TOTAL PROTEIN SYSTEM PACK

(BIURET METHOD)

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200 , Beaconic chem 200,Beaconic B200,Beaconic analyzer 120, Bonavera chem 100(Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
BA231	Total Protein System Pack	5x40 ml
BA231A	Total Protein System Pack	2x40 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.

[4]

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
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 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 comparison 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

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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 200, Unicorn 230, Unicorn 120 & Bonavera Chem200,Beaconic chem 200,Beaconic B200,Beaconic analyzer 120,Bonavera chem 100
(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	17
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 1 (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

1. Comall,A.G., Bardawil, C.J., David, M. M. J. Biol. Chem. 177,751,1949.
2. Doumas, B.T., Bayse, D.D.akol.: Clin. Chem. 27, 1642, 1981.
3. Chromy, V., Fischer, J.: Clin. Chem. 23,754, 1977.
4. Chromy, V., Fischer, J., Voznieek, 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

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BSCIC ISO 9001 : 2015 JAS-ANZ BSCIC ISO 13485:2016