INTRODUCTION

1. AutoZyme Total protein is a reagent set for determination of total protein **based on Biuret method.**
2. AutoZyme Total protein is a **single reagent system, ready-to-use.**
3. AutoZyme Total protein is **linear** upto 18 gm%.
4. Total protein can be determined in just **5 minutes.**
5. AutoZyme Total protein **does not require serum blank** for lipemic samples.
6. AutoZyme Total protein can be used on any **Colorimeter, Spectrophotometer, Discrete semiautomated and Automated analyzer.** Programme can be designed for any specific analyzer upon request.
7. The **shelf-life** of AutoZyme Total protein is 18 months.

PRINCIPLE

Proteins react with cupric ions under alkaline pH to produce a colour complex. This colour complex absorbs light at 546 nm.(530-570 nm). The intensity of the colour is directly proportional to the protein concentration in specimen.

Proteins $\xrightarrow[\text{Alkaline pH}]{Cu^{2+}}$ **Blue colour complex**

PREPARATION OF WORKING SOLUTION

The reagent is ready-to-use.

REAGENT STORAGE & STABILITY

The reagents are for *in vitro* diagnostic use.

Biuret reagent & standard should be stored at temperature indicated on the bottle label.

COMPONENTS & CONCENTRATION OF WORKING SOLUTION

Component	Concentration
• Cupric sulphate	7 mmol/l
• Potassium Iodide	6 mmol/l
• Tartarate	20 mmol/l
• Surfactant	0.05% w/v
• Stabilizer	

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Avoid the use of plastic or siliconized containers for blood collection which may prolong clotting time. Serum or plasma should be separated from the cells within 60 minutes.

For plasma separation following anticoagulants may be used :

• EDTA	2 mg/ml of blood
• CITRATE	6 mg/ml of blood
• HEPARIN	200 IU/ml of blood
• OXALATE	3 mg/ml of blood
• SODIUM FLUORIDE	10 mg/ml of blood

Proteins are stable in the serum and plasma for 7 days when stored at 2-8°C and for a month when stored at -10°C.

PROCEDURE

- ☐ **Reaction type** ..... **End-Point**
- ☐ **Reaction time** ..... **5 mins. at 37°C**
- ☐ **Wavelength** ..... **546 nm.(530-570 nm.)**
- ☐ **Zero setting with** ..... **Reagent Blank**
- ☐ **Sample volume** ..... **0.01 ml (10 µl)**
- ☐ **Reagent volume** ..... **1.0 ml**
- ☐ **Standard concentration** ..... **6 gm%**
- ☐ **Linearity** ..... **18 gm%**

Manual assay procedure

Prewarm at room temperature (25-30°C) the required amount of working solution before use.

Perform the assay as given below :

1.0 ml procedure

	Serum / Plasma	Standard	Blank
	0.01 ml	0.01 ml	—
Working solution	1.0 ml	1.0 ml	1.0 ml

Incubation

Incubate the assay mixture for 5 minutes at 37°C. After completion of incubation period measure the absorbance of specimen and standard against blank. Final colour is stable for 8 hours if not exposed to direct light.

Calculation :

$$\text{Total protein in gm\%} = \frac{\text{Absorbance of Sample}}{\text{Absorbance of Standard}} \times 6$$

TP-2009-03-001

EXPECTED VALUE

Expected Value : 6.3 to 8.4 gm%

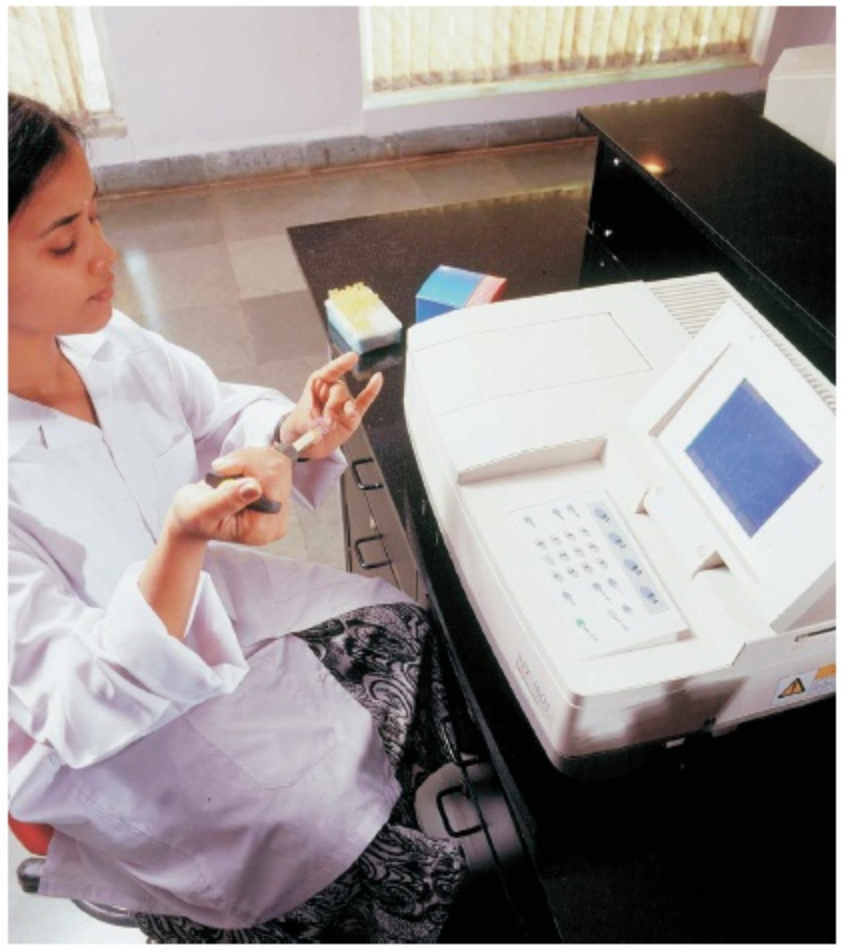
Expected range varies from population to population. It is recommended that each laboratory should establish the normal range for its own population.

PROCEDURE LIMITATIONS

1. The working reagent is considered unsatisfactory and should not be used if it develops insoluble precipitate.
2. If the total protein content of a specimen exceeds 18 gm% dilute the specimen with an equal volume of saline and repeat the assay. Multiply the result by two to obtain correct value.
3. For Haemolyzed and Icteric samples (Bilirubin > 5 mg%) a saline blank should be run along with the assay. Read the absorbance of saline blank against distilled water and subtract it from sample absorbance.

QUALITY CONTROL

To ensure adequate quality control, it is recommended that each batch should include a normal and an abnormal commercial reference control serum. It should be realised that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glassware and accuracy of pipetting.



Quality Assurance - On line testing

REFERENCES

1. Strikland, R.D. et al, *Anal. Chem.* 33, (1961).
2. Henri, R.J. et al, *"Clinical Chemistry-Principles and techniques"* Harper & Row, II Ed. (1974).

IVD	*In Vitro* Diagnostic Use		Date of Manufacturing
	Consult Instructions for use		Use by (YYYY-MM-DD)
REF	Catalogue Number		Temperature Limitation
LOT	Batch Code		Manufacturer

CE
European Conformity

AR. No.: I 20 *TP-2009-03-001*

ACCUREX BIOMEDICAL PVT. LTD.
Head Office - Mumbai. Tel.: 91(022) 67446744; Fax: 91(022) 66662667
E-mail: accurex@vsnl.com; Website: www.accurex.org
Plant : G-54, MIDC Tarapur, Boisar, Thane - 401 506. INDIA.

AutoZyme

TOTAL PROTEIN

Biuret