



TOTAL PROTEIN KIT

(Biuret Method)

(For veterinary invitro diagnostic use only)

INTENDED USE

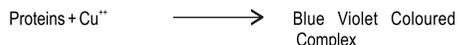
QUADRAPED™ Total Protein kit is used for the determination of Total Proteins in serum and plasma.

SUMMARY

Proteins are constituents of muscle, enzymes, hormones and several other key functional and structural entities in the body. They are involved in the maintenance of the normal distribution of water between blood and the tissues. Consisting mainly of albumin and globulin the fractions vary independently and widely in diseases. Increased levels are found mainly in dehydration. Decreased levels are found mainly in malnutrition, impaired synthesis, protein losses as in hemorrhage or excessive protein catabolism.

PRINCIPLE

Proteins, in an alkaline medium, bind with the cupric ions present in the Biuret reagent to form a blue-violet coloured complex. The intensity of the colour formed is directly proportional to the amount of Proteins present in the sample.



EXPECTED VALUES

Species	Total Proteins (g/dl)
Dog	5.4 - 7.5
Cat	6.0 - 7.9
Cow	6.7 - 7.5
Horse	5.6 - 7.6
Pig	7.9 - 8.9
Sheep	6.0 - 7.9
Goat	6.4 - 7.0
Rabbit	5.4 - 7.5
Buffalo	6.5 - 8.5

It is recommended that each laboratory establish its own range as reference ranges may vary between laboratories.

PRESENTATION

REF	1126200025
Pack Size	25 ml
Carton 1	
L1 Biuret Reagent	25 ml
Carton 2	
S Protein Standard (8 g/dl)	5 ml

COMPOSITION

Potassium Iodide 15mM; Potassium Sodium Tartrate 30mM; Copper Sulphate 12mM; Sodium Hydroxide 200mM; Detergent.

STORAGE / STABILITY

Carton 1: Biuret Reagent is stable at 23-29°C till the expiry mentioned on the label.

Carton 2: Protein Standard is stable at 2-8°C till the expiry mentioned on the label.

REAGENT PREPARATION

Reagents are ready to use. Protect from bright light.

SAMPLE MATERIAL

Serum or plasma. Proteins are reported to be stable in the sample for 6 days at 2-8°C.

SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.

Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

Handle specimens, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

MATERIALS REQUIRED BUT NOT PROVIDED

Photometer analyzer with standard thermostatic cuvette holder, micropipette and appropriate laboratory equipment.

PROCEDURE

Wavelength / filter : 550 nm (Hg 546 nm) / Yellow-Green
Temperature : R.T./37°C
Light path : 1 cm

Pipette into clean dry test tubes labelled as Blank (B), Standard (S) and Test (T):

Addition Sequence	B (ml)	S (ml)	T (ml)
Biuret Reagent (L1)	1.0	1.0	1.0
Distilled Water	0.02	-	-
Protein Standard (S)	-	0.02	-
Sample	-	-	0.02

Mix well and incubate at 37°C for 10 mins or at R.T. for 30 mins. Measure the absorbance of the Standard (Abs. S), and Test Sample (Abs. T) against the Blank, within 60 mins.

CALCULATIONS

$$\text{Total Proteins in g/dl} = \frac{\text{Abs. T}}{\text{Abs. S}} \times 8$$

QUALITY CONTROL

The following process is recommended for QC during the assay of Total Protein. *Define and establish acceptable range for your laboratory.

- Two levels of control (Normal and Abnormal) are to be run on a daily basis.
- If QC results fall outside acceptance criteria, recalibration may be necessary.
- Review QC results and run acceptance criteria following a change of reagent lot.

SPECIFIC PERFORMANCE CHARACTERISTICS

LOB: 0.079 g/dl at 546 nm

LOD: 0.1 g/dl at 546 nm

LOQ: 1.0 g/dl at 546 nm

Lower Limit: 0.1 g/dl

Higher Limit : 15 g/dl

If values exceed this limit, dilute the sample with distilled water and repeat the assay. Calculate the value using the proper dilution factor.

Interferences:

Sample when spiked with interferent such as upto 40 mg/dl Bilirubin, 1000 mg/dl intralipid and 500 mg/dl haemoglobin does not affect the ability of the kit to determine the Total Protein concentration.

Precision:

Within run

Within run	n	Mean	SD	% CV
Sample 1	10	6.30	0.06	0.97
Sample 2	10	5.54	0.08	1.41
Sample 3	10	7.93	0.09	1.19

Between run

Between run	n	Mean	SD	% CV
Sample 1	10	6.34	0.05	0.71
Sample 2	10	5.57	0.05	0.82
Sample 3	10	7.96	0.09	1.07

Method comparison:

Comparative studies were done to compare our reagent with another commercial Total Protein Assay. No significant differences were observed. Details of the comparative studies are available on request.

NOTE

In vitro diagnostic reagent for laboratory and professional use only Not for medicinal use. The reagent contain sodium azide 0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water. Only clean and dry glassware must be used. Do not use if the reagent shows turbidity or black precipitates. Do not use turbid, deteriorated or leaking reagents.

REFERENCES

- Gornall, A.G., et al, (1949) Biol. Chem. 177:751.
- Dumas, B.T, (1975) Clin Chem. 21:1159.
- Clinical Chemistry, Principles, Procedures, Correlations, Michael L. Bishop, et.al., 5th Edition.
- Duncan and Prasse's Veterinary Laboratory Medicine: Clinical Pathology, Kenneth S. Latimer, ISBN Jane Wardrop, 6th Edition - 2010.
- Clinical Biochemistry of Domestic Animals, Sixth Edition, 2008 by Kaneko J.J., Harvey J.W. & Bruss M.L.
- Data on file: Coral Clinical Systems.

System Parameters

Reaction	: End Point	Interval	: ---
Wavelength	: 550 nm	Sample Vol.	: 0.02 ml
Zero Setting	: Reagent Blank	Reagent Vol.	: 1.00 ml
Incub. Temp.	: 37°C / R. T.	Standard	: 8 g/dl
Incub. Time	: 10 min. / 30 min.	Factor	: ---
Delay Time	: ---	React. Slope	: Increasing
Read Time	: ---	Linearity	: 15 g/dl
No. of read.	: ---	Units	: g/dl

SYMBOL KEYS

Use by (Last day of stated month)	Manufacturer	IVD In vitro Diagnostic Medical Device	L1 Biuret Reagent 29°C Store at 23-29°C	Biuret Biuret Method
Date of Manufacture	Consult Instructions for use	LOT Batch Number	S Protein Standard (8 g/dl) (Store at 2-8°C)	This way up
REF Catalogue Number				



Manufactured by:

Coral Clinical Systems

A Division of Tulip Diagnostics (P) Ltd.

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