TECO DIAGNOSTICS
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TOTAL PROTEIN REAGENT
TC MATRIX-240/480

INTENDED USE
The test is applied for the quantitative determination of protein total in serum or plasma.

SUMMARY AND PRINCIPLE[1, 2, 3, 4, 5, 6]
Total Protein test is used for the aid in the diagnosis and treatment of various diseases involving the liver, kidney or bone marrow, as well as other metabolism and nutritional disorders.

High protein levels can be observed in cases of severe dehydration and diseases such as multiple myeloma.

Conditions such as nephrotic syndrome, excessive bleeding, sprue (inadequate protein absorption), severe burns, salt retention syndromes, and Kwashiorkor (acute protein deficiency) can lead to low protein levels.

The peptide bonds of the proteins interact with Cu(II) to form a blue-violet complex in alkaline solution and the absorbance is measured at 520-560 nm. Each Cu(II) can complex up to 6 peptide bonds. Iodide ions are added to prevent self-reduction of the alkaline cupric complex as a tartrate salt stabilizer. For automatic analyzers, set the reference wavelength to 600-700 nm.

REAGENTS

Cupric sulphate	≤8 mM
Sodium-potassium Tartrate	≤24 mM
Potassium iodide	≤8 mM
NaOH	≤0.8 M

REAGENT PREPARATION
Reagents are ready for use.

PRECAUTIONS
IVD: For in Vitro Diagnostic use only.
Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines.
Contains sodium azide.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

REAGENT STORAGE AND STABILITY[7]
Reagents are stable at 2-8°C until the expiration date stated on the label which is only for closed vials.

Once opened vials are stable for 30 days at 2-8°C in optimum conditions. On board stability is strongly related to auto analyzers' cooling specification and carry-over values.
Reagent stability and storage have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol.

SPECIMEN STORAGE
Samples are collected according to the standard procedures.
Total Protein is stable for:
8 hours at 20-25°C,
3 days at 2-8°C,
6 months at -20°C

Samples that have been frozen and thawed before should be thoroughly mixed before assay.

CALIBRATION
Calibration stability is 30 days. Calibration stability depends on the application characteristics and cooling capacity of the autoanalyzer used.

At least two level controls must be run once in every 24 hours. Each laboratory should determine its own quality control scheme and procedures. If quality control results are not within acceptable limits, calibration is required

Note: Refer to the TC Matrix manual for further instructions on calibrating the instrument

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT
Arcal Auto Calibrator
At least two levels of control material

REFERENCE INTERVAL (NORMAL VALUES) [7]
Ambulatory adult 6.3 - 8.3 g/dL
Recumbent adult 6.0 - 7.8 g/dL

(After age of 60, levels are approximately 0.2 g/dL lower)
It is recommended that each laboratory establish its own normal range.
Reference interval has been verified by using CLSI EP28- A3c protocol.

PROCEDURE
Settings for TC-Matrix 240/480

Test Name:	Total Protein	R1:	150
Full Name:	Total Protein	R2:	0
Pri. Wave:	546 nm	Sample volume:	3
Sec. Wave:	700 nm	Calibration Type:	2 Point Linear
Assay/ Point:	1-point End	K Value:	/
Start - End:	1 - 17	Point:	2
Decimal place:	2	Blank Type:	Reagent
Unit:	g/dL	Point 0 (Blank) Con.:	0.0
Linearity Range:	1.000 - 12.000	Point 1 (CAL) Con.:	Standard/
Correlation Factor:	1.0000 - 0.0000		Calibrator

INTERFERING SUBSTANCES[3, 4, 12]
No significant interactions were observed for conjugated bilirubin, lipemia up to the interferent concentration given in the table.

Interfering Substance and Concentration	Total Protein Target (g/dL)	N	Observed Recovery %
Bilirubin 48.33 mg/dL	6.48	3	92
Lipemia 433.4 mg/dL	7.16	3	108

Non-hemolysis samples should be used.

The acceptable interference limit is set 10% below the highest interference concentration within ± 10% recovery of the target.

Interferences may affect the results due to medication or endogenous substances.

These performance characteristics have been obtained by using an analyzer. Results may vary if a different instrument or a manual procedure is used.

PERFORMANCE CHARACTERISTICS

Limit of Detection (LoD): The limit of the test detection is 0.1 g/dL.

Limit of Quantitation (LoQ) [LoQ values are based on Coefficient of Variation Percentage (CV) ≤20%]:[9] 0.8 g/dL

LoD and LoQ values have been verified by using CLSI EP17-A protocol.

Precision[10]**:**

Repeatability (Within Run)

Mean Concentration (g/dL)	SD	CV%	n
3.62	0.07	2.00	40
7.17	0.14	2.06	40

Reproducibility (Run-to-Run)

Mean Concentration (g/dL)	SD	CV%	n
3.52	0.09	2.59	84
6.68	0.25	3.70	84

±10% CV% differences can be observed between devices.
Precision Studies data have been verified by using CLSI EP05-A3 protocol.

Method Comparison[11, 12]:
Correlation with a comparative method is: r= 0.97
According to Passing-Bablok Fit:
Slope: 1.02
Intercept: -0.11

Linearity: The method is linear up to 12 g/dL.
For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilution factor.
Linearity may considerably vary depending on the instrument used.

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