CE IVD

ALB Reagent Kit (BCG Colorimetric Method)

Instructions for Use REF CC1004

PRODUCT NAME

ALB Reagent Kit (BCG Colorimetric Method)

PACKAGE SPECIFICATION

R:1×10 mL	R:1×20 mL	R:1×50 mL	R:2×30 mL
R:2×35 mL	R:2×40 mL	R:2×45 mL	R:2×50 mL
R:2×55 mL	R:2×60 mL	R:4×20 mL	R:4×30 mL
R:4×35 mL	R:4×40 mL	R:4×45 mL	R:4×50 mL
R:4×55 mL	R:4×60 mL	R:5×20 mL	R:5×120 mL
R:6×20 mL	R:6×30 mL	R:6×35 mL	R:6×40 mL
R:6×45 mL	R:6×50 mL	R:6×55 mL	R:6×60 mL
R:6×100 mL	R:8×20 mL	R:10×20 mL	R:4×1000 mL
R:2×2000 mL	R:2×300T (2×100 mL)		
R:12×72 T (12×25 mL)		Calibrator (optional):1×1 mL	

INTENDED USE

Used for the *in vitro* quantitative determination of Albumin (ALB) in human serum and plasma.
Mainly used clinically to assist in the evaluation of liver function and nutritional assessment.
For professional and laboratory use only.

TEST PRINCIPLE

This reagent is prepared according to the Bromocresol Green (BCG) method recommended by the World Health Organization (WHO).
The principle is as follows: in acidic solution (pH4.15), albumin and BCG form a green complex, of which absorbance at 600 nm is proportional to the concentration of albumin, and its content can be measured against the standard.

MAIN COMPONENTS

Kit content	Reagent components	Concentration
Reagent	Succinate Buffer (pH 4.15)	10 g/L
	Polyoxyethylene (23) Lauryl Ether	2.5 g/L
	Bromocresol green	0.3 g/L
Calibrator (optional)	Albumin, aqueous matrix	30-50 g/L

The components in different batches of a multi-component kit are not interchangeable.
Calibrator traceability: traceable to National Reference Material GBW (E) 090619.

STORAGE AND SHELF LIFE

Unopened reagents should be stored at 2°C-8°C away from light, with a shelf life of 18 months. Opened reagents are stable for 42 days when stored at 2°C-8°C.
Please refer to the label on the reagent kit for the production date and expiration date.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

Serum and heparin anti-coagulated plasma should be separated promptly after blood collection to avoid Hemolysis, and serum and plasma could be stabilised at 15-25°C for 7 days, at 2-8°C for 1 month and at −20°C for 4 months.

TEST PROCEDURE

1. Reagent preparation: Use directly.
2. Test conditions: (Different load parameters can be requested based on different testing instruments)

Primary/secondary wavelength	600nm/700 nm	**Calibration type**	Linearity
Sample/Reagent	2/300 μL	**Time of mixture of serum + R1**	1 min
Method	One-point end point assay	**Total reaction time**	1 min
Calibration method	Two-point calibration	**Direction of reaction**	Upward

(Absorbance (A) read by the instrument=$A_{\text{Primary wavelength}}$-$A_{\text{Secondary wavelength}}$)
Operating procedures:
Single-reagent operation

Substances added	Test tubes	Standard tubes	Blank tubes
Reagent	300 μL	300 μL	300 μL
Sample	2 μL	-	-
Standard solution	-	2 μL	-
Distilled water	-	-	2 μL
Mix well, incubate at 37°C for 1 min, and then calibrate the with a blank and read the absorbance A of each tube.			

3. Calibration procedure: A calibrator from Getein is recommended, and a calibration serum from Randox can also be used.
4. Quality control procedure: select quality control serum from Randox, and its measured value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:
   4.1 Check whether the parameter settings and light source are correct.
   4.2 Check whether the cuvettes and sampling probes are clean.
   4.3 Check whether water is contaminated, and bacterial growth will cause incorrect results.
   4.4 Check reaction temperature.
   4.5 Check the expiration date of the kit.
5. Result calculation:
   ALB concentration (g/L)=Concentration of ALB Standard Reference Material (SRM) ×$\triangle A_{\text{test sample}}/\triangle A_{\text{SRM}}$

REFERENCE RANGE

Appropriate level: 40-55 g/L
The reference range is for reference only. It is recommended that each laboratory should establish its own reference range.

RESULT INTERPRETATION

Hemolysis interferes with the assay and should be avoided as much as possible during the procedure. The time the sample is left in place also has an effect on the assay.

LIMITATIONS

There is no interference with measurement when hemoglobin ≤ 400 mg/dL, ascorbic acid ≤ 30 mg/dL, bilirubin ≤ 40 mg/dL, and triglycerides ≤ 500 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Reagent in the kit is a slightly yellowish green clear liquid, which may contain a small number of subvisible particles that do not affect determination.
2. Reagent blank absorbance
   Reagent blank absorbance $|A_{600nm}| \leq 0.500$.
3. Accuracy
   The relative deviation should not fall outside the range of ± 6.0%.
4. Linear range
   For serum sample testing within the reagent linear range of [3, 60.0] g/L:
   a) The linear correlation coefficient (r) should not be less than 0.990;
   b) The deviation from linearity should not fall outside the range of ± 2.5 g/L for testing within the linear range of [3, 8] g/L; the deviation from linearity should not fall outside the range of ± 10.0% for testing within the linear range of (8, 60] g/L.
5. Analytical sensitivity
   When a sample has a concentration of 40 g/L, its absorbance difference should be ≤ 0.800.
6. Precision
   6.1 Repeatability
   The repeatability (coefficient of variation, CV) of repeat test results for serum at a concentration of (40 ± 5) g/L should not exceed 2.0%.
   6.2 Between-run precision
   Inter-assay variation of serum at a concentration of (40 ± 5) g/L should not be more than 5.0%.

PRECAUTIONS

1. General precautions
   1.1 This product is for *in vitro* diagnosis only.
   1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
   1.3 Please use this product according to the IFU.
   1.4 Reagents from different manufacturers used to test the same sample may produce different results, which should be considered in conjunction with clinical findings.
2. Precautions for operation
   2.1 Please treat the specimens as dangerous substances that may be infected with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
   2.2 If the reagents get into the eyes or mouth, or come into contact with the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
3. Precautions for use
   3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
   3.2 Please do not use expired reagents whose test results may be inaccurate.
   3.3 Please avoid adding reagents halfway during a test.
   3.4 Please avoid direct sunlight during operation.
   3.5 The reagents cannot be used if they are cloudy.
   3.6 Serum, heparin anti-coagulated plasma, should be separated promptly after blood collection to avoid haemolysis, do not use haemolysed samples.
4. Precautions for waste disposal
   Samples, waste liquids, etc. are potentially biologically contaminated. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
   5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
   5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
   5.3 Please do not use the reagent bottles for other purposes.
   5.4 A result calculated with the k value is not as reliable as that obtained using the SRM (calibrator).
   5.5 Please do not mix reagents in different batches.

REFERENCE

Shang Hong, et al. National Standard Operating Procedure for Clinical Testing (4th Edition). People's Medical Publishing House, 2015: 203-206

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on ALB Reagent Kit (BCG Colorimetric Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

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