TOTAL PROTEIN

Cat. No.	Pack Name	Packaging (Content)
BLT00054	TP 250	R1: 5 x 50 ml, R2 standard: 1 x 5 ml
BLT00055	TP 500	R1: 2 x 250 ml, R2 standard: 1 x 5 ml

EN

CE IVD

INTENDED USE
Diagnostic reagent for quantitative *in vitro* determination of Total Protein in human serum and plasma.

CLINICAL SIGNIFICANCE
Total protein is useful for monitoring gross changes in protein levels caused by various disease states. It is usually performed in conjunction with other tests such as serum albumin, liver function tests or protein electrophoresis. An albumin/globulin ratio is often calculated to obtain additional information.
Increased levels of serum protein are observed in dehydration, multiple myeloma and chronic liver disease.
Decreased levels are encountered in renal diseases and terminal liver failure.

PRINCIPLE
Biuret method. The peptide bonds of protein react with copper II ions in alkaline solution to form a blue-violet ion complex, (the so called biuret reaction), each copper ion complexing with 5 or 6 peptide bonds. Tartrate is added as a stabiliser whilst iodide is used to prevent auto-reduction of the alkaline copper complex. The colour formed is proportional to the protein concentration and is measured at 546 nm (520-560).

REAGENT COMPOSITION
R1

Copper II Sulphate	12 mmol/l
Potassium Sodium Tartrate	31.9 mmol/l
Potassium Iodide	30.1 mmol/l
Sodium Hydroxide	0.6 mol/l
R2 standard	See bottle label

REAGENT PREPARATION
Reagents are liquid, ready to use.

STABILITY AND STORAGE
The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2–8°C.

SPECIMEN COLLECTION AND HANDLING
Use unheamolytic serum or plasma (heparin, EDTA)
It is recommended to follow NCCLS procedures (or similar standardized conditions).

Stability

6 days	at 20–25°C
4 weeks	at 4–8°C
at least one year	at -20°C

Discard contaminated specimens.

CALIBRATION
Calibration with the standard included in the kit or the calibrator XL MULTICAL, Cat. No. XSYS0034 is recommended.

QUALITY CONTROL
For quality control ERBA NORM, Cat. No. BLT00080 and ERBA PATH, Cat. No. BLT00081 are recommended.

UNIT CONVERSION
g/dl x 10 = g/l

EXPECTED VALUES [5]

	(g/dl)
Adults:	6.4 – 8.3
Premature	3.6 – 6.0
Newborn	4.6 – 7.0
1 week	4.4 – 7.6
7 – 12 months	5.1 – 7.3
1 – 2 years	5.6 – 7.5
> 2 years	6.0 – 8.0

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

PERFORMANCE DATA
Data contained within this section is representative of performance on ERBA XL systems. Data obtained in your laboratory may differ from these values.
Limit of quantification: 0.37 g/dl
Linearity: 15 g/dl
Measuring range: 0.37 – 15 g/dl

PRECISION

Intra-assay precision Within run (n=20)	Mean (g/dl)	SD (g/dl)	CV (%)
Sample 1	4.914	0.072	1.46
Sample 2	7.314	0.040	0.55

Inter-assay precision Run to run (n=20)	Mean (g/dl)	SD (g/dl)	CV (%)
Sample 1	5.177	0.038	0.73
Sample 2	6.761	0.078	1.15

COMPARISON
A comparison between XL-Systems Total Protein (y) and a commercially available test (x) using 40 samples gave following results:

y = 0.986 x + 0.163 g/dl
r = 0.997

INTERFERENCES
Following substances do not interfere:
haemoglobin up to 7.5 g/l, bilirubin up to 40 mg/dl, triglycerides up to 1500 mg/dl.

WARNING AND PRECAUTIONS
For *in vitro* diagnostic use. To be handled by entitled and professionally educated person.
R1 contains 2.4 % sodium hydroxide.

C

Corrosive

Risk phrases (R):
R 34 Causes burns.
R 52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety phrases (S):
S 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S 37/39 Wear suitable gloves and eye/face protection.
S 45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
S 60 This material and its container must be disposed of as hazardous waste.
S 61 Avoid release to the environment.

WASTE MANAGEMENT
Please refer to local legal requirements.

ASSAY PROCEDURE
Wavelength: (520-560) nm
Cuvette: 1 cm

	Reagent blank	Sample	Standard (Calibrator)
Reagent R1	1.00 ml	1.00 ml	1.00 ml
Distilled water	0.02 ml	–	–
Sample	–	0.02 ml	–
Standard (calibrator)	–	–	0.02 ml

Mix and incubate for 10 minutes (in case of automatic procedure incubate for 5 minutes) incubation in the dark. Absorbance of the sample A_1 and the standard (calibrator) A_2 against reagent blank is read in interval 30 minutes.

CALCULATION
$$\text{Total protein (g/dl)} = \frac{A_1}{A_2} \times C_{st}$$

C_{st} = standard (calibrator) concentration

Applications for automatic analysers are available on request.

ASSAY PARAMETERS

Mode	End Point
Wavelength 1 (nm)	546
Sample Volume (µl)	10/20
Reagent Volume (µl)	500/1000
Incubation time (min.)	10
Incubation temp. (°C)	37
Normal Low (g/dl)	6.4
Normal High (g/dl)	8.3
Linearity Low (g/dl)	0.37
Linearity High (g/dl)	15
Concentration of Standard	See bottle label
Blank with	Reagent
Absorbance limit (max.)	0.4
Units	g/dl

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