



台塑總蛋白試劑（TP）- Biuret method

效能：
用於臨床實驗體外定量分析人體血清中總蛋白的含量。

臨床意義：
血清總蛋白濃度主要反映肝臟合成功能和因腎病造成的蛋白流失的情況。通常總蛋白的升高發生在脫水、免疫球蛋白增加等病症；而總蛋白的降低則發生在營養不良、腎病綜合症、各種肝病、惡性腫瘤等病症。

方法學原理：
$$\text{Protein} + \text{Cu}^{2+} \xrightarrow{\text{Alkali}} \text{Cu-protein complex (violet)}$$

- 試劑：**
- 產品規格：
詳見外盒包裝標示。
 - 成份與濃度：

成份	濃度
CuSO ₄	12 mmol/L
NaOH	0.6 mmol/L
Potassium sodium tartrate	32 mmol/L
KI	30 mmol/L

保存溫度：
2-8℃ 保存，請勿冰凍。

檢體：
使用無溶血之血清，血清收集後室溫放置不超過一星期，若超過則檢體須保存在 2-4℃，可維持一個月。

- 操作步驟：**
- 測定主波長：546 nm 測定副波長：700nm
溫度：37℃ 比色杯光徑：1.0 cm
 - 本試劑盒為液態單試劑，可直接上機使用。
- | 加入物（ml） | 空白管 | 標準管 | 檢體管 |
|---------|------|------|------|
| 去離子水 | 0.02 | --- | --- |
| 標準液 | --- | 0.02 | --- |
| 檢體液 | --- | --- | 0.02 |
| 試 劑 | 1.0 | 1.0 | 1.0 |

分別混合均勻，37℃ 保溫 10 分鐘，以空白管調“零”點，分別在 546nm 及 700nm 處檢測各管吸光值 A，A = A₅₄₆ - A₇₀₀。分別檢測各吸光值（A_{檢體}和 A_{標準}）。



台塑总蛋白试剂（TP）- Biuret method

效能：
用于临床实验体外定量分析人体血清中总蛋白的含量。

临床意义：
血清总蛋白浓度主要反映肝脏合成功能和因肾病造成的蛋白流失的情况。通常总蛋白的升高发生在脱水、免疫球蛋白增加等病症；而总蛋白的降低则发生在营养不良、肾病综合症、各种肝病、恶性肿瘤等病症。

方法学原理：
$$\text{Protein} + \text{Cu}^{2+} \xrightarrow{\text{Alkali}} \text{Cu-protein complex (violet)}$$

- 试剂：**
- 产品规格：
详见外盒包装标示。
 - 成份与浓度：

成份	浓度
CuSO ₄	12 mmol/L
NaOH	0.6 mmol/L
Potassium sodium tartrate	32 mmol/L
KI	30 mmol/L

保存温度：
2-8℃ 保存，请勿冰冻。

检体：
使用无溶血之血清，血清收集后室温放置不超过一星期，若超过则检体须保存在 2-4℃，可维持一个月。

- 操作步骤：**
- 测定主波长：546 nm 测定副波长：700nm
温度：37℃ 比色杯光径：1.0 cm
 - 本试剂盒为液态单试剂，可直接上机使用。
- | 加入物（ml） | 空白管 | 标准管 | 检体管 |
|---------|------|------|------|
| 去离子水 | 0.02 | --- | --- |
| 标准液 | --- | 0.02 | --- |
| 检体液 | --- | --- | 0.02 |
| 试 剂 | 1.0 | 1.0 | 1.0 |

分别混合均匀，37℃ 保温 10 分钟，以空白管调“零”点，分别在 546nm 及 700nm 处检测各管吸光值 A，A = A₅₄₆ - A₇₀₀。分别检测各吸光值（A_{检体}和 A_{标准}）。

结果计算
检体中总蛋白浓度（g/dL）
$$= \frac{A_{\text{检体}}}{A_{\text{标准}}} \times \text{蛋白标准液浓度（g/dL）}$$

