# TOTAL PROTEIN SYSTEM PACK

(BIURET METHOD)

B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic chem 400 (Fully Auto Biochemistry Analyzer)

BEACON

| Code | Product Name | Pack Size |
|---|---|---|
| UNI31 | Total Protein System Pack | 4x50 ml |

## INTENDED USE

Diagnostic reagent for quantitative *in vitro* determination of Total Protein in human serum and plasma.

## CLINICAL SIGNIFICANCE

Total protein is useful for monitoring gross changes in protein levels caused by various disease states. It is usually performed in conjunction with other tests such as serum albumin, liver function tests or protein electrophoresis. An albumin/globulin ratio is often calculated to obtain additional information.

Increased levels of serum protein are observed in dehydration, multiple myeloma and chronic liver disease.

Decreased levels are encountered in renal diseases and terminal liver failure.

## PRINCIPLE

Biuret method. The peptide bonds of protein react with copper II ions in alkaline solution to form a blue-violet ion complex, (the so called biuret reaction), each copper ion complexing with 5 or 6 peptide bonds. Tartrate is added as a stabiliser whilst iodide is used to prevent auto-reduction of the alkaline copper complex. The colour formed is proportional to the protein concentration and is measured at 546 nm (520-560).

## REAGENT COMPOSITION

**Reagent 1 : Biuret Reagent**

| | |
|---|---|
| Copper II Sulphate | <10 mmol/L |
| Potassium Sodium Tartrate | >20 mmol/L |
| Potassium Iodide | >0.6 mol/L |
| Sodium Hydroxide | 742 mol/L |

## REAGENT PREPARATION

Reagents are liquid, ready to use.

## STABILITY AND STORAGE

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at +2 - +8°C.

On board stability: Min. 21 days if refrigerated (+8 - +14°) and not contaminated.

## SPECIMEN COLLECTION AND HANDLING

Use unheamolytic serum or plasma (heparin, EDTA)

It is recommended to follow NCCLS procedures (or similar standardized conditions).

**Stability**

| | |
|---|---|
| 6 days | at +20 - +25°C |
| 4 weeks | at +4 - +8°C |

Discard contaminated specimens.

## CALIBRATION

Calibration with the Beacon Multicalibrator is recommended.

## QUALITY CONTROL

Its recommended to run normal and abnormal control sera to validate reagents performance.

## UNIT CONVERSION

gm/dL x10=gm/L

## EXPECTED VALUES

Serum 6.0 to 8.0 gm/dl

**It is recommended that each laboratory verify this range or derives reference interval for the population it serves.**

## PERFORMANCE DATA

Data contained within this section is representative of performance on Beacon system.

Data obtained in your laboratory may differ from these values.

**Limit of quantification:** 0.37 gm/dL

**Linearity:** 15 gm/dL

**Measuring Range:** 0.37 - 15 gm/dL

**PRECISION**

| Intra-assay precision Within run (n=20) | Mean (gm/dL) | SD (gm/dL) | CV (%) |
|---|---|---|---|
| Sample 1 | 6.05 | 0.10 | 1.65 |
| Sample 2 | 4.63 | 0.07 | 1.57 |

| Inter-assay precision Run to run (n=20) | Mean (gm/dL) | SD (gm/dL) | CV (%) |
|---|---|---|---|
| Sample 1 | 5.629 | 0.09 | 1.58 |

## COMPARISON

A comparison between Total Protein System Pack (y) and commercially available test (x) using 20 samples gave following results:

y = 1.0533x - 0.4199 gm/dL

r = 0.999

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**INTERFERENCES**

Following substances do not interfere:
Haemoglobin up to 7.5 gm/L, bilirubin up to 40 mg/dL, triglycerides up to 1500 mg/dL.

**WARNING AND PRECAUTIONS**

MSDS will be provided on request.

**WASTE MANAGEMENT**

Please refer to local legal requirements.

Parameter For B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400& Beaconic chem 400 (Fully Auto Biochemistry Analyzer)

| Test Name | TOTAL PROTEIN |
|---|---|
| Full Name | TOTAL PROTEIN |
| PRI Wave | 546 nm |
| SEC Wave | - |
| Assay/Point | 1 Point End |
| Start | - |
| End | 33 |
| Decimal | 2 |
| Unit | gm/dL |
| Linearity Range Low | 0.37 |
| Linearity Range High | 15 |
| Sample Volume | 2 µl |
| Reagent 1 (R1) Volume | 200 µl |
| Reagent 2 (R2) Volume | - |
| Substrate Depleted/Abs.limit | - |
| Linearity | 15 gm/dL |
| Out Of Linearity Range | - |
| Calibration Type | 2 Point linear |
| Points | 2 |
| Blank Type | Reagent |
| Concentration Blank | 0.00 |
| Concentration Std | Refer calibrator value sheet |

**NOTE**

The program is made as per the in house testing, it can be modified as per requirements.
Clinical diagnosis should not be made on findings of a single test results, but both clinical and laboratory data.

**REFERENCES**


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4. Chromy, V., Fischer, J., Voznieek, J.: Z. Med. Labor.-Diagn. 21, 333, 1980.
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6. Ashwood, E.R., Bruns, D.E.; 5th edition, WB Saunders Company 2012.


**Symbols Used On Labels**

| | | | |
|---|---|---|---|
| REF | Catalogue Number | | Manufacturer |
| | See Instruction for Use | LOT | Lot Number |
| CONT | Content | | Storage Temperature |
| | Expiry Date | IVD | In Vitro Diagnostics |


BEA/24/TOP/UN/IFU Ver-03
28/01/2026