TECO DIAGNOSTICS
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TOTAL PROTEIN
BIURET METHOD
TC MATRIX

INTENDED USE
For the quantitative determination of total protein in serum or plasma on TC Matrix analyzers

INTRODUCTION
Proteins form the major portion of the solutes dissolved in the plasma fluid. Total protein determinations are useful in detecting hyperproteinemia due to homoconcentration as occurred in dehydration, paraproteinemia, or monoclonal disease (multiple myeloma, macroglobulinemia, cryoglobuliemia) and in some chronic polyclonal diseases, liver cirrhosis, sarcoidosis, systemic lupus erythematosus, and chronic infections.
Conditions which result in serum protein decrease involving overhydration, protein loss through kidneys, severe burns, or in failure of protein synthesis (starvation, protein malnutrition, liver cell damage).
Serum protein determination is also useful when determing the calcium concentration because the nondiffisible calcium fraction is bound to protein and varies directly as the serum protein.
The determination of total protein in serum or plasma makes use of the Biuret color reaction, known since 1878. Past attempts to stabilize the cupric ions in the alkaline reagent were unsuccessful until the addition of sodium potassium tartrate as a complexing agent. The present method for quantitative determination of total protein in serum is based on the method proposed by-the American Association for Clinical Chemistry (AACC) and National Committee for Clinical Laboratory Standards (NCCLS).
The TC Matrix System automatically proportions the appropriate sample and reagent volumes into the cuvette. The system monitors the change in absorbance at 520 nanometers. This change in absorbance is directly proportional to the concentration of total protein in the sample and is used by the TC Matrix System to calculate and express the total protein concentration.

$$\text{Protein} + Cu^{2+} \xrightarrow{\text{Alkali}} \text{Cu-protein complex (violet)}$$

REAGENT CONTENTS:
Each kit contains: Six Total Protein Reagent (6×40 ml)
Instruction Insert.

REAGENT PREPARATION
No preparation is required.

REAGENT COMPOSITION
Cu^{2+}: 12 mmol/L
NaOH: I0.6 mmol/L
Also non-reactive chemicals for optimal system performance.

REAGENT STORAGE AND STABILITY
Total Protein Reagent stored unopened at room temperature stable until the expiration date showed on the bottle label. Once opened, Total Protein Reagent is stable for 30 days, unless the expiration date is exceeded.
DO NOT FREEZE.

SPECIMEN COLLECTION AND HANDLING
1. The test can be performed on serum, plasma. For serum, blood is drawn into a tube which does not contain anticoagulant and allow clotting. The serum is them separated from the clot. A maximum limit of two hours from the time of collection is recommended.
2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum and plasma should be stored at 2ºC to 8ºC. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15ºC to -20ºC. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.
3. For plasma, add whole blood directly into a tube containing anticoagulant. Acceptable anticoagulants are listed in the "LIMITATIONS" section.

CALIBRATION
1. Calibrator required: TECO MULTI Calibrator.
2. The system must have a valid calibration in memory before controls or patient samples can be run.
3. The TC Matrix system will automatically perform checks on the calibration and produce data at the end of calibration.

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

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT
TECO MULTI Calibrator
At least two levels of control material.

LIMITATIONS
1. The anticoagulants Potassium Oxalate, Sodium Fluoride and Sodium Citrate were found to be incompatible with this method.
2. The anticoagulants EDTA, Ammonium Heparin, Lithium Heparin and Sodium Heparin were found to be compatible with this method.

INTERFERENCE
1. Hemoglobin levels up to 400 mg/dl, Triglyceride levels up to 1000mg/dl and Bilirubin levels up to 30 mg/dl were found to exhibit negligible interference.
2. On this method, refer to the work of Young for a review of drug and comprehensive list of substances effect on total protein level.

EXPECTED VALUE
6.2 to 8.5 g/dL or 62 to 85 g/L

PRECAUTIONS:
1. For in vitro diagnostic use only.
2. Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.
3. Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.

PROCEDURES

TEST NAME:	TP	R1:	200
TEST NO.		R2:	0
FULL NAME:	Total Protein	SAMPLE VOLUME:	4
REFERENCE NO.:		R1 BLANK:	/
ANALY.TYPE:	Endpoint	MIX REAG. BLANK:	0.1 - 1.5
PRI. WAVE :	546 nm	CONCENTRATION:	/
SECON. WAVE:	/	LINEARITY LIMIT:	3-12
TREND:	Ascending	SUBSTRATE LIMIT:	/
REACT. TIME:	0 - 11	FACTOR:	/
INCUBATE TIME:	/	PROZONE CHECK:	/
UNIT:	g/dl	Q1: / Q2: / Q3: / Q4: /	
PRECISION:	0.1	PC: / ABS.: /	
Calibration Type: Calibrate+Reag.Blank		Calibration Rule: Two-point linear	

PERFORMANCE CHARACTERISTICS

Analytical Range: 3.0- 12.0 g/dL
For total protein analyte by Total Protein Reagent on TC Matrix System, this method has been demonstrated to be linear from 3.0-12.0 g/dL

Accuracy: Comparison study was performed on TC Matrix System from 40 samples. Beckman Coulter Total Protein Reagent was used to compare with Total Protein Reagent. The results of this study in yield a correlation coefficient of 0.99 with a regression equation of y=0.99X - 0.8.

Precision: Within Run precision for Total Protein Reagent Set was determined following a modification of NCCLS EP5-A.Two commercial human serum were assayed on TC Matrix System for 25 times.

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	6.7	4.7
Standard Deviation (mg/dl)	0.21	0.17
Coefficient of Variation (%)	3.6	3.1

Run-Day precision for Total Protein Reagent was determined following a modification of NCCLS EP5-A.Two commercial human serum were assayed on TC Matrix Systems five times per day for five days for the total of 25 values.

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	6.8	4.7
Standard Deviation (mg/dl)	0.23	0.19
Coefficient of Variation (%)	3.1	3.2

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Manufactured by:

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