# SBio TOTAL PROTEIN KIT

**(Biuret Method)**

(For invitro diagnostic use only)

| REF | 9079 2150 | 90801000 |
|---|---|---|
| Pack Size | 2 x 150 ml | 1000 ml |

CE

| | | | | |
|---|---|---|---|---|
| L1: Store at 15-30°C<br>S: Store at 2-8°C | Manufacturer | IVD *In vitro* Diagnostic Medical Device | S Protein Standard (8 g/dl) | Biuret<br>Biuret Method |
| Use by (Last day of stated month) | Consult Instructions for use | LOT Batch Number | This way up | EC REP<br>Authorised Representative in the European Community |
| Date of Manufacture | REF Catalogue Number | L1 Biuret Reagent | | |

## INTENDED USE

Total Protein Kit is used for the determination of Total Proteins in serum and plasma.

## PRINCIPLE OF THE TEST

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.

Proteins + $Cu^{++}$ ⟶ Blue Violet Coloured Complex

## CLINICAL SIGNIFICANCE

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.

| PRESENTATION | 2 x 150 ml | 1000 ml |
|---|---|---|
| Carton 1 | | |
| L1 : Biuret Reagent | 2 x 150 ml | 1000 ml |
| Carton 2 | | |
| S : Protein Standard (8 g/dl) | 5 ml | 5 ml |

## COMPOSITION

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

## STORAGE / STABILITY

Carton 1: Biuret Reagent is stable at R.T. till the expiry mentioned on the label.

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

## SAMPLE REQUIRED

Serum or plasma.

## REAGENT PREPARATION

Reagents are ready to use. Protect from bright light.

## 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.

This product requires the handling of human specimen. It is recommended that all human sourced material are considered potentially hazardous and are handled in accordance with the OSHA standard on blood borne pathogens.

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

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

## PROCEDURE

Wavelength/filter : 550 nm (Hg 546 nm) / Yellow-Green

Temperature : R.T. / 37° C

Light path : 1 cm

## MATERIALS REQUIRED BUT NOT PROVIDED

General laboratory instrumentation like Spectrophotometer/Analyzer, Thermostatic Cuvette holder, Cuvettes, Micropipettes, Test tubes, Waterbath, Stopwatch/Timer.

Pipette into clean dry test tubes labeled 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 minutes or at R.T for 30 minutes. Measure the absorbance of the Standard (Abs. S), and Test Sample (Abs. T) against the Blank, within 60 minutes.

## 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.

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

## SPECIFIC PERFORMANCE CHARACTERISTICS

**Linearity:**

This procedure is linear upto 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.

**Limit of detection:**

The limit of detection for Total Protein is 0.1 g/dl.

**Interferences:**

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

**Precision:**

Precision studies were performed with two controls using NCCLS protocol EP5-A. The results of the precision studies are shown below:

| Sample | Within-run | | Between-run | | Total | |
|---|---|---|---|---|---|---|
| | Mean | CV% | Mean | CV% | Mean | CV% |
| Control 1 | 6.27 | 1.30 | 6.85 | 1.85 | 13.12 | 3.15 |
| Control 2 | 4.89 | 1.31 | 4.94 | 2.40 | 9.83 | 3.71 |

**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.

## REFERENCE RANGE

Serum and Plasma : 6.0 - 8.0 g/dl

It is recommended that each laboratory establish its own normal range representing its patient population*.

## NOTE

Proteins are reported to be stable in the sample for 6 days at 2-8°C. Do not use if the reagent shows turbidity or black precipitates. The reagent may be used in several automated analyzers. Instructions are available on request. Do not use turbid, deteriorated or leaking reagents.

## REFERENCES


1. Gornall, A.G., et al, (1949) Biol. Chem. 177:751.
2. Doumas, B.T, (1975) Clin Chem. 21:1159.
3. Clinical Chemistry, Principles, Procedures, Correlations, Michael L. Bishop, et.al., 5th Edition.



Mfd. for:

Singapore SB Biosciences PTE Ltd.

11 Yishun Street 51, # 04-23, The Criterion, Singapore 767971.

EC REP

CMC Medical Devices & Drugs S.L.,
C/ Horacio Lengo No. 18, CP 29006, Malaga, Spain.

TPR1(SBio)/0420/VER-02