This package insert follows the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan.

In Vitro Diagnostics
Marketing Notification No. 13A2X00197218033

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This package insert must be read carefully prior to use.

Albumin assay kit for blood tests
(Classification No.: 30155001)

Autosera ALB

General Precautions **

1. This product is for in vitro diagnostic use, and must not be used for any other purposes.
2. Clinicians should make a comprehensive clinical decision based on assay results in conjunction with clinical symptoms and other examination results.
3. For the effects of an administered drug on the measured value, carefully read the Precautions for Use in the package insert of the drug, especially the section about the effects on laboratory test results. Please also read carefully the "2. Interfering Substances," in the "Procedural Precautions" section, as well as "2. Precautions for Assessment" in the "Assessment of Assay Results" section, of this package insert.
4. This product should be used only as directed in this package insert. Reliability of results cannot be guaranteed if there are any deviations from the instructions in this package insert.
5. If the reagent accidentally comes in contact with eyes and/or mouth, rinse immediately with ample water as first aid, and consult the doctor if required.
6. Carefully read the operating instructions for each type of automated analyzers prior to using this product. Parameters for each type of analyzers are available, and can be requested from SEKISUI MEDICAL CO., LTD. if required.
7. Perform a quality control test prior to assay to ensure accuracy.

Description (Kit Components) **

Component: Ingredients
ALB Reagent: Bromocresol green

Intended Use

Measurement of albumin in serum

Albumin accounts for 50% to 70% of total protein in serum. It plays an important role in maintaining the colloid osmotic pressure and in transporting various substances through the blood, including drugs. Because albumin is synthesized in the liver, it is measured as an important index of parenchymal liver disease and disorders of systemic protein metabolism.

Assay Principle

1. Assay Principle

Albumin in the sample binds to bromocresol green to form a complex with a blue-green color. The albumin content is determined by measuring the absorbance of the blue-green color complex.

Albumin in a sample + Bromocresol green
⟶ Colored complex (blue-green color)

2. Features

Assay results are hardly affected by interfering substances in samples such as bilirubin, hemolyzed blood, or ascorbic acid.

Procedural Precautions **

1. Properties of Samples and Sampling Methods

1) Samples
Serum may be used.
2) Storage of samples[3)]
If the isolated serum sample cannot be tested on the same day, specimens should be stored as follows:
2–10°C: for tests within 1 month
≤ -20°C: for tests after more than 1 month
Bring samples to room temperature (15–30°C) before use.

2. Interfering substances

Assay results are not affected by bilirubin (up to 20 mg/dL) or hemoglobin (up to 500 mg/dL).

3. Others

1) Always use Serum Multicalibrator (SEKISUI), Seronorm Multicalibrator, Seronorm Human or Anaserum ALB/TP Standard Solution for calibration.
2) Precautions for assay range
If the concentration of sample exceeds assay range, dilute the sample with saline and repeat the measurement.

Dosage/Administration (Assay Procedure) **

1. Preparation of reagents

Reagent (1): ALB Reagent is ready to use.

2. Assay Procedure

This product is compatible with various types of automated analyzer. An example of the assay procedure is indicated below.

Sample 3 µL + Reagent (1) 350 µL —(37°C, 10 min)→ Measurement (Absorbance※)
⟶ Calculation of concentration

※Absorbance: The difference in absorbance between 700 nm and 660 nm.
Calibration material: Serum Multicalibrator (SEKISUI), Seronorm Multicalibrator, Seronorm Human, or Anaserum ALB/TP Standard Solution. (manufacture's assigned value)
Reagent blank: Purified water or saline

Assessment of Assay Results **

1. Reference standard range[4)]

4.1–5.1 g/dL (Within the JCCLS common standard)

2. Precautions for Assessment

There may be reactions or interfering reactions with non-target substances. If assay results appear to be unreliable, repeat the measurement (if

necessary, after dilution) or try another analytical methods.

Performance **

1. Sensitivity

1) Reagent blank: absorbance being equal to or lower than 0.10
2) Sensitivity: The absorbance is 0.35–0.45 per 5.3 g/dL of albumin.

2. Accuracy: 90–110 % of the expected assay value

3. Within-run Reproducibility:
Coefficient of variation ≤ 3 %
(Test methods used for 1.–3. are in-house methods.)

4. Measurement Range[5]: (On Hitachi 7170S automated analyzer)
0.1–6.0 g/dL

5. Correlation[5]
Serum N=71 r=0.999 y=1.00x–0.02
Control method: Approved in vitro diagnostic (BCG method)

6. Standard Material
SRM927 (NIST), CRM470 (IRMM)

Precautions for Use or Handling *

1. Precautions for Handling (to Ensure Safety)

1) All samples used in the test should be handled as a material possibly infected with HIV, HBV, HCV, or other viruses. To prevent infection, use disposable gloves and avoid mouth pipetting during the test.
2) Sodium azide is added as an antiseptic agent in the ALB Reagent. Therefore, if the reagent comes in accidentally contact with eyes, mouth or skin, rinse immediately with ample water as first aid, and consult the doctor if required.

2. Precautions for use

1) This product should be stored as directed, without freezing. Freezing can deteriorate the reagents, which can produce inaccurate results. Therefore, avoid using the reagents which have been previously frozen.
2) Do not use expired reagents. Use of such reagents cannot guarantee the reliability of measurement values.
3) Do not replenish the reagents.
4) Do not perform the assay under direct sunlight

3. Precautions for Disposal

1) Before disposal, used samples and their containers must be immersed in sodium hypochlorite solution at a concentration of greater than 0.1% for longer than 1 hour or autoclaved at 121ºC for 20 minutes.
2) To prevent infections from spilled samples or solutions containing samples, wipe the spilled area thoroughly with disinfectants such as sodium hypochlorite solution at a concentration of greater than 0.1%.
3) The reagents and treated samples should be discarded as medical waste or industrial waste according to the waste disposal regulations.
4) The reagents should be disposed of in accordance with the Water Pollution Control act or related regulations.
5) Sodium azide has been added as an antiseptic agent in the ALB Reagent. It can react with lead or copper pipes to produce the highly explosive metal azide. Therefore, the reagent should be flushed with large amounts of water during disposal.

4. Other precautions

Do not use the containers for other purposes.

Storage and Shelf Life *

1. Storage temperature: room temperature

2. Shelf life: 2 years from the date of manufacture
(The expiration date is printed on the outer package.)

Packaging *

Name		Package
Autosera ALB	ALB Reagent	4 × 50 mL
		4 × 95 mL

References **
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1) Kitamura M. et al. Practical Clinical Chemistry. Tokyo: Ishiyaku Shuppan; 1974. Japanese.
2) Kanai M, editor. Kanai's manual of clinical laboratory medicine. 33th ed. Tokyo: Kanehara Shuppan; 2010. Japanese.
3) Sasaki M. et al. Sampling of constituents of the human body. Tokyo: Kodansha; 1972. Japanese.
4) Kanai M, editor. Kanai's manual of clinical laboratory medicine. 35th ed. Tokyo: Kanehara Shuppan; 2020. Japanese.
5) SEKISUI MEDICAL CO., LTD. In house data. Japanese.

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