

產品型號: BC-0005
V1.0

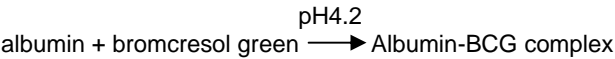


台塑白蛋白試劑（ALB）- Bromcresol green method

效能：
用於臨床實驗體外定量分析人體血清或血漿中白蛋白的含量。

臨床意義：
白蛋白合成於肝細胞中，為正常人體血清主要的蛋白質組成部分，佔總蛋白 50%以上，其濃度之增減足以左右總蛋白的濃度。同時它作為一個結合和轉運分子，對人體營養狀況起著重要的調節作用。白蛋白的檢測對脫水、營養不良、腎病綜合症和肝功能不良的診斷具有較高的價值。

方法學原理：
它具有與許多陰離子有機物結合的特性，如：脂肪酸、膽紅素、色素結合或指示劑。



試劑：

1. 產品規格： 詳見外盒包裝標示。	
2. 成份與濃度：	濃度
成份	
Succinate buffer(pH4.2±0.2)	75 mmol/L
Bromcresol green	0.15 mmol/L

保存溫度：
2-8℃ 保存，請勿冰凍。

檢體：
新鮮血清或肝素、EDTA 抗凝的血漿。

操作步驟：

1. 測定主波長：600 nm
溫度：37

測定副波長：700nm
比色杯光徑：1.0 cm

2. 本試劑盒為液態單試劑可直接使用。

加入物 (ml)	空白管	標準管	檢體管
檢體 ml	---	---	0.01
標準液 ml	---	0.01	---
去離子水 ml	0.01	---	---
試劑 ml	1.0	1.0	1.0

分別混合均勻，於 37 保溫 5 分鐘，以空白管調“零”點，分別在 600nm 及 700nm 處檢測各管吸光值 A， $A = A_{600} - A_{700}$ 。分別檢測各吸光值 ($A_{\text{檢體}}$ 和 $A_{\text{標準}}$)。

6. 以上操作步驟適用於手工操作及一般半自動及全自動生化分析儀。

7. 本品操作時需穿戴手套及必要之防護措施，若不慎沾上，應用水或肥皂水清洗。(詳細溶液物化性請洽經銷商索取物質安全資料表)

8. 用畢應按醫療事業廢棄物處理。(詳細溶液物化性請洽經銷商索取物質安全資料表)

9. 有效期限見試劑盒上標籤所示。

10. 經專業人員建議，試劑與檢體用量可根據所用分析儀

結果計算
檢體中白蛋白濃度（g/dL）

$$= \frac{A_{\text{檢體}}}{A_{\text{標準}}} \times \text{白蛋白標準液濃度（g/dL）}$$

IVD 供體外診斷使用
For *In Vitro* Diagnostic

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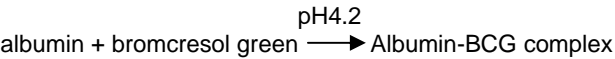


台塑白蛋白试剂（ALB）- Bromcresol green method

效能：
用于临床实验体外定量分析人体血清或血浆中白蛋白的含量。

临床意义：
白蛋白合成于肝细胞中，为正常人体血清主要的蛋白质组成部分，占总蛋白 50%以上，其浓度之增减足以左右总蛋白的浓度。同时它作为一个结合和转运分子，对人体营养状况起着重要的调节作用。白蛋白的检测对脱水、营养不良、肾病综合症和肝功能不良的诊断具有较高的价值。

方法学原理：
它具有与许多阴离子有机物结合的特性，如：脂肪酸、胆红素、色素结合或指示剂。



试剂：

1. 产品规格： 详见外盒包装标示。	
2. 成份与浓度：	浓度
成份	
Succinate buffer(pH4.2±0.2)	75 mmol/L
Bromcresol green	0.15 mmol/L

保存温度：
2-8℃ 保存，请勿冰冻。

检体：
新鲜血清或肝素、EDTA 抗凝的血浆。

操作步骤：

1. 测定主波长：600 nm 测定副波长：700nm
温度：37 比色杯光径：1.0 cm

2. 本试剂盒为液态单试剂可直接使用。

加入物（ml）	空白管	标准管	检体管
检体 ml	---	---	0.01
标准液 ml	---	0.01	---
去离子水 ml	0.01	---	---
试剂 ml	1.0	1.0	1.0

分别混合均匀，于 37 保温 5 分钟，以空白管调“零”点，分别在 600nm 及 700nm 处检测各管吸光值 A，A = A₆₀₀-A₇₀₀。 分别检测各吸光值（A_{检体}和 A_{标准}）。

销商索取物质安全数据表)

8. 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)

9. 有效期限见试剂盒上标签所示。

10. 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。

11. 试剂特性及参数设定请参见第四页。

结果计算
检体中白蛋白浓度（g/dL）

$$= \frac{A_{\text{檢體}}}{A_{\text{標準}}} \times \text{白蛋白標準液濃度（g/dL）}$$

同时测定血清检体的总蛋白浓度，减去血清白蛋白浓度，即得血清球蛋白浓度。并可计算血清白蛋白、球蛋白的比值。

IVD 供体外诊断使用
For *In Vitro* Diagnostic



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**MeDiPro ALBUMIN TEST (ALB) - Bromcresol green method****INTENDED USE**

For the quantitative determination of albumin in serum or plasma.

