

- **Reagent Preparation and Stability:**

Reagent is ready for use.
Before use, mix reagent by gently inverting each bottle.
Reagent is stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contaminations prevented during their use.
Do not use reagents over the expiration date.
Do not freeze and protect from light. R1 is transparent and colorless but R2 is transparent and light yellow.
The following table is the preparation of calibrator with normal saline.
The normal saline 0.9%NaCl use as a zero.

Dilution	Neat	1:2	1:4	1:8	1:16
Dilution Factor	1	0.5	0.25	0.125	0.06

Waste Management:

Refer to local legal requirements for chemical disposal regulations.
Warning: Handle waste as potentially biohazardous material.
Dispose of waste according to accepted laboratory instructions and procedures.

- **Warnings and Precautions:**

For In Vitro Diagnostics Use Only.
For Professional Use Only.
In case of serious damage to the bottle or cap, resulting in product leakage or contamination, do not use the reagent pack and contact your distributor.
Take all necessary precautions required when handling laboratory reagents.
Do not use components past the expiry date stated on the Bottles.
Do not interchange caps among components as contamination may occur and compromise test results. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.

- **Type of Specimen:**

Use fresh serum non- haemolysied and no lipema. The stability of CRP in serum/plasma samples at 2-8°C for 8 days and at-20°C for 3 months. Avoid any contamination, freezing and DE freezing the samples
The serum should be collected from the blood less than 2 hours.

Required but not Supplied:

CRP calibrator from TKS or other valid calibrators.
CRP Control Level 1 & 2 from TKS or other valid controls.
Saline solution 0.9 % NaCl
General laboratory equipments

- **Notes:**

Carefully read instructions for use.
It is recommended to use disposable material. If glassware is used the material should be scrupulously cleaned with hydrochloric acid 1 N and then thoroughly rinsed it with distilled water.
Use clean disposable pipette tips for its dispensation.
Disposable and glassware material used must be free of metals, ions and detergents.

Performance Characteristics:

Performance results can vary with the instrument used.
Data obtained in each individual laboratory may differ from these values.

The Maximum concentration will be obeying base of calibrator
LOD: 2 mg/L
For samples with a higher concentration (base on maximum concentration of your calibrator), dilute 1:1 with 0.9 % NaCl and re-assay. Multiply result by 2.

Prozone:

In this assay, till 500mg/dl concentration no prozone will not be observed.

Precision:
Intra Assay-Within run CRP

Sample	n	Mean (mg/dl)	SD (mg/L)	CV (%)
1	20	11.7	0.36	3.05
2	20	75.4	0.89	1.18

Inter Assay-Between run CRP

Sample	n	Mean (mg/L)	SD (mg/L)	CV (%)
1	20	11.4	0.42	3.71
2	20	75.3	1.00	1.33

- **Accuracy:**

Results obtained using BIOMEDIC reagents (y) did not show systematic differences when compared with other commercial reagents (x).
Correlation coefficient (r): 0.999
Regression equation: Y = 1.015 (X) + 0.653 mg/L
The results of the performance characteristics depend on the analyzer used.

- **Interfering Substances:**

the less concentration of below items are not interfering in this assay.

Bilirubin (mixed isomer)	Less than 10% interference up to 600 µmol/l Bilirubin
Lipemia	Less than 10% interference up to 5 g/L Intralipid
Haemolysis	Less than 10% interference up to 5g/L Hemoglobin.

Manufactured by: TOSE'E KIMIA SA'ADAT, No.5, 32nd Alley, Asadabadi St. Yousef abad, Tehran-IRAN
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Rev 01: Issued on 20 February 2023

ISO 13485:2016
ISO 9001:2015

IVD

- **Reference Values:**

Adults	**<۱۰ mg/L**

Each laboratory should establish its own expected values. The creatinine results should always be reviewed with the patient's medical examination and history.

- **Assay Procedure:**

Allow reagents to reach working temperature before using.
A proportional variation of the reaction volumes indicated does not change the result

Assay conditions:

340nm	**Wavelengths**
37°C	**Incubation Temperature**
1 cm	**Cuvette**

Adjust the instrument to zero with distilled water.

Control/Sample/Calibrator	**Blank**	
1000l µ	1000 µl	**R1**
60 µl	-	**Control/Sample/Calibrator**
Gently mix and incubate 37°C **for 5 minutes**. Measure the first absorbance OD1 then added R2.		

200 µl	200 µl	**R2**
Gently mix and incubate 37°C for 10 minutes. Measure the second absorbance OD2.		

- **Calculations:**

ΔAbs= [(A2-A1) sample or calibration]

The calculation of change of absorbance ΔA is should applied by A2 minus to A1. Then, make logarithm table so base on the curve the concentration of control and samples are determine.

Conversion units:

CRP (mg/L) = mg/dl x 10

TOSE'E KIMIA SA'ADAT has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

- **References:**

1-Claus DR.Osmaud AP, Gewurz H. J Lab Clin Med 87.120.128(1976)
2-Burtis CA. Ashwood ER. Tietz Fund. Of Clin.Chem. 5th ed.:30-54 and 462-494.
3-Shire B, De Beer FC, Pepys MB, Clin,Chem. Acta 117.13-23(1981)
4-Baudner S, Dati F. Standardization of the measurement of 14 proteins in human serum based on the new IFCC/BCR/CAP international reference material CRM470. J Lab Med 1996; 20:145-152.

Symbols:

The following symbols are used in the labelling of TOSE'E KIMIA SA'ADAT systems:

IVD	In Vitro Diagnostics	Σ	Contains sufficient for <n> tests
LOT	Batch Code		Temperature limit
REF	Catalogue No.		Consult instruction for use
	Expiry Date		Caution
	Date of Manufacture		Keep dry
	Manufactured by		This way up
	Biological Risks		Keep away from sunlight

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