Total protein Assay Kit (TP)

Method: Biuret Reaction method

Cat .No.	Package Size	Analyzer
EGS0911G	8×70 ml	For Hitachi917& OlympusAU640/400/600
EGB0910G	6×100 ml	For Hitachi 717 &ShimadzuCL7200/8000
EGH0911G	6×50 ml	For Hitachi 902
EGD0911G	36×4.3 ml	For Siemens Dupont/Siemens Behring Series
EGTP460BS	2×25mL	For Mindray BS120/180/190/200/220/230/240/430/460/830
EGGTP	2×25mL	For Semi Auto Analyzer

INTENDED USE

For in vitro quantitative determination of TP in human serum or plasma.

CLINICAL SIGNIFICANCE

Total protein is the sum of albumin and globulin. Its clinical significance depends on the changes of albumin and globulin. Increased in various causes of dehydration caused by blood concentration (such as diarrhea, vomiting, shock, high fever), resulting in monoclonal increase of globulin diseases (such as autoimmune diseases); decreased in various causes of serum protein loss and inadequate intake, as well as protein synthesis disorders.

ASSAY PRINCIPLE[1,2]

In alkaline environment, copper (II) ion reacts with polypeptide bond in protein to form colored complex. The content of total protein is directly proportional to the color.

REAGENT COMPOSITION

Contents	Concentration
$CuSO_4$	12 mmol/L
NaOH	0.6 mol/L
KI	30 mmol/L
potassium sodium tartrate	30 mmol/L

STABILITY AND PREPARATION OF REAGENTS

1. Stable up to the expiry date when the reagent is sealed and stored in dark at 2-8 ℃.
2.The production date and expiry date are shown on the label.
3.Once opened, the reagents are stable for 28 days when refrigerated on the analyzer or refrigerator.
4.Reagents should not be contaminated.

APPLICABLE INSTRUMENT

This kit is theoretically suitable for all biochemistry analyzers and spectrophotometers covering the wavelength range of 546nm.
It is recommended to use this kit on a biochemistry analyzer for testing according to laboratory conditions.

SAMPLE COLLECTION AND PREPARATION

Fresh serum.
EDTA sodium salt, heparin lithium anticoagulant plasma.

ASSAY PROCEDURE

Test Condition(Hitachi 917)

Main wavelength	546nm	Sample(S)	4 μl
Secondary wavelength	700 nm	Reagent 1(R1)	200μl
Reaction temperature	37℃	Reagent 2(R2)	-
Cuvette diameter	1cm	Reaction type	End point method

Operate procedure

Add into cuvette：	
Sample(S)	4μl
Reagent 1(R1)	200μl
Mix well and incubate for 10 minutes at 37℃, Measure the absorbance of the sample A1.	

Note: Parameters above are only introduced with Hitachi 917 as an example. The parameters of different biochemistry analyzers are slightly different. Please read the manual carefully before setting parameters.

CALIBRATION

It is recommended to use Gcell calibrator serum. Calibrator traces to the international reference materials SRM 927.
1. According to the requirements of the calibration procedure in the operation manual of biochemistry analyzer, each laboratory establishes its own calibration procedure according to the specific conditions.
2 Requirements for calibration and frequency: It is recommended to calibrate at least once every two weeks. When the following situations occur, it is recommended to re-calibrate: change the reagent batch number, the indoor quality control runs out of control, the biochemistry analyzer carries out major maintenance or replaces the main parts such as light source or cuvette.

QUALITY CONTROL

It is recommended to use Gcell control serum**.** The absorbance of quality control should be within the labeled value range. If the results deviate from the scope, please find out the reason by following steps:
1 Check the parameter setting and light source.
2 Check the cleanliness of the cuvette and sampling needle.
3 Check whether water is contaminated or not. Bacterial growth can lead to incorrect results.
4 Check the reaction temperature.
5 Check the validity of the kit.

CALCULATION OF RESULTS

$$\text{Concentration} = \frac{A_{sample} - A_{blank}}{A_{calibrator} - A_{blank}} \times \text{Calibrator value}$$

REFERENCE RANGE

Adult serum: 66-87g/L (6.6-8.7g/dL)
New born serum：53-89g/L (5.3～8.9g/dL)
Laboratories are suggested to establish its own reference interval according to age, sex, diet and region.

INTERFERENCE

The effect of Hb ≤ 500mg/dL, VitC ≤ 30mg/dL, TBIL ≤ 40 mg/dL, Intralipid ≤333mg/dL, is less than 10%.

ACCURACY

The kit is tested with international reference materials SRM927, the relative deviation of the test results of the kit shall ≤10%.

SENSITIVITY

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When the sample concentration is 45g/L, the absorbance change should ≥ 0.0300.

LINEARITY

In the range of [2.0，120.0]g/L, the linearity correlation coefficient r ≥ 0.995. In the range of [2.0，10.0]g/L, the absolute deviation should ≤±1.0g/L; In the range of (10.0，120.0]g/L, the relative deviation should ≤±10%.

PRECISION

Repeatability precision was obtained by testing control or sample for 20 times of repeated measurement. Intermediate precision was obtained by testing human samples or control for 2 batches per day, and each batch was measured for 2 times separately in morning and afternoon, for total 20 days. The results are as follows:

a)Repeatability(N=20)

	Mean(g/L)	CV(%)
Level1	41.83	0.60
Level 2	46.91	1.02

b)Intermediate precision(N=80)

	Mean(g/L)	CV(%)
Level1	57.41	0.46
Level 2	46.49	0.77

SAFETY PRECAUTIONS AND WARNINGS

1. The reagent contains preservative. If it enters eyes, mouth or skin, please rinse it thoroughly with clean water immediately. If necessary, go to the hospital.
2. The reagent contains preservative, which can react strongly with copper, lead and other metals to form azide metal. Therefore, please dilute the waste liquid and flush the drain pipe to avoid residue in the drain pipe.
3. In the process of detection, please do not mix or exchange reagents with different numbers.
4. The unsealed reagent should be stored in a sealed way according to the specified method, and it is forbidden to use it after expiration.
5. Please dispose the test tube and other instruments that have touched the test specimen according to the relevant regulations on the treatment of medical waste. The following processing methods can be selected: Sterilize with pressure sterilizer at 121 ℃ for 15 minutes (but do not use pressure sterilizer for waste containing hypochlorite solution), or soak in hypochlorite solution (effective concentration greater than 1000ppm) for more than one hour.

REFERENCES

1. Weichselbaum, T.E., Amer. J. Clin. Path., 16: 40.
2. Henry, R.J., Cannon, D.C., Winkelman, J.W., "Clinical Chemistry, principles and Techniques", Harper & Row,2nd Ed. 1974.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

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