SIEMENS Healthineers

Albumin BCP (AlbP)

Current Revision and Date[a]	Rev. 02, 2019-11	
Product Name	Atellica CH Albumin BCP (AlbP)	REF 11097530 (6400 tests)
Abbreviated Product Name	Atellica CH AlbP	
Test Name/ID	AlbP	
Systems	Atellica CH Analyzer	
Materials Required but Not Provided	Atellica CH AlbP CAL	REF 11099310
Specimen Types	Serum, plasma (lithium heparin, potassium EDTA)	
Sample Volume	4 µL	
Measuring Interval	0.5–8.0 g/dL (5–80 g/L)	

[a] A vertical bar in the page margin indicates technical content that differs from the previous version.

CE

Intended Use

The Atellica® CH Albumin BCP (AlbP) assay is for *in vitro* diagnostic use in the quantitative measurement of albumin in human serum and plasma (lithium heparin, potassium EDTA) using the Atellica® CH Analyzer. Albumin measurements are used in the diagnosis and treatment of numerous diseases primarily involving the liver or kidneys.

Summary and Explanation

The Atellica CH Albumin BCP (AlbP) assay is an adaptation of the bromocresol purple (BCP) dye-binding method reported by Carter[1] and Louderback, *et al*.[2]

Principles of the Procedure

In the Atellica CH AlbP assay, serum or plasma albumin quantitatively binds to BCP to form an albumin-BCP complex that is measured as an endpoint reaction at 596/694 nm.

Reaction Equation

$$\text{Albumin} + \text{BCP dye} \xrightarrow{\text{pH 4.9}} \text{Albumin-BCP complex}$$

Reagents

Material Description	Storage	Stability[a]
Atellica CH AlbP **Pack 1 (P1)** Well 1 (W1) Reagent 1 (R1) 18.3 mL Bromocresol Purple (1.1 mmol/L); acetate buffer; surfactant; microbial inhibitor Well 2 (W2) Reagent 1 (R1) 18.3 mL Bromocresol Purple (1.1 mmol/L); acetate buffer; surfactant; microbial inhibitor	Unopened at 2–8°C Onboard per well	Until expiration date on product 20 days

[a] Refer to *Storage and Stability*.

Warnings and Precautions

For *in vitro* diagnostic use.

For Professional Use.

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

Safety data sheets (SDS) available on siemens.com/healthineers.

H317 **P280, P272, P302+P352, P333+P313, P363, P501**	**Warning!** May cause an allergic skin reaction. Wear protective gloves/protective clothing/eye protection/face protection. Contaminated work clothing should not be allowed out of the workplace. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. Dispose of contents and container in accordance with all local, regional, and national regulations. **Contains:** 2-chloracetamide

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.

Note For information about reagent preparation, refer to *Preparing the Reagents* in the *Procedure* section.

Storage and Stability

Unopened reagents are stable until the expiration date on the product when stored at 2–8°C.

Do not use products beyond the expiration date printed on the product labeling.

Onboard Stability

Reagents are stable onboard the system for 20 days per well. Discard reagents at the end of the onboard stability interval. Do not use products beyond the expiration date printed on the product labeling.

Specimen Collection and Handling

Serum and plasma (lithium heparin, potassium EDTA) are the recommended sample types for this assay.

Collecting the Specimen

- Observe universal precautions when collecting specimens. Handle all specimens as if they are capable of transmitting disease.[3]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[4]
- Follow the instructions provided with your specimen collection device for use and processing.[5]
- Allow blood specimens to clot completely before centrifugation.[6]
- Keep tubes capped at all times.[6]
- Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of 2 hours from the time of collection.[6]

Storing the Specimen

Specimens may be stored for up to 3 days at 2–8°C or stored frozen for up to 30 days at -20°C.[7]

Thawed frozen specimens which are turbid must be clarified by centrifugation prior to testing.

The handling and storage information provided here is based on data or references maintained by the manufacturer. It is the responsibility of the individual laboratory to use all available references and/or its own studies when establishing alternate stability criteria to meet specific needs.

Transporting the Specimen

Package and label specimens for shipment in compliance with applicable federal and international regulations covering the transport of clinical specimens and etiological agents.

Preparing the Samples

This assay requires 4 µL of sample for a single determination. This volume does not include the unusable volume in the sample container or the additional volume required when performing duplicates or other tests on the same sample. For information about determining the minimum required volume, refer to the online help.

Note Do not use specimens with apparent contamination.

Before placing samples on the system, ensure that samples are free of:

- Bubbles or foam.
- Fibrin or other particulate matter.

Note Remove particulates by centrifugation according to CLSI guidance and the collection device manufacturer's recommendations.[6]

Note For a complete list of appropriate sample containers, refer to the online help.

Procedure

Materials Provided

The following materials are provided:

REF	Contents	Number of Tests
11097530	**Pack 1 (P1)** Well 1 (W1) 18.3 mL of Atellica CH AlbP Reagent 1 Well 2 (W2) 18.3 mL of Atellica CH AlbP Reagent 1	4 x 1600

Materials Required but Not Provided

The following materials are required to perform this assay, but are not provided:

REF	Description	
	Atellica CH Analyzer[a]	
11099310	Atellica CH AlbP CAL (calibrator)	3 x 2.0 mL calibrator CAL Calibrator lot-specific value sheet CAL LOT VAL
	Commercially available quality control material	

[a] Additional system fluids are required to operate the system: Atellica CH Diluent, Atellica CH Wash, Atellica CH Conditioner, Atellica CH Cleaner, Atellica CH Reagent Probe Cleaner 1, Atellica CH Reagent Probe Cleaner 2, Atellica CH Reagent Probe Cleaner 4, Atellica CH Lamp Coolant, and Atellica CH Water Bath Additive. For system fluid instructions for use, refer to the Document Library.

