AGD
CliniPak

TOTAL PROTEIN

(Biuret)

Code	Pack Size
AGDSP - TP160	8 x 20 mL
AGDSP - TP144	8 x 18mL
AGDSP - TP184	8 x 23mL

INTENDED USE

Total protein is a single reagent kit is intended for in vitro quantitative determination of Total protein concentration in serum or plasma.

CLINICAL SIGNIFICANCE

Protein forms the major portion of dissolved substances in the plasma. They form the basic structural components of the body.They constitute the enzymes present in our body and also acts as secondary source of energy.

Increased Levels : are observed in dehydration, myolema, hyperglobulinemia.

Decreased Levels : are observed in serum or plasma protein concentration decrease in malnutrition, albuminuria, liver disease etc.

PRINCIPLE

Cupric ions in an alkaline solution react with the peptide bonds of proteins and polypepetide containing at least two peptide bonds to produce a violet colored complex. The absorbance of the complex is directly proportional to the concentration of protein in the sample.

Cu^{++} + Protein $\longrightarrow$ Cu- Protein Complex

PROCEDURE

Reagent + Sample + Incubation → Measurement
(300µL) (3 µL) (300sec) (546nm)

REAGENT COMPOSITION

Cupric sulphate	≈ 7 mmol/L
Pot.Iodide	≈ 6 mmol/L
Tartarate	≈ 20 mmol/L
Surfactant	≈ 0.05%W/V

REAGENT STORAGE AND STABILITY

Total protein reagent is a single reagent system ready to use.The reagent is stable till the expiry date stated on the reagent bottle label when stored at 2-8°C protected from light.

SAMPLE

Collected sample using standard sampling tube preferably use serum free of hemolysis .

BASIC PARAMETER

SHORT NAME	TP
NAME	Total Protein
METHOD	Biuret
ASSAY	End point (two point reagent blank)
MAIN WAVE	546nm
SUB WAVE	0
DECIMAL	2
UNIT	g/dL
R1 VOLUME	300µL
INCUBATION	36 secs
R2 VOLUME	0
SAMPLE VOLUME	3µL
INCUBATION	0 secs
MIXING SPEED	0
REACTION TIME (DELAY)	260 secs
CHECK TIME (READ)	40 secs
LINEAR RANGE	0 -12
ABSORBANCE RANGE	0-2.5
DISCREPANCY	0
CALIBRATION TYPE	SINGLE SPOT LINEARITY
DILUTION RATIO	6
SAMPLE VOLUME	50

*Enter calibrator value as per the lot of calibrator and method.

LINEARITY

Reagent is linear up to 12 g/dL.Dilute the sample appropriately and re-assay if total protein concentration exceeds 12 g/dL.Multiply result with dilution factor.

PRECISION

Reproducibility of within run determined using quality control sera as shown below. n=15

Quality control material	Mean g/dL	SD g/dL	% CV
Low Control serum	5.58	0.04	0.76
High Control serum	4.46	0.03	0.74

REFERENCE NORMAL VALUE

6.2 - 8.0 g/dL

QUALITY CONTROL

To ensure adequate quality control,it is recommended that laboratory should use a normal and abnormal commercial reference control serum.The quality control material is used to check the function of reagents and the machine together.

LIMITATIONS & PRECAUTIONS

- Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
- Storage condition as mentioned on the kit to be adhered.
- Before the assay bring all the reagents to the room temperature.
- Avoid contamination of the reagent during assay process.
- Use clean glassware free from dust and debris.
- Reagent to sample ratio as mentioned above must be strictly adhered, as any changes it affects the factor and result.
- In case reagent comes in contact with eyes,immediately rinse with plenty of water and seek medical advice.

CE | IVD

AGD Biomedical Pvt. Ltd.
Site 2 : Plot No. W-29 E, TTC Industrial Area,MIDC,Thane Belapur Road, Rabale, Navi Mumbai,Thane, Maharashtra,(India)- 400701.
E : indiasales@agdbio.com
W : www.agdbio.com

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EU REP
Obelis s. a.
Bd General Wahis
53 1030 Brussels Belgium
Phone : +32 2 732 59 54