参考值：
6.0-8.2（g/dL）

注意事项：

- 本试剂请用专用标准品(calibrator)，不另外提供质控血清(control)，建议质控血清为 Bio-Rad Lyphochek control。
- 建议各实验室建立独立之品管系统，并定义专属之参考值范围。
- 本检验试剂限由医师或医检师临床使用。
- 为保证结果的准确性，必须在检体加入后 30 分钟内检测吸光值。避免使用溶血及乳糜血之血清，因为溶血及乳糜血之血清会导致测定值增加。
- 本试剂线性可达 10g/dL。当检体中的蛋白浓度大于 10g/dL 时，可用生理食盐水稀释检体再重新分析，结果乘以稀释倍数。
- 以上操作步骤适用于手工操作及一般半自动及全自动生化分析仪。
- 本品操作时需穿戴手套及必要之防护措施，若不慎沾上，应用水或肥皂水清洗。(详细溶液物化性请洽询经销商索取物质安全数据表)
- 用毕应按医疗事业废弃物处理。(详细溶液物化性请洽询经销商索取物质安全数据表)
- 有效期限见试剂盒上标签所示。
- 经专业人员建议，试剂与检体用量可根据所用分析仪的要求按比例调整，其吸光值不变，不影响监测结果。
- 试剂特性及参数设定请参见第四页。



MeDiPro TOTAL PROTEIN TEST (TP) - Biuret method

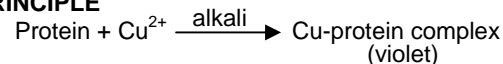
INTENDED USE

For the quantitative determination of Total Protein in serum or plasma.

CLINICAL SIGNIFICANCE

Proteins form the major portion of the solutes dissolved in the plasma fluid. The determination of total protein is useful in detecting hyperproteinemia due to homoconcentration will occur in dehydration, paraproteinemia, or monoclonal disease (multiple myeloma, macroglobulinemia, cryoglobulinemia) and in some chronic polyclonal diseases, liver cirrhosis, sarcoidosis, systemic lupus erythematosus, and chronic infections. Conditions will result in serum protein decrease including overhydration, protein loss through kidneys, severe burns, or in failure of protein synthesis (starvation, protein malnutrition, liver cell damage). Serum protein determination is also useful when determining the calcium concentration because the nondiffusible calcium fraction is bound to protein and varies with the serum protein.

PRINCIPLE



REAGENT

- Package: please see the reagent box label shown.
- Components:

Component	Conc.
CuSO ₄	12 mmol/L
NaOH	0.6 mmol/L
Potassium sodium tartrate	32 mmol/L
KI	30 mmol/L

STORE TEMPERATURE

The standard is stable up to the end of the indicated expiration date. If stored at **2 – 8 °C**., reagent should be protected from light and contamination should be avoided.

Do not freeze the reagent!

SPECIMEN COLLECTION AND PREPARATION

Serum and plasma are the specimen of choices. Avoid from hemolysis. Lipemic sera may cause elevated results. Sera with BSP will cause falsely elevated results. Proteins in serum are stable for 1 week at room temperature, up to one month in the refrigerator and longer when stored in the freezer.

PROCEDURES

- Main wavelength : 546 nm
Sub. wavelength : 700nm
Reaction Temperature : 37°C
Optical path length : 1.0 cm
- This kit contains single reagent, ready to use.