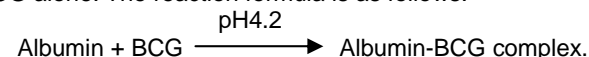
CLINICAL SIGNIFICANCE

Albumin is the most abundant individual protein in serum. The liver is the site of albumin synthesis, hence liver disease is one of the common causes of decreased albumin level. Other conditions such as congestive heart failure, malnutrition, starvation, nephritis, gloemlonephritis, leukemia and severe burns also results in the decrease of albumin level.

Albumin levels may be elevated in dehydration, shock, hemoconcent ration, or upon administration of large quantities of concentrated albumin intravenously.

PRINCIPLE

Bromcresol green (BCG), an ionic dyes, binds tightly to albumin when serum is added. The albumin- BCG complex absorbs light at 600 nm more intensively than BCG alone. The reaction formula is as follows:

**REAGENT**

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

Component	Conc.
Succinate buffer(pH4.2±0.2)	75 mmol/L
Bromcresol green	0.15 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

Fresh serum, heparin or EDTA-treated plasma, and avoid hemolysis.

PROCEDURES

- Main wavelength : 600 nm
Sub. wavelength : 700nm
Reaction Temperature : 37°C
Optical path length : 1.0 cm
- This kit contains single reagent, ready to use.

	Blank	Control	Sample
Sample (ml)	---	---	0.01
Control (ml)	---	0.01	---
Dist. Water (ml)	0.01	---	---
Reagent (ml)	1.0	1.0	1.0

Mix, incubate at 37°C for 5 min, and read the absorbance against reagent blank. $A = A_{600} - A_{700}$

CALCULATION

With standard or calibrator

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

REFERENCE RANGE

Age	Conc. (g/dL)
Adult	3.5-5.0
>60yr.	3.4-4.8
Pregnancy	2.5-4.0

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.
- The test is developed to determine albumin concentrations up to 5.5 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

**MeDiPro ALBUMIN TEST (ALB) - Bromcresol green method**

adjusted in a ratio for full-automatic biochemical analysis instrument use. It won't affect the absorbance and the result.

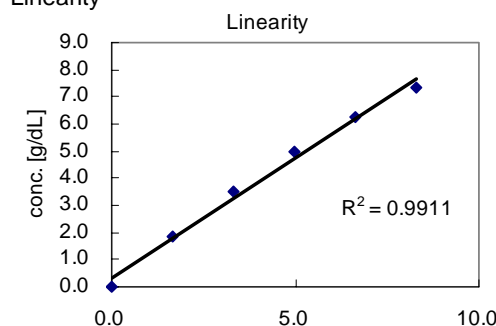
- Validity please see the reagent box label shown.

REAGENT CHARACTERS

- Precision (Within run)

N=15	Mean[g/dL]	SD [g/dL]	CV[%]
Sample1	2.77	0.01	0.52
Sample2	2.80	0.01	0.51
Sample3	3.99	0.03	0.64

- Linearity



This kit has a good linearity up to 7.0g/dL.

- Interference

Interference	Influence effect
Hemoglobin	No interference was observed by hemoglobin up to 300mg/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 40mg/dL
Bilirubin (conjugate form)	No interference was observed by bilirubin up to 20mg/dL
Intrafat	No interference was observed by intrafat up to 2.0%

- Stability

Expire day	1 year
Open vial stability	30 day

REFERENCE

Doumas BT, Watson WA, Biggs HG. Albumin standards and the measurement of serum albumin with bromcresol green. Clin. Chim. Acta. 1971. 31:87-96.

PARAMETER SETUP**Hitachi 7170/917 Applications**

TEST	[ALB]
ASSAY CODE	[1POINT]:[10]-[0]
SAMPLE VOLUME	[2]
R1 VOLUME	[200]
R2 VOLUME	[0]
WAVELENGTH(nm)	[700][600]
CALIB. METHOD	[Linear]

Hitachi 7150/717 Applications

TEST	[ALB]
ASSAY CODE	[1POINT]:[15]-[0]
SAMPLE VOLUME	[3]
R1 VOLUME	[300]
R2 VOLUME	[0]
WAVELENGTH(nm)	[700][600]
CALIB. METHOD	[Linear]

ORDERING INFORMATION

Cat. No.	Product	Package
BC-0005M	MeDiPro ALBUMIN TEST	R1 6x20ml
BC-0005A	MeDiPro ALBUMIN TEST	R1 4x60ml
BC-0005B	MeDiPro ALBUMIN TEST	R1 4x100ml
BC-0005C	MeDiPro ALBUMIN TEST	R1 4x300ml
BC-0005D	MeDiPro ALBUMIN TEST	R1 4x500ml

**FORMOSA BIOMEDICAL TECHNOLOGY CORP.**

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