TRUEchemie Total Proteins Test Kit (BIURET)

for the quantitative determination of Total proteins concentration in human serum

INTENDED USE

The TRUEchemie Total Proteins Test Kit (BIURET) is used for the quantitative determination of total proteins concentration in human serum or plasma. INTRODUCTION

Serum protein is involved in the maintenance of normal distribution of water between blood and tissues through osmotic pressure. Low protein is primarily caused by malnutrition, impaired synthesis, loss as by hemorrhage or excessive protein catabolism. Elevated

protein levels are caused mainly by dehydration. The determination of total protein in serum 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.

	PRINCIPLE
tein + Cu ⁺⁺	Alkaline DH Cu - Protein Complex

Protein in serum forms a violet coloured complex when reacted with cupric ions in an alkaline solution. The intensity of the violet colour is proportional to the amount of protein present when compared to a solution with known protein concentration.

PACK SIZE

Kit size	2 x 50 ml	
Cat. no.	ADX281	
Kit contents		
1) Total Proteins Reagent	2 x 50 ml	
2) Total Proteins Standard (6 g/dL)	1 x 5 ml	

REAGENT COMPOSITION

Pro

1) Total Proteins Reagent:

Sodium hydroxide : 6 mmol/L Copper sulfate 12 mmol/L Sodium potassium tartrate : 32 mmol/L

Non-reactive ingredients.

2) Total Proteins Standard : 6 g/dL

REAGENT PREPARATION Ready to use reagents. WARNINGS AND PRECAUTIONS For in vitro diagnostic use 1

Handle in accordance with good laboratory procedures. Avoid indestion and eve or skin 2 contact

Specimens should be considered infectious and handled appropriately. 3 The disposal of the residues has to be done as per local legal regulations

CALIBRATION

The procedures are calibrated with the standard solution which is included with each series of tests. Its absorbance is used to calculate the results.

REAGENT STORAGE & STABILITY

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2-8°C. Do not use reagents over the expiration date

SPECIMEN COLLECTION AND STORAGE

Serum free from haemolysis. The sample will remain stable for up to 5 days when kept at 2 - 8 °C. MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipettes to accurately measure required volumes

2. Test tubes/rack

3. Timer

4. 37 °C heating block or water bath

5. Photometer capable of accurately measuring absorbance at 545 nm

TEST PROCEDURE Wavelength 545 nm 37°C Temperature Prewarm the reagent to reaction temperature Blank (µL) Standard (µL) Sample (µL) Total Proteins Reagent 1000

Total Proteins Standard	 10	
Sample	 	10

Mix well and incubate for 3 min at 37°C or 5 min at room temperature (20 - 25°C). After incubation, zero the Photometer with the reagent blank. Read and record the incuated standard and samples.

Final colour stability: A minimum of 3 hours

Sample OD

x 6 = q total proteins / dL Standard OD

S.I. Units (g/dI) x 10 = mmol/L

Calculation:

QUALITY CONTROL

Quality Controls are recommended to monitor the performance of automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances

EXPECTED VALUE

Normal values Serum : 6.6 - 8.7 g/dL

It is strongly recommended that each laboratory establish its own normal range

PERFORMANCE CHARACTERISTICS

Sensitivity: 0.15 g/dL

Linearity: Upto 14 g/dL under the described assay conditions. Samples that have Total proteins values greater than 14 g/dL should be diluted with saline water (NaCl 0.9 %) 1:1, re-assayed and the results multiplied by 2. The linearity limit depends on the sample / reagent ratio, as well as the analyzers used.

PRECISION:

Intra-assay precision within run (n=10)	Mean (g/dL)	SD (g/dL)	CV (%)
Control Level - 1	6.7	0.1	1.6
Control Level - 2	4.6	0.1	2.2

Inter-assay precision run to run (n=12)	Mean (g/dL)	SD (g/dL)	CV (%)
Control Level - 1	6.7	0.1	1.2
Control Level - 2	4.4	0.1	2.8

The reagent was tested for 12 days, using two different Total Proteins concentrations. The coefficient of variation was <5% AUTOMATED PROCEDURE

Appropriate program sheet is available for different analyzers upon request.

METHOD COMPARISON

Results obtained using TRUEchemie Total Proteins reagent (y) did not show systematic differences when compared with another commercial reagent (x) with similar characteristics. The results obtained is below: The correlation coefficient (r^2) was 0.974 and the regression equation is y=0.877x+0.933. The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

- Lipemia (intralipid) may affect the results
- Bilirubin (20 mg/dl) does not interfere.
- Hemoglobin may affect the results. Other drugs and substances may interfere.
- Dextrans used as plasma volume expanders for the treatment of low blood pressure, complex with copper and tartrate forming a precipitate

WASTE MANAGEMENT

Please refer to local regulation requirements SYSTEM PARAMETERS Mode End point Std conc 6 545 nm Wave length Units g/dL 37°C Flow cell temp Blank Reagent Reagent volume 1000 µL Sample volume 10 µL 3 min. at 37°C Incubation 6.6 Low norma 8.7 High normal Sensitivity 0.15 Linearity 14 Reaction Slope Increasing REFERENCES

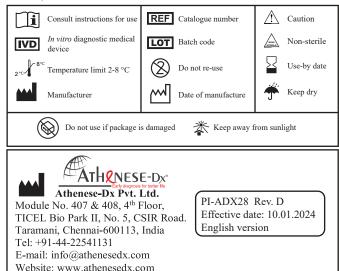
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- supplied by the manufacturer Part 1: General requirements

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