	Blank	Control	Specimen
ddH ₂ O (ml)	0.02	---	---
Control (ml)	---	0.02	---
Specimen (ml)	---	---	0.02
R1 (ml)	1.0	1.0	1.0

Mix, incubate at 37°C for 10 min, and read the absorbance against reagent blank. $A = A_{546} - A_{700}$

CALCULATION

With standard or calibrator

$$\text{Protein (g/dL)} = \frac{A_{\text{sample}}}{A_{\text{std./cali.}}} \times \text{conc. Std./cali. (g/dL)}$$

REFERENCE RANGE

6.0-8.2 (g/dL)

WARNINGS AND PRECAUTIONS

- This kit offers an optional calibrator, which is sold individually. Bio-Rad Lyphochek control is recommended to use as serum control.
- Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.
- This kit is for professionals and *in vitro* diagnostic use only.
- To ensure the accuracy of result, the absorbance should be measured within 30 minutes after sample addition. Hemolysis and lipemia might interfere the test result.
- The test is developed to determine total protein concentrations up to 10 g/dL. When values exceed this range, samples should be diluted with normal saline and calculate the results by multiplying the dilution factor.
- The above-mentioned procedures are suitable either for the general semi-automatic, full-automatic biochemical analysis instrument or manual operation.
- Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.
- Waste management please refers to the local legal requirements.
- Please refer to the manufacturer's safety data sheet and the product labeling for information on potentially hazardous components. (MSDS could be obtained from local dealer.)
- According to the technical suggestion, the volume of reagent and specimen could be adjusted in a ratio for full-automatic biochemical analysis instrument use. It won't affect the absorbance and



FORMOSA BIOMEDICAL TECHNOLOGY CORP.

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MeDiPro TOTAL PROTEIN TEST (TP) - Biuret method

the result.

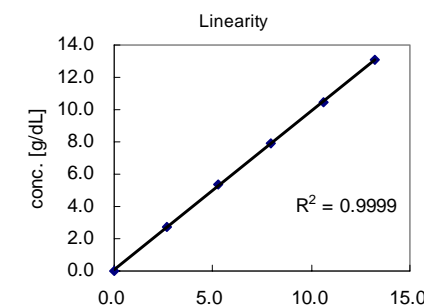
- Validity please see the reagent box label shown.

REAGENT CHARACTERS

- Precision (Within run)

N=15	Mean[g/dL]	SD [g/dL]	CV[%]
Sample1	4.11	0.03	0.77
Sample2	4.16	0.03	0.77
Sample3	6.54	0.05	0.73

- Linearity



This kit has a good linearity up to 12g/dL.

- Interference

Interference	Influence effect
Hemoglobin	No interference was observed by hemoglobin up to 50mg/dL
Ascorbic acid	No interference was observed by ascorbic acid up to 50mg/dL
Bilirubin (free form)	No interference was observed by bilirubin up to 12mg/dL
Bilirubin (conjugate form)	No interference was observed by bilirubin up to 40mg/dL
Intrafat	No interference was observed by intrafat up to 0.2%

- Stability

Expire day	1 year
Open vial stability	30 day

REFERENCE

Doumas BT, Bayse D, Borner K, et al. A candidate reference method for determination of total protein in serum : I. development and validation. Clin. Chem. 1981. 27:1642.

PARAMETER SETUP

Hitachi 7170/917 Applications

TEST	[TP]
ASSAY CODE	[1 POINT]:[34]-[0]
SAMPLE VOLUME	[4]
R1 VOLUME	[200]
R2 VOLUME	[0]
WAVELENGTH(nm)	[700][546]
CALIB. METHOD	[Linear]

Hitachi 7150/717 Applications

TEST	[TP]
ASSAY CODE	[1 POINT]:[50]-[0]
SAMPLE VOLUME	[6]
R1 VOLUME	[300]
R2 VOLUME	[0]
WAVELENGTH(nm)	[700][546]
CALIB. METHOD	[Linear]

ORDERING INFORMATION

Cat. No.	Product	Package
BC-0026M	MeDiPro TOTAL PROTEIN TEST	R1 6x20ml
BC-0026A	MeDiPro TOTAL PROTEIN TEST	R1 4x60ml
BC-0026B	MeDiPro TOTAL PROTEIN TEST	R1 4x100ml
BC-0026C	MeDiPro TOTAL PROTEIN TEST	R1 4x300ml
BC-0026D	MeDiPro TOTAL PROTEIN TEST	R1 4x500ml



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