Total protein Assay Kit (TP)

Method: Biuret Reaction

Cat .No.	Size	Instrument
GB0910G	R1:6×100 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS0911G	R1:8×70 ml	For Hitachi917 & OlympusAU640/400/600
GH0911G	R1:6×50 ml	For Hitachi902
GX0911G	R1:2×100 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-800
GT0911G	R1: 7×50 ml	For TOSHIBA

INTENDED USE
For the quantitative *in vitro* determination of total protein in human serum .

CLINICAL SIGNIFICANCE
The assay kit is for determination of serum total proteins (TP). Proteins are constituents of muscle, enzymes, hormones and several other key functional and structural entities in the body. They are involved in the maintenance of the normal distribution of water between blood and the tissues. Consisting mainly of albumin and globulin the fractions vary independently and widely in diseases. Increased levels are found mainly in dehydration. Decreased levels are found mainly in malnutrition, impaired synthesis, protein losses as in hemorrhage or excessive protein catabolism.

ASSAY PRINCIPLE[1,2]
Total proteins bind with the Cu^{2+} in a buffered medium to form a coloured complex. The intensity of the colour formed is directly proportional to the amount of total proteins present in the sample at 546 nm.

SAMPLE COLLECTION AND PREPARATION
Serum.
Serum samples are stable for a week at room temperature.

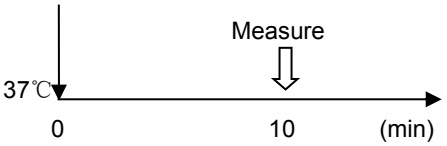
REAGENT COMPOSITION

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

STABILITY AND PREPARATION OF REAGENTS
Reagent is ready to use.
Protect from bright light. Stable up to the expiry date when stored at 2-8℃.

ASSAY PROCEDURE
Test Procedure for Analyzers
Assay Mode: End Point
Wave Length (main/sub): 546 nm/700 nm

Sample: 6 µl
R1: 300 µl



1. Mix 6 µl sample with 300 µl R1 and incubate at 37℃ for 10 minutes.
2. Measure the absorbance of the sample (A_{sample}) and calibrator ($A_{calibrator}$) against reagent blank.

CALCULATION

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

CALIBRATION
Recommend that this assay should be calibrated using Randox Calibration Serum Level 3 or Level 2.

QUALITY CONTROL
Randox Assayed Multisera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:
1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE
Adult Serum: 66-87 g/L (6.6-8.7 g/dl)
Neonatal Serum: 53-89 g/L (5.3-8.9 g/dl)
It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY
The method is linear up to 128 g/L. If the sample above this concentration should be diluted with 0.9% NaCl and repeat assay. Multiply the result by dilution factor.

PRECISION
The CV of the test should be less than 5%

Inter assay precision		
N=5	Level1	Level 2
Mean (g/L)	57.355	46.327
SD	0.226	0.202
CV	0.394%	0.436%
Intra assay precision		
N=20	Level1	Level 2
Mean (g/L)	57.412	46.494
SD	0.265	0.359
CV	0.462%	0.773%

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INTERFERENCE

The following analyze were tested up to the levels indicated and found not to interfere:

Hemoglobin:	200 mg/dl
Intralipid	3000 mg/dl
Bilirubin:	40 mg/dl
Ascorbic Acid:	30 mg/dl

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. The reagents contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

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

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