Assay Procedure

The system automatically performs the following steps:

1. For serum/plasma, dispenses 50 µL of primary sample and 200 µL of Atellica CH Diluent into a dilution cuvette.
2. Dispenses 20 µL of Reagent 1 and 56 µL of special reagent water into a reaction cuvette.
3. Dispenses 4 µL of pre-diluted sample into a reaction cuvette.
4. Mixes and incubates the mixture at 37°C.
5. Measures the absorbance after sample addition.
6. Reports results.

Note For information about special reagent water requirements, refer to the online help.

Test Duration: 3 minutes

Preparing the Reagents

All reagents are liquid and ready to use.

Preparing the System

Ensure that the system has sufficient reagent packs loaded in the reagent compartment. For information about loading reagent packs, refer to the online help.

Performing Calibration

For calibration of the Atellica CH AlbP assay, use Atellica CH AlbP CAL. Use the calibrators in accordance with the calibrator instructions for use.

Calibration Frequency

Perform a calibration if one or more of the following conditions exist:

- When changing lot numbers of primary reagent packs.
- At the end of the lot calibration interval, for a specified lot of calibrated reagent on the system.
- At the end of the pack calibration interval, for calibrated reagent packs on the system.
- When indicated by quality control results.
- After major maintenance or service, if indicated by quality control results.

At the end of the onboard stability interval, replace the reagent pack on the system with a new reagent pack. Recalibration is not required, unless the lot calibration interval is exceeded.

Stability Interval	Days
Lot Calibration	30
Pack Calibration	8
Reagent Onboard Stability	20

For information about lot calibration and pack calibration intervals, refer to the online help.

Follow government regulations or accreditation requirements for calibration frequency. Individual laboratory quality control programs and procedures may require more frequent calibration.

Performing Quality Control

For quality control of the Atellica CH AlbP assay, use at least two levels (low and high) of the appropriate quality control material of known analyte concentration. Use the quality control material in accordance with the quality control instructions for use.

For the assigned values, refer to the lot-specific value sheet provided. A satisfactory level of performance is achieved when the analyte values obtained are within the expected control range for the system or within your range, as determined by an appropriate internal laboratory quality control scheme. Follow your laboratory's quality control procedures if the results obtained do not fall within the acceptable limits. For information about entering quality control definitions, refer to the online help.

Follow government regulations or accreditation requirements for quality control frequency. Individual laboratory quality control programs and procedures may require more frequent quality control testing.

Taking Corrective Action

If the quality control results do not fall within the assigned values, do not report results. Perform corrective actions in accordance with established laboratory protocol. For suggested protocol, refer to the online help.

Results

Calculation of Results

The system determines the result using the calculation scheme described in the online help. The system reports results in g/dL (common units) or g/L (SI units), depending on the units defined when setting up the assay.

Conversion formula: g/dL x 10 = g/L

For information about results outside the specified measuring interval, refer to *Measuring Interval*.

Interpretation of Results

Results of this assay should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

Limitations

The Atellica CH AlbP assay is limited to the detection of albumin in human serum and plasma (lithium heparin, potassium EDTA).

A number of substances cause physiological changes in serum or plasma analyte concentrations. A comprehensive discussion of possible interfering substances, their serum or plasma concentrations, and their possible physiological involvements is beyond the scope of this document. Consult the listed reference for specific details on known potential interfering substances.[8]

As with any chemical reaction, you must be alert to the possible effect on results of unknown interferences from medications or endogenous substances. The laboratory and physician must evaluate all patient results in light of the total clinical status of the patient.

Do not use hemolyzed samples.

Expected Values

Reference Interval

A reference interval for healthy adults was established in accordance with CLSI Document EP28-A3c and verified on the Atellica CH Analyzer.[9]

The reference interval for albumin is 3.4–5.0 g/dL (34–50 g/L) for adults.[10]

As with all *in vitro* diagnostic assays, each laboratory should determine its own reference interval for the diagnostic evaluation of patient results. Consider these values as guidance only.[9]

Performance Characteristics

Measuring Interval

The Atellica CH AlbP assay provides results from 0.5 g/dL (5 g/L) to 8.0 g/dL (80 g/L). The system flags all values that are outside the specified measuring interval.

Detection Capability

Detection capability was determined in accordance with CLSI Document EP17-A2.[11] The assay is designed to have a limit of blank (LoB) ≤ 0.1 g/dL (≤ 1 g/L), a limit of detection (LoD) ≤ 0.6 g/dL (≤ 6 g/L), and a limit of quantitation (LoQ) ≤ 0.6 g/dL (≤ 6 g/L).

The LoD corresponds to the lowest concentration of albumin that can be detected with a probability of 95%. The LoD for the Atellica CH AlbP assay is 0.2 g/dL (2 g/L), and was determined using 165 determinations, with 90 blank and 75 low level replicates, and a LoB of value 0.1 g/dL (1 g/L).

The LoQ corresponds to the lