

Plasma/Serum test for albumin

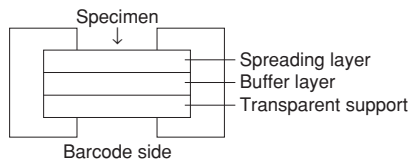
FUJI DRI-CHEM SLIDE ALB-P

[Warnings and precautions]

- Only the required number of slides should be taken out of the refrigerator and warmed up to room temperature before opening the individual packages.
- Do not touch either the center part of the surface or the back of the slide.
- A new slide must be used for each measurement. Do not reuse.
- Handle all patient specimens, control serum and used tips carefully as biohazardous samples. Wear proper gloves, glasses and other protective gear for your safety.
- Used slides are categorized as infectious waste. Make sure to dispose them in accordance with the Waste Disposal Law and other related regulations, which prescribe the proper method of disposal, such as incineration, melting, sterilization or disinfection.
- Bicarbonate salts give plus bias. Do not use the specimen from a patient administered bicarbonate salt, such as sodium bicarbonate.

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

- Bromocresol green 0.12 mg (0.18 μmol)

[Intended use]

Quantitative measurement of albumin concentration in plasma or serum.

For *in vitro* diagnostic use only.

[Principle of the measurement]

10 μL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE ALB-P.

After depositing, the specimen spreads uniformly on the spreading layer.

In the process, albumin reacts with bromocresol green (BCG) to form an albumin-BCG complex.

The albumin-BCG complex diffuses onto the underlying layer. The slide is incubated at 37 °C for a fixed time in the FUJI DRI-CHEM analyzer and the optical reflection density is measured at 625 nm. The optical reflection density is then converted into the albumin concentration using calibration curve preinstalled in the analyzer.

Albumin + Bromocresol green \longrightarrow Blue color dye

[Additional special equipment]

Analyzer: FUJI DRI-CHEM ANALYZER

Other implements: FUJI DRI-CHEM QC CARD (attached)

: FUJI CLEAN TIPS

: FUJI HEPARIN/PLAIN TUBE or Blood collection tube specified in the "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER

[Specimen requirements]

- After collecting the blood sample, immediate measurement is recommended.
- For plasma, heparin and EDTA salt can be used as the anticoagulant. When using heparin, less than 50 units of heparin should be used per 1 mL of whole blood. When using EDTA salt, less than 5 mg should be used per 1 mL of whole blood. Do not use sodium fluoride, citric acid, oxalic acid and monoiodoacetic acid.
- Avoid using plasma or serum with precipitate such as fibrin.
- Do not use hemolytic plasma or serum.

[Procedure]

- Read in the new QC-card when you switch to a new box of slides.
- Set slides on FUJI DRI-CHEM analyzer.
- Set a sample tube in the specified sample rack.
- Input a sequence No. and a sample ID if appropriate.
- Press the "START" key to initiate testing.
For further details of operation procedure, consult "INSTRUCTION MANUAL" for FUJI DRI-CHEM analyzer.

[Reference intervals]

38–50 g/L (3.8–5.0 g/dL)

As the reference intervals depend on the population of the test, it is required that each laboratory set its own reference intervals. The clinical diagnosis must be made by the doctor in charge based on the measured results in the light of clinical symptoms and other test results.

[Performance characteristics]

1. **Dynamic range** 10–60 g/L (1.0–6.0 g/dL)

Concentration range	Accuracy
10–60 g/L	Within $\pm 15\%$

3. **Precision**

Concentration range	Precision
10–20 g/L	SD ≤ 1 g/L
20–60 g/L	CV $\leq 5\%$

4. **Correlation**

Correlation was evaluated between bromocresol green method and FUJI DRI-CHEM system. Bromocresol green method was run on a HITACHI automated analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.

	n	Slope	Intercept	Correlation coefficient
Serum	54	0.987	0.2	0.981

5. Known interfering substances

- When albumin concentration is lower than the reference intervals and the A/G ratio is low, the result may have a plus bias.
- The effects on the measured value were examined by adding substances as shown below to a serum sample obtained from a healthy volunteer or a control serum. No significant effect was observed to the following concentration for each substance.

Ascorbic acid 0.57 mmol/L

Bilirubin 340 $\mu\text{mol/L}$

Hemoglobin 1000 mg/L

These results are representative;

- Test condition may have some influence on your results.
- Interferences from other substances are not predictable.

[Internal quality control]

The accuracy and precision of this product can be evaluated with FUJI DRI-CHEM CONTROL QP-L and/or QP-H.

- Select control level in accordance with your purpose.
- Measure FUJI DRI-CHEM CONTROL QP-L and/or QP-H in the same way as patient specimens.
- When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QP-L or QP-H, investigate the cause.
For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL QP-L or QP-H.

[Traceability of calibrators and control materials]

Albumin...IRMM (CRM470)

Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.

IRMM: Institute for Reference Materials and Measurement

[Storage and shelf life]

- Storage: This product must be stored between 2–8 °C (35.6–46.4 °F) before use.
- Expiry date is printed on the carton.
- Use immediately after opening the individual package.

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