Total Protein (TP)
(Biuret/Colorimetric Method)

- **Kit Specifications:**

	Reagent/Quantity	Storage
Cat. No.: **TP0011**	R.1: 6 x 50 ml total 3·0 ml	2-8°C
Cat. No.: **TP0017**	R.1: 5 x 60 ml total 300 ml	2-8°C

- **Intended Use:**

In Vitro Diagnostic reagent pack for the quantitative determination of Total Protein in human serum/plasma on automated and semi-automated photometric systems.

- **Summary and Explanation:**

There is a more than 300 kind of proteins in human plasma. Which most of them produce in liver. The protein is a constituent part of muscle, enzymes and hormones. Protein is an essential and key point of most of the existence material in the human body. The main duty of it is divide water between blood and tissue. Mostly, formed from Albumin and globin but the amount of these are different in depends on person by person and the diseases. The increase level of protein which caused by losing the water. Meanwhile, in chronic malignant anomalies, liver cirrhosis and dehydration observed this increasing.

The decrease level of total protein may cause by mal nutrition, internal bleeding, burning, digestion problems and lack of synthesis. Also, the total protein decrease by imperfect protein synthesis in liver, faulty absorption in intestine, kidney failure and mal nutrition.

The hyper proteinimia is not common compare to hypo proteinimia but lose the water in plasma caused by diarrhea, vomiting and increase the exclusive protein in serum such as immunoglobins observed. The total protein measurement usually tested by others assays such as albumin serum, liver assays and protein electrophoresis.

Principle of the Method:

This method is based on protein peptide binding in the sample in alkaline background with Copper ions (Cu2+) to make a Blue-purple/cobalt blue complex which measurement on 540 nm. The intensity of the color will have measured on 530-550 Nano meter wavelength which is correlate with the amount of Total protein on the sample.

$$\text{Protein} + Cu^{2+} \xrightarrow{\text{Alkaline pH}} \text{Copper-Protein Complex (Blue-purple /cobalt blue Color)}$$

- **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.
The reagent is transparent and light blue color.

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.
Carefully read instructions for use.
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-hemolysis, plasma heparinized or EDTA. The stability of Total protein in the samples at 25-15°C in 6 days, 2-8°C in 30 days and at-20°C in 12 months. The plasma /serum should be collected immediately after blood collection.

Required but not Supplied:

General chemistry calibrator from TKS or other valid calibrators.
General chemistry 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. The reference of total protein is light blue. Do not use if any turbidity and dark particles see in the reference.

Performance Characteristics:

Performance results can vary with the instrument used.
Data obtained in each individual laboratory may differ from these values.
Maximum determination in this assay is 14g/dl
LOQ: 1 g/dl
For samples with a higher concentration (14g/dl), dilute 1:1 with 0.9 % NaCl and re-assay. Multiply result by 2.
Precision:
Intra Assay-Within run Total Protein

Sample	n	Mean (g/dl)	SD (g/dl)	CV (%)
1	20	6.53	0.01	0.21
2	20	4.89	0.01	0.24

Inter Assay-Between run Total Protein

Sample	n	Mean (g/dl)	SD (g/dl)	CV (%)
1	20	6.77	0.07	1.05
2	20	5.08	0.05	0.94

- **Accuracy:**

Results obtained using BIOMEDIC reagents (y) did not show systematic differences when compared with other commercial reagents (x).
Correlation coefficient (r): 0.97002
Regression equation: Y = 0.954 (X) + 0.511 g/dl
The results of the performance characteristics depend on the analyzer used.

- **Interfering Substances:**

Bilirubin (mixed isomer)	Less than 10% interference up to 600 µmol/l Bilirubin
Lipemia	Less than 13% interference up to 1.25 g/l Intralipid.
Haemolysis	Less than 10% interference up to 2.5g/l Haemoglobin.

- **Reference Values:**

Serum/Plasma	
Infants boys 1 to 30 days	**4.1-6.3 g/dl**
Infants girls1 to 30 days	**4.2-6.2 g/dl**
Boys 1 to 6 months	**4.7-6.7g/dl**
Girls 1 to 6 months	**4.4-6.6 g/dl**
Boys Child 7 to 12 months	**5.5-7.0 g/dl**

Manufactured by: TOSE'E KIMIA SA'ADAT, No.5, 32nd Alley, Asadabadi St. Yousef abad, Tehran-IRAN
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Girls Child 7 to 12 months	**5.6-7.9 g/dl**
Boys 2 to 18 years	**5.7-8.0 g/dl**
Girls 2 to 18 years	**5.7-8.0 g/dl**
Adults	**6.6-8.8 g/dl**

Each laboratory should establish its own expected values. The Total Protein 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:

540 (530-550) nm	**Wavelengths**
37 °C	**Incubation Temperature**
1 cm	**Cuvette**

Adjust the instrument to zero with distilled water.

Control/Sample/Calibrator	**Blank**	
1000 µl	1000 µl	**R**
25 µl	-	**Control/Sample/Calibrator**
Gently mix and incubate for 5 minutes at 37°C. or 10 minutes at 25°C Avoid direct sunlight. Then measure the absorbance from A sample and A calibrator. The absorbance of sample and calibrator against the blank. The stability of color is 30 minutes. Avoid direct sunlight.		

- **Calculations:**

Total Protein(g/dl) = Abs. Sample x Cal. Conc. (g/dl)
Abs. Calibrator

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

- **References:**

1-Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: THBooks Verlagsgesellschaft; 1998.p.644-7.
2-Johnson Am, Rohlfs EM, Silverman LM. Proteins. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed.
3-Flack C.P. and Woolen J.W., Clin Chem., 30(1984)-559.
4-Tietz NW, ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia, Pa:WB Saunders Company, 1995:518-522
5-Henry RJ, Cannon DG, Winkelman JW, "Clincial Chemistry, Principles and Techniques." Harper & Row, 2nd ed. 1974.

Biological Risks

Keep away from sunlight

ISO 13485:2016
ISO 9001:2015

IVD

Rev 01: Issued on 20 February 2023

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