TOTAL PROTEIN SYSTEM PACK

Unicorn 480, Bonavera Chem 480 & Bonavera Chem 400

(Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
UNI31	Total Protein System Pack	4 x 50 ml

BEACON

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 albu min/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 alka line 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 (2-10°) 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
at least one year	at –20°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 x 10 = 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	5.58	0.13	2.37
Sample 2	4.61	0.11	2.30

Inter-assay precision Run to run (n=20)	Mean (gm/dl)	SD (gm/dl)	CV (%)
Sample 1	6.00	0.07	1.19

COMPARISON

A comparision between Total Protein System Pack (y) and commercially available test (x) using 20 samples gave following results:
y = 1.003x - 0.195 gm/dl
r = 0.983

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.

WASTE MANAGEMNT

Please refer to local legal requirements.

Parameter for Unicorn 480, Bonavera Chem 480 &

Bonavera 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 µ l
REAGENT 1 (R1) VOLUME	200 µl
REAGENT 1 (R2) VOLUME	-
SUBSATRATE DEPLETED	-
LINEARITY	15 gm/dl
OUT OF LINEARITY RANGE	-
CALIBRATION TYPE	2 Point linear
POINTS	2
BLANK TYPE	Reagent
CONCENTRATION BLANK	0.00
CONCENTARTION STD	Refer calibrator value sheet.
SAMPLE VOLUME	2 µ l

NOTE

The program is made as per the in house testing, it can be modified as per requirements.

REFERENCES

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2. Doumas, B. T., Bayse, D. D. a kol.: Clin. Chem. 27, 1642, 1981.
3. Chromý, V., Fischer, J.: Clin. Chem. 23, 754, 1977.
4. Chromý, V., Fischer, J., Vozníèek, J.: Z. Med. Labor.-Diagn. 21, 333, 1980.
5. Tietz Textbook of Clinical Chemistry and Molecular diagnostics. Burtis, C.A.,
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