



INSTRUCTIONS FOR USE

VITROS ALB Slides

ALB

Albumin

Intended Use

For in vitro diagnostic use only.

VITROS ALB Slides quantitatively measure albumin (ALB) concentration in serum and plasma.

Summary and Explanation of the Test

Of all serum proteins, albumin is present in the highest concentration. It maintains the plasma oncotic pressure and the transport of many substances. Increased serum albumin may indicate dehydration or hyperinfusion with albumin; a decrease is found in rapid hydration, overhydration, severe malnutrition and malabsorption, severe diffuse liver necrosis, chronic active hepatitis, and neoplasia. Albumin is commonly reduced in chronic alcoholism, pregnancy, renal protein loss, thyroid dysfunction, peptic ulcer disease, and chronic inflammatory diseases.¹

Principles of the Procedure

The VITROS ALB Slide is a dry, multilayered, analytical element coated on a polyester support.

A 10 µL drop of patient sample is deposited on the slide and is evenly distributed by the spreading layer to the underlying layers.

When the fluid penetrates the reagent layer, the bromocresol green (BCG) dye diffuses to the spreading layer and binds to albumin from the sample. This binding results in a shift in wavelength of the reflectance maxima of the free dye. The color complex that forms is measured by reflectance spectrophotometry. The amount of albumin-bound dye is proportional to the concentration of albumin in the sample.

Test Type	Wavelength	Assay Time and Temperature
Colorimetric	630 nm	Approximately 5 minutes at 37°C

Reaction Sequence



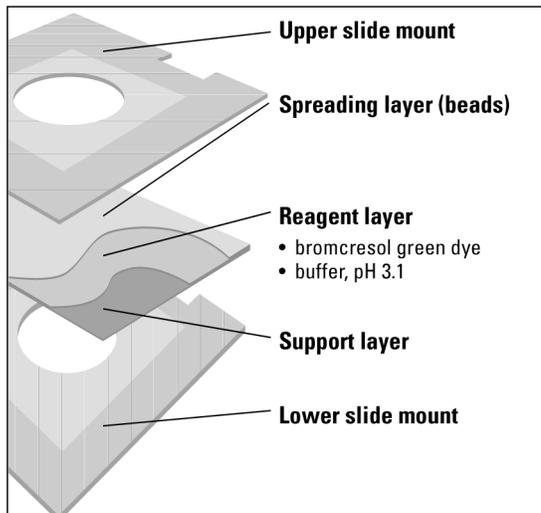
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Reagents**Slide Ingredients**

The reactive ingredient is bromcresol green dye.

Other ingredients include polymeric beads, binders, buffer, and surfactants.

Slide Diagram**Slide Labeling**

The cartridge's outer carton is labeled with the test name, slide lot number, expiration date, and required storage temperature.

Slide Cartridge Handling

CAUTION: Protect the inner wrapper from damage before opening.

- Do not drop a case of cartridges.
- Do not cut into the inner wrapper with a sharp instrument when opening the case.

Slide Storage***Unopened slide cartridges:***

Store at or below 2°–8°C (36°–46°F).

Cartridges in the system's slide supply:

- Leave in the slide supply for no more than one week, then replace with a fresh cartridge.
- Leave in the slide supply when the system is turned off for up to two hours.
- Verify performance with control materials:
 - If the system is turned off for more than two hours
 - After reloading cartridges that have been removed from the slide supply and stored for later use

Slide Stability

VITROS ALB Slides are stable until the expiration date on the carton when they are stored and handled as specified.

Slide Preparation

- Remove slide cartridges from storage.
- The slide cartridge must reach room temperature, 18°–28°C (64°–82°F), before it is unwrapped and loaded into the slide supply. Allow the cartridge to warm up at least:
 - 60 minutes after removing from the freezer
 - or
 - 30 minutes after removing from the refrigerator
- Remove the inner wrapper and immediately load into the slide supply.

NOTE: Load the cartridges within 24 hours after they reach room temperature.

Specimen Collection and Preparation

Patient Preparation

No special patient preparation is necessary.

Recommended Specimen Types

Serum; lithium and sodium heparin plasma.

