TOTAL PROTEIN (2-8°C)

CATALOGUE NUMBER	KIT SIZE (ML)
MPRTP02	6x60ml / 1x5ml

Intended Use:
For *In Vitro* diagnostic use by professionals only.
This reagent is intended for the quantitative determination of Total Protein in human serum and plasma.

Clinical Significance:
Plasma proteins are synthesised predominantly in the liver, plasma cells, lymph nodes, spleen and bone marrow. In the course of disease total protein concentration and the percentage represented by the individual fractions can deviate significantly from normal values. Hypoproteinaemia can be caused by diseases and disorders such as loss of blood, nephrotic syndrome, severe burns and salt retention.
Hyperproteinaemia can be observed in cases of severe dehydration and illnesses such as multiple myeloma.
Changes in the relative percentage of plasma proteins can be due to a change in the percentage of one plasma protein fraction. Often in such cases the total protein does not change and it is common to use the A/G ratio as an index of the distribution of albumin and globulin fractions. Marked changes in this ratio can indicate acute/chronic inflammation, cirrhosis of the liver, glomerulonephritis, hepatitis and lupus erythematosus among others. Total protein measurements are therefore used in the diagnosis of a variety of disease states involving the liver, kidneys or bone marrow, as well as metabolic or nutritional disorders.

Test Principle:
Divalent copper reacts in alkaline solution with protein peptide bonds to form the characteristic purple coloured Biuret complex. The intensity of the complex, which can be determined spectrophotometrically, is directly proportional to the protein concentration in the sample.

Reagent Composition:

REAGENT	COMPONENT	CONCENTRATION
Biuret Reagent R1	Potassium Iodide	30 mmol/l
	Potassium sodium tartrate	32 mmol/l
	Copper Sulphate	18 mmol/l
	Sodium Hydroxide	200 mmol/l
Standard	BSA	40 g/l (4 g/dl)

Reagent Preparation and Stability:
R1: Liquid, ready to use.
Standard: Liquid, ready to use.
R1 and Standard are stable to the expiry date when stored unopened at 2 - 8°C. Dispose of reagents carefully in line with local guidelines.

Sample Collection, Preparation and Stability:
Collect serum and heparin or EDTA plasma by standard venepuncture technique. Total Protein will be stable in the sample for up to 72 hours at 2 - 8°C or up to 6 months at -20°C. Total protein concentration may be 0.4 – 0.8 mg/dl lower when the sample is collected from a patient situated in the recumbent position rather than upright. Centrifuge samples containing precipitate before performing the assay.

Assay Procedure:

WAVELENGTH	546 nm (530 – 570 nm)
TEMPERATURE	20 - 37°C
CUVETTE	1cm Path Length
BLANK	Reagent Blank

	Blank	Standard	Sample
Sample	-	-	20 µl
Standard	-	20 µl	-
Reagent	1000 µl	1000 µl	1000 µl
Mix and incubate for 10 minutes at assay temperature. Read the absorbance (Δ Abs) of Sample/Standard against the Reagent Blank.			

Calculation:
Concentration (g/l) = $\frac{\Delta Abs\ Sample}{\Delta Abs\ Standard}$ x Concentration of Standard
By factor: 19 x ΔA sample = Protein in g/dl

Performance Characteristics:

Measuring range:
2 - 130 g/l (0.2 - 13.0 g/dl)
Dilute samples with higher concentrations using Normal saline 1+2 and rerun the assay. Multiply the result by the dilution factor (for 1+1 dilution, the dilution factor is 3)

Analytical Sensitivity: (Lowest detection limit):
2.0 g/l

Imprecision
Intra-Assay Precision:

Sample	Mean (g/dl)	SD (g/dl)	CV %
Pool 1	5.20	0.039	0.73
Pool 2	5.37	0.039	0.75
Pool 3	5.70	0.037	0.65

Inter-Assay Precision:

Sample	Mean (g/dl)	SD (g/dl)	CV %
Pool 1	5.15	0.070	1.36
Pool 2	5.48	0.086	1.57
Pool 3	5.95	0.085	1.43

Method Comparison:
Prestige Diagnostics Total Protein (y) was compared with another commercially available reagent (x) and gave the following results:
y = 0.951 x + 2.75, r = 0.999

Interferences:
Criterion: Recovery within +/- 10%.
Icterus: No significant interference up to 22 mg/dl of Bilirubin.
Haemolysis: No significant interference up to 1100 mg/d of haemoglobin.
Lipaemia: No significant interference up to Triglycerides concentration of 2150 mg/dl. There is a poor correlation between turbidity and triglycerides concentration.

Reference Range:

Adult	6.6 – 8.7 g/dl (66 – 87 g/l)

Expected values according to Tietz:

Umbilical Cord	4.8 – 8.0 g/dl
Premature	3.6 – 6.0 g/dl
Newborn	4.6 – 7.0 g/dl
1 week	4.4 – 7.6 g/dl
7months – 1 year	5.1 – 7.3 g/dl
1-2 years	5.6 – 7.5 g/dl
>3 years	6.0 – 8.0 g/dl
Adult (ambulatory)	6.4 – 8.3 g/dl

Each laboratory should establish its own mean reference range according to the population.

Limitations:
The result from this test should not be used as the sole criteria for diagnosis, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Automated systems:
Contact Prestige Diagnostics Technical Department for applications on a wide range of automated analysers.
For automation we recommend the use of a serum based calibrator.

Quality Control and Calibration Material:
Calibration Serum: **QCCCAL1 / QCCCAL2**
Human Assayed Control Normal: **QCCHAN1 / QCCHAN2**
Human Assayed Control Elevated: **QCCHAE1 / QCCHAE2**

References:

1. Tietz N. W. (ed) Clinical Guide to laboratory tests 3rd Philadelphia, Pa: W8 Saunders Company. 1995; 518 – 522.
2. Bablok W et al, A General Regression Procedure for Method Transformation. J Clin Chem Biochem 1988; 26;783-790.
3. Brobeck J.R (ed) Physiological Basis of Medical Practice, 9th Baltimore MD: Wilkins and Wilkins, 1973; 4-7.
4. Welchselbaum T.E Amer H Clin Path 1946; 16:40.
5. Josephson B, Gyllensward C. The Development of the Protein Fractions and of Cholesterol Concentration in the serum of Normal Infants and Children. Scandinav J Clin Lab Investigation 1957; 9:29.

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		

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V3: rev Oct 2018