

TOTAL PROTEINS

Biuret Method - Endpoint

2 x 100 ml
4 x 100 ml

CL49-200S
CL49-400S

INTENDED USE

Kit for quantitative determination of total proteins in serum and plasma.

CLINICAL MEANING

Proteins are mainly synthesized in: liver, plasma cells, lymph nodes, spleen, bone marrow.

During a disease, the concentration of total proteins and of every single fraction can differ greatly from normal values.

PRINCIPLE

In an alkaline environment, proteins and peptides form a violet complex with copper ions.

The intensity of the colour is proportional to the concentration of proteins in the sample.

SAMPLE

Serum, plasma.

Do not use hemolyzed samples.

STABILITY: 1 week at 15-25°C, over a month at 2-8°C.

REAGENTS

Only for in Vitro diagnostics.

Liquid mono-reagent, ready to use.

Reagents marked by an asterisk (*) contain dangerous substances.

Package contents	CL49-200S	CL49-400S
*REAGENT 1 Sulphate copper 7 mmol/L, sodium-potassium tartrate 20 mmol/L, sodium hydroxide 0,75 mol/L, potassium iodide 6 mmol/L.	2 x 100 ml	4 x 100 ml
STANDARD (Std) Albumin 4 g/dl.	1 x 4 ml	1 x 4 ml

STABILITY: if stored away from light at 2-8°C, these reagents are stable up to the expiration date indicated on the label. Keep the bottles closed when not in use.

NECESSARY ITEMS – NOT PROVIDED

Usual laboratory equipment: UV/VIS Spectrophotometer with temperature control; automatic micropipettes; Optical glass cuvettes or, alternatively, disposable ones in optical polystyrene; Saline solution.

MANUAL ASSAY PROCEDURE

Method: increasing endpoint
Wavelength: 550 nm (540 - 570)
Optical path: 1 cm
Temperature: 25 - 37°C
Reaction time: 10 minutes
Reading: against blank reagent
Sample/Reagent Ratio: 1/100

Bring the reagent to the chosen temperature for the analysis.

Pipette in cuvette:

	Blank reagent	Standard	Sample
Distilled water	10 µl	-	-
Standard	-	10 µl	-
Sample	-	-	10 µl
Reagent 1	1,0 ml	1,0 ml	1,0 ml

Mix and incubate at the chosen temperature for 10 minutes. Then read the absorbance of the standard (AbsStd) and of the sample (AbsC) against blank reagent.

Reaction volumes can be proportionally varied without any change in calculation.

CALCULATION

Calculate the concentration in the sample using the following formula:

$$[\text{g/dl}] \text{ total proteins} = \text{AbsC} / \text{AbsStd} \times 4$$

REFERENCE VALUES

Serum / plasma: 6,6 ÷ 8,3 g/dl

Each laboratory should define its own reference values for this method.

QUALITY CONTROL – CALIBRATION

All Clinical Chemistry laboratories should implement a quality control program. Control serums of human origin are available for this purpose on request:

PRE-NORM serums with normal values

PRE-PATH serums with pathological values

If the method requires it, a multi-parameter calibrator of human origin is available.

PERFORMANCE CHARACTERISTICS

Sensitivity

The method discriminates up to 0,1 g/dl.

Linearity

The method is linear up to 12 g/dl.

For higher values, dilute the sample 1:10 with saline solution and multiply the result by 10.

Precision

Within run (n=10)	Average [g/dl]	SD	CV %
Sample 1	5,56	5,28	3,23
Sample 2	0,18	0,09	1,70

Within run (n=20)	Average [g/dl]	SD	CV %
Sample 1	5,61	0,09	1,61
Sample 2	5,28	0,09	1,70

Interferences

Up to 20 mg/dl, bilirubin does not interfere.

Sample haemolysis causes overestimated values.

Correlation against a reference method

The correlation of method (Y) against a reference method (X) gives the following equation:

$$Y = 1,0068X - 0,0670$$

$$r = 0,9974$$

DISPOSAL

Dispose of reagents and of waste according to local regulations.

WARNINGS AND PRECAUTIONS



WARNING Reagent 1 causes severe eye irritation (H319) and skin irritation (H315). It is also dangerous for aquatic organisms, with long-term effects (H412). IN CASE OF CONTACT WITH THE SKIN: rinse thoroughly with water (P302+P352). IN CASE OF CONTACT WITH THE EYES: rinse thoroughly for several minutes. If the irritation continues, see a doctor (P337+P313).

REFERENCES

- Gornall A.G., Bardawill C.J. and David M.M., J.Biol.Chem.177,751 (1949)
- Henry R. J., Cannon D. C. and Winkelman J. W., Clinical Chemistry, Harper & Row, 2nd Ed. (1974), p. 415.
- Kaplan LA, Pesce AJ: "Clinical Chemistry", Mosby Ed. 1989.

MANUFACTURER

FAR

Via Fermi, 12 - 37026 Pescantina - VERONA - ITALY
tel +39 045 6700870/6700871 - fax +39 045 7157763

website <http://www.farddiag.com>

e-mail: order@farddiag.com

e-mail: farddiag@farddiag.com

KEY SYMBOLS

	in Vitro diagnostic medical device
	batch number
	catalog number
	temperature limits
	use by
	caution
	consult accompanying documents

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