Bioway Chemistry Reagent Series

The Serum TP Reagent Kit

Detection of Total Protein in Human Serum or Plasma on Chemistry Analyzers

Cat. No. R053K11 ***The Serum TP Reagent Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram

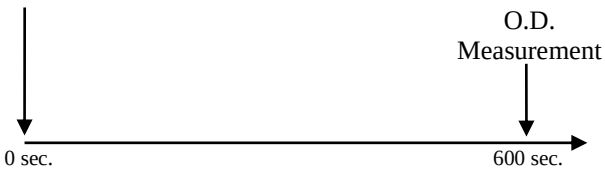

Table 1: Instrument Parameters*

Calibration method	2-point Linear	Slope of reaction	Increase
Testing wavelength	Dλ : 540 nm Sλ : 660 nm	Sample volume	4 µl
Test method	1 point end	R1 volume	200 µl
Reaction temperature	37℃		

*Refer to Figure 1 and the package insert for detail

INTENDED USE

Bioway Chemistry Reagent Series **TP Reagent Kit** (the Kit) is an assay intended for *in vitro* qTPntitative detection of total protein in human serum or plasma on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Total protein is an easy way to monitor the process of many different diseases. If the test result is abnormal, additional tests should be performed to identify which specific protein is out of the range for diagnosis. The elevated total protein may indicate the possibility of inflammation, infection or bone marrow disorders. On the other hand, the low total protein level may be caused by kidney diseases, liver disorder and bleeding.

TEST PRINCIPLES

The Kit utilizes enzymatic and kinetic reactions to measure the amount of TP (g/L) in human serum or plasma.

$$\text{Protein} + Cu^{2+} \xrightarrow{\text{Alkali}} \text{Blue-violet complex}$$

Serum protein react with cupric ions under alkali condition. Each ion complexs with 5 or 6 peptide bonds and produce blue-violet complexes. Tartrate and iodide are added into the reaction to prevent auto-reduction of the alkaline copper complexes.

The color formed which can be measured at 540nm is directly proportional to the TP activity in the sample.

MATERIALS PROVIDED

Reagents:

R1	Sodium hydroxide	600 mmol/L
	Copper	12 mmol/L
	Potassium sodium tartrate	32 mmol/L
	Potassium iodide	30 mmol/L

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer
2. TP control and calibrator set (commercially available)

INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

STORAGE AND STABILITY

Store the reagents at 2-8℃. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. The reagent is stable for 1 month at 2-8℃ after opening.

PRECAUTIONS

1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect blood or serum with EDTA, heparin or oxalic acid and prevent hemolysis.
It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, specimens may be stored at room temperature for a week.

TEST PROCEDURE (see Figure 1)

Reagent 1 is liquid stable ready-to-use, no preparation needed.

Calibration: Recommend using commercially available calibrator set for optimal results.

Test procedure: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

1. Add 4 µl of sample and 200 µl of R1; mix well and incubate at 37℃ for 10 minutes.
2. Take optical density measurement.
3. Calculate average Δ A

RESULT

The amount of TP in g/L can be obtained by the following calculation:

$$\text{TP (g/L)} = \frac{\Delta A\text{test}}{\Delta A\text{standard}} \times \text{standard solution (g/L)}$$

Please refer to instrument application if testing under different conditions.

EXPECTED VALUES

After walking 64~83 g/L
While lying 60~78 g/L
It is recommended for each laboratory to establish its own expected values

QTPLITY CONTROL

Using commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly

performed and all reagents and the instrument are functional as specified.

LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. The test result from the Kit should not be used as the only basis for definite diagnosis.
3. Samples with TP exceeding the maximum measurement range should be diluted with saline and retested.
4. The alkaline waste reagent should be discarded with large amount of water.

PERFORMANCE CHARACTERISTICS

Linearity: 0 – 120 g/L (R≥0.990)

Accuracy: Bias proportion 90%~110%

Precision: Within Run: CV≤4%;
Run-to-Run: CV≤6%

Interference: no interference detected for: Unconjugated bilirubin (≦171μmol/L), ascorbic acid (≦50mg/dl), bilirubin (≦171mg/dl), hemoglobin (≦200mg/dl) and lipid (≤1000NTU).

Reagent Blank Absorbance: At 540nm wavelength and 10mmoptical diameter, O.D. ≤0.20.

REFERENCES

1. Gornall A. *et al.*, J. Biol. Chem., 177:752 (1949)
2. Young D. S. *et al.*, Clin. Chem., 21:1D (1975).
3. Flack C. P. *et al.*, Clin. Chem., 30:559 (1984)

Not Intended for Sale in the United States.

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