

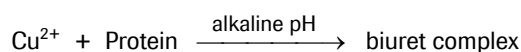
Total Protein Assay for Cedex Bio and Bio HT Analyzers

Fast automated determination of the protein concentration

The Total Protein assay developed for Cedex Bio and Cedex Bio HT Analyzers provides fast and accurate quantitative determination of the protein concentration in aqueous solutions like cell culture and fermentation media.

Assay principle

The colorimetric assay is based on the biuret reaction: Copper ions in alkaline solution form a purple-colored complex with the peptide bounds of proteins. The increase in absorbance at 552 nm is proportional to the total protein concentration.



Process control based on fast and reliable analytics

- Automated assay with highly reproducible results
- Wide measuring range, option for on-board dilution
- Determination of any protein, no development of product-specific assays necessary
- No sample filtration or other pretreatment required

High accuracy

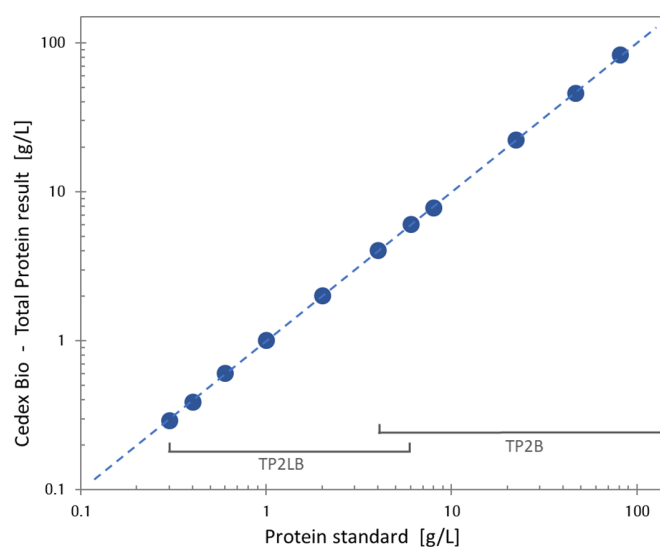


Fig. 1: Accuracy of the protein determination

Standard solutions of serum albumin from 0.3 to 100 g/L (w/v) were tested for Total Protein on a Cedex Bio Analyzer. Using two protocols for the low (TP2LB) and high (TP2B) range, the recovery was within $\pm 3.2\%$ for all concentrations, confirming a perfect linearity and accuracy over the whole range. (Excerpt from Roche verification data)

Wide measuring range, low sample volume required

The same reagent is used with several protocols to cover a wide protein concentration range from 0.3 g/L to maximal solubility with perfect precision and accuracy.

Only 2 – 20 µl of sample are used in the test, depending on the need for high sensitivity or automated predilution for higher protein concentrations.

Protocol	Protein range	Sample vol.
TP2LB low range	0.3- 6 g/L	30 µL
TP2B high range	4 – 120 g/L	2 µL
TP2D high + dilution	40 – 1 200 g/L	20 µL

Precision

Representative performance data from Cedex Bio HT Analyzers are shown. Results obtained in individual laboratories may differ.

Coefficients of variation (CV) were calculated for in-run precision (n=21) and inter-run precision (on 10 days).

Protein conc.	Level 1	Level 2	Level 3
Mean	52.6 g/L	65.4 g/L	92.0 g/L
CV in-run	0.5%	0.5%	1.0%
CV inter-run	1.0%	1.5%	2.2%

Specificity

The biuret reaction used in this assay detects peptide bounds in every protein. The variation of the signal intensity in dependence on sequence, size and structure of the protein is very low.

Therefore, the common calibration of the test using the provided 'Calibrator A Bio' (containing albumin and immunoglobulin) results in a good test accuracy (typically within 5%) for the majority of proteins.

If extreme conditions of the sample matrix (e.g., high salts) or very special protein structures show an influence on the assay, then the optimal accuracy will be achieved with a specific calibration using a standard solution of the individual protein product and buffer matrix (30 – 60 g/L protein required). Several product-specific calibrations can be used with the same Total Protein kit (additional protocol copies are available for specific analysis of several products on the same analyzer).

Potential interferences

There is a risk of matrix effects if samples contain special components in higher concentrations, especially when using the low range protocol TP2LB (0.3 – 6 g/L) with higher sample input. If a slight interference is observed but the biuret reaction is not completely inhibited, the effect can be compensated using a custom standard for product-specific calibration of the test with the same buffer matrix (see chapter *Specificity*).

Following components may cause a critical interference in the test. The concentration limits depend on the protocol:

Reagent	TP2LB low range	TP2B high range
Tris	≥ 10 mmol/L	≥ 25 mmol/L
Citrate	≥ 50 mmol/L	≥ 100 mmol/L
Imidazol	≥ 100 mmol/L	≥ 200 mmol/L
Histidin	≥ 5 mmol/L	≥ 10 mmol/L

Ordering information

Product	Pack size	Catalog no.
Total Protein Bio ¹	2 x 100 tests	07 374 593 001
Total Protein Bio HT ¹	300 tests	06 990 169 001
Calibrator A Bio ²	6 x 1 ml	06 682 189 001
Control A Level 1 Bio ²	6 x 1 ml	06 682 189 001
Control A Level 2 Bio ²	6 x 1 ml	06 682 227 001
Control A Level 3 Bio ²	6 x 1 ml	06 682 545 001

Regulatory disclaimer

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² For quality control/manufacturing of IVD/medical devices/pharmaceutical products only.

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Published by

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