PROTEIN TOTAL

Biuret

Diagnostic reagent for determination of protein total concentration.

Liquid. Mono Reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
A2300	5 x 100 mL	R2300	1364 Tests	BY2301	2525 Tests	M2300	2273 Tests
A2301	5 x 50 mL	R2301	455 Tests	N2300	758 Tests	M2301	1364 Tests
T2300	4091 Tests	S2300	1745 Tests	N2301	424 Tests	L2300	5000 Tests
T2301	1136 Tests	S2301	1091 Tests	K2300	3333 Tests	L2301	2667 Tests
DM300	990 Tests	BY2300	7955 Tests	K2301	2381 Tests		

INTENDED USE

The test is applied for the quantitative determination of protein total in serum or plasma.

TEST PRINCIPLE

Proteins peptidic bonds react with Cu(II) in alkaline solution to form blue-purple complex, the absorbance of which is measured at 520-560 nm. Each Cu(II) can complex up to 6 peptidic bonds. Tartrate salt as a stabilizer and iodide ions are added to prevent self-reduction of alkaline cupric complex. For automatic analyzers, set the reference wavelenght to 600-700 nm.

TEST PARAMETERS

Method	: Colorimetric, Endpoint, Increasing Reaction, Biuret
Wavelength	: Hg 546 nm (520- 560)
Temperature	: 25°C, 37°C
Sample	: Serum or plasma
Linearity	: 0.8 g/dL - 12 g/dL (150 g/L)

REAGENT COMPOSITION

Cupric sulphate	≤ 8 mM,
Sodium-potassium Tartrate	≤ 24 mM,
Potassium iodide	≤ 8 mM,
NaOH	≤ 0.80 M.

REAGENT PREPARATION

Use reagent ready to use.
Stability of reagent is up to expiration date on labels at 2-8°C.

Stability of first opening vials is more than 60 days at 2-8°C.

REAGENT STABILITY AND STORAGE

Once opened vials (reagent 1) are stable minimum 30 days at 2-8°C at optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

SAMPLE

Either serum or plasma may be used, but serum is preferred.

A fasting specimen is not required but may be desirable to decrease lipemia. Hemolysis should be avoided. Tightly stoppered samples of serum are stable for 1 week at room temperature or 1 month at 2-8°C. Specimens that have been frozen and thawed should be thoroughly mixed before assay.

TEST PROCEDURE

Sample Start
There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

$$\frac{\text{A Sample}}{\text{A Standard}} \times \text{conc. of standard}$$

= g/dL of Total Protein sample

Unit Conversion

g/dL x 10 = g/L

REFERENCE INTERVAL (NORMAL VALUES) (Based on CLSI C28-P Document)*

Ambulatory adult : 6.3 - 8.3 g/dL

Recumbent adult : 6.0 - 7.8 g/dL

(after age of 60 years, levels are approximately 0.2 g/dL lower)

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

Commercially available control material with established values determined by this method may be used.
We recommend:

"ARCON N", Assayed Control Serum Normal
Cat.No. A3910

"ARCON P", Assayed Control Serum Abnormal
Cat.No. A3920

The assay requires the use of a Protein Standard or a Protein Calibrator. We recommend:
ARCON Standard
Cat.No. A2300S (Conc. 6 g/dL)

Any commercially available Standard or Calibrator suitable for this method may be used.

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 20 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity: 0.8 g/dL

High Linearity: The method is linear up to 12 g/dL.

If the limit value is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

Linearity may considerably vary depending on the instrument used.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatibility (within run) (Intra-assay)

Mean conc.	SD	CV	n
5.03 g/dL	0.10	2.00%	10
5.54 g/dL	0.10	1.80%	10

Reproducibility (run to run) (Inter-assay)

Mean conc.	SD	CV	n
5.12 g/dL	0.11	2.20%	20
5.31 g/dL	0.17	3.20%	20

Sensitivity (LOD) (Based on CLSI EP17 document): The limit of detection is 0.1 g/dL.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Interferences: No interference was observed by the presence of:

Hemoglobin	≤ 350 mg/dL
Bilirubin	≤ 20 mg/dL
Lipids	≤ 200 mg/dL

Methods comparison: A comparison between Archem and a commercially available product gave the following results:

Proteins total Archem = x
Proteins total competitor = y
n = 97
$y = 1.02x - 0.11$ g/dl $r^2 = 0.97$

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1&R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.

S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

REFERENCES

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4. Flack C, Wollen JW. Prevention of interference by dextran with biuret-type assay of serum proteins. Clin Chem. 1984;(30):559–561.
5. Kaplan, A. and Szabo, J., Clinical Chemistry: Interpretation and Techniques, 2nd Ed., 157, Lea & Febiger, Philadelphia, PA, 1983.
6. Clinical and Laboratory Standards Institute (formerly NCCLS). Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Second Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2004. NCCLS Document EP05-A2.
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SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

CE

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