Special Precautions

Albumin concentrations vary with posture. Results from an upright posture may be approximately 0.3 g/dL (3 g/L) higher than those from a recumbent posture.²

Specimen Collection and Preparation

- Collect specimens using standard laboratory procedures.^{3,4}
- Refer to the operator's manual section on sample handling for recommended minimum specimen volumes for your system.
- Centrifuge specimens and remove the serum from the clot within 3 days of collection.⁵

Handling and Storage Conditions

- Handle specimens as biohazardous material.
- Handle specimens in stoppered containers to avoid contamination and evaporation.
- Storage requirements:⁶
 - Store at room temperature up to seven days
 - Refrigerate up to one month
 - Freeze at or below -18°C (0°F) for storage beyond one month

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Testing Procedure**Materials Required But Not Provided**

The following items are required to perform the test for ALB:

- VITROS Chemistry Calibrator Kit 4
- Quality-control materials, such as VITROS Performance Verifiers
- For dilution, isotonic saline or reagent-grade water

Operating Instructions

Refer to the operator's manual for complete instructions on operation of your system.

Sample Dilution

If samples show albumin concentration that exceeds the system's reportable (dynamic) range, follow this procedure.

1. Dilute 10 parts of sample with 1 part isotonic saline or reagent-grade water.
2. Reanalyze.
3. Multiply the results by 1.1 to obtain the original sample's albumin concentration.

Calibration**Required Calibrators**

VITROS Chemistry Calibrator Kit 4

Calibrator Preparation, Handling, and Storage

Refer to the calibrator package insert for information about reconstitution and use of the Chemistry Calibrator Kit.

Calibration Procedure

Refer to the calibration section of your operator's manual.

When to Calibrate

- Calibrate when the slide lot number changes.
- Calibrate when critical system parts are replaced due to service or maintenance.
- If quality-control results are consistently outside acceptable limits, calibration might be required. Refer to your operator's manual for more detail.
- Calibrate when government regulations require. In the US, CLIA regulations require calibration or calibration verification at least once every six months.

Reference Method

Calibration is traceable to the ten-second end-point bromocresol green dye-binding method.⁷

Calibration Model

Colorimetric test (described in your operator's manual).

Quality Control

Procedure Recommendations

- Handle quality-control materials as biohazardous material.
- Analyze quality-control materials in the same manner as patient samples, before or during patient sample processing.
- Analyze control materials at least once per day to verify system performance.
- Choose control levels that check the clinically relevant range.
- Refer to the quality control section in your operator's manual for additional information on quality-control procedures for VITROS Systems.
- Refer to *Internal Quality Control Testing: Principles and Definitions* for general quality-control recommendations.⁸

Quality-Control Material Selection

- VITROS Performance Verifiers are specially formulated for use with VITROS Systems.
- Other control materials may show a difference when compared with other albumin methods if they:
 - Depart from a true human serum/plasma matrix
 - Contain high concentrations of preservatives, stabilizers, or other nonphysiological additives
- Controls low in carbon dioxide concentration may show a negative bias⁹ that can be avoided by reconstituting lyophilates with a bicarbonate diluent instead of water.
- Do not use control materials stabilized with ethylene glycol.

Quality-Control Material Preparation and Storage

Refer to the manufacturer's product literature for preparation, storage, and stability information.

Expected Values and Reporting Results

Reference Interval¹⁰

Conv. Units (g/dL)	SI Units (g/L)	Alternate Units ($\mu\text{mol/L}$)
3.5–5.0	35–50	532–760

Each laboratory should verify the validity of this range for the population it serves.

Reporting Units and Unit Conversion

Conventional Units	SI Units	Alternate Units
g/dL	g/L (g/dL x 10)	$\mu\text{mol/L}$ (g/dL x 152)

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Limitations of the Procedure

Known Interfering Substances

The VITROS ALB method was screened for interfering substances. The following substances, when tested at the concentrations indicated, caused the bias shown.

Interferent*	Conventional Units		SI Units	
	Interferent Concentration (mg/dL)	Average Bias	Interferent Concentration (mmol/L)	Average Bias
Hemolysis	100	+6%	0.015	+6%
	200	+12%	0.031	+12%
	400	+24%	0.062	+24%
Triglycerides	800	-0.23 g/dL	9.03	-2.3 g/L

* It is possible that other interfering substances may be encountered. These results are representative; however, your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Other Limitations

Some drugs and patient conditions are known to alter albumin concentration in vivo. A compilation of this information is available in the literature.^{11, 12}

Performance Characteristics

Reportable Range (Dynamic Range)

Conv. Units (g/dL)	SI Units (g/L)	Alternate Units (μmol/L)
1.00–6.00	10.0–60.0	152–912

Refer to Sample Dilution under “Testing Procedure” for out-of-range samples.

Sensitivity

The lower limit of the reportable (dynamic) range is 1.00 g/dL (10.0 g/L; 152 μmol/L).

Precision

Precision was evaluated with quality-control materials on VITROS 250, 700, and 950 Chemistry Systems following NCCLS Protocol EP5-T2.¹³

These results are guidelines. Variables such as instrument maintenance, environment, slide handling/storage, control material reconstitution, and sample handling can affect the reproducibility of test results.

ALB Precision

SYSTEM	Conventional Units (g/dL)			SI Units (g/L)			Within Lab CV% ^{**}	No. Observ.	No. Days
	Mean Conc.	Within Day SD [*]	Within Lab SD ^{**}	Mean Conc.	Within Day SD [*]	Within Lab SD ^{**}			
VITROS 250	2.5	0.03	0.06	25	0.3	0.6	2.4	80	20
	4.3	0.05	0.09	43	0.5	0.9	2.2	80	20
VITROS 700	2.5	0.02	0.04	25	0.2	0.4	1.6	120	20
	2.6	0.02	0.06	26	0.2	0.6	2.3	120	20
	4.1	0.05	0.07	41	0.5	0.7	1.7	120	20
VITROS 950	2.8	0.03	0.04	28	0.3	0.4	1.3	91	23
	4.4	0.05	0.07	44	0.5	0.7	1.5	92	23

* Within Day precision was determined using two runs/day with two to three replications.

** Within Lab precision was determined using a single lot of slides and calibrating weekly.

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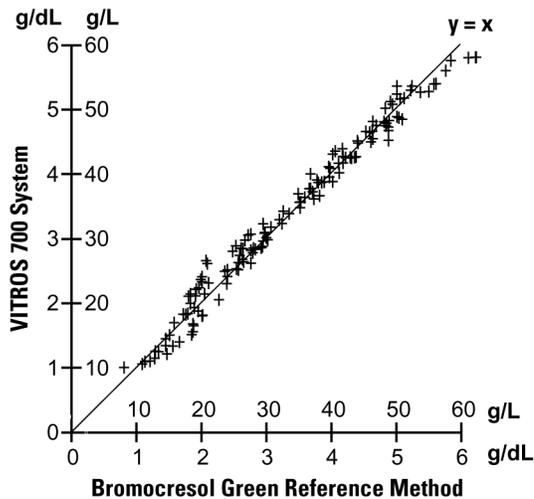
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Accuracy

The plot and table show the results of a comparison of serum specimens analyzed on the VITROS 700 System with those analyzed using the bromocresol green reference method. Testing followed NCCLS Protocol EP9-A.¹⁴

The table also shows the results of comparisons of the VITROS 250 and 950 Systems with the VITROS 700 System.

ALB/Serum



Method Comparison (Serum)

	n	Slope	Correlation Coefficient	Conventional Units (g/dL)			SI Units (g/L)		
				Range of Sample Concentration	Intercept	Sy.x	Range of Sample Concentration	Intercept	Sy.x
700 System vs. reference method	143	0.97	0.981	1.0–5.8	0.14	0.18	10–58	1.44	1.82
250 System vs. 700 System	60	1.01	0.999	1.2–5.7	-0.09	0.04	12–57	-0.90	0.40
950 System vs. 700 System	124	0.99	0.999	1.0–5.6	-0.01	0.03	10–56	-0.12	0.31

Specificity

The following substances were tested with VITROS ALB Slides and found not to interfere (bias < 0.2 g/dL):

Compound	Concentration	Compound	Concentration
Ascorbic acid	3 mg/dL	Ethanol	300 mg/dL
Bicarbonate	40 mmol/L	Tolbutamide	22 mg/dL
Bilirubin	20 mg/dL	Triglycerides	800 mg/dL
Cholesterol	500 mg/dL	Urea nitrogen	100 mg/dL
Dextran	1000 mg/dL		

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Revision History

Date of Revision:	Version:	Description:
2002APR19	1.0	New format, technically equivalent to 11/96.

When this Instructions For Use is replaced, sign and date below and retain as specified by local regulations or laboratory policies, as appropriate.

Signature _____
Obsolete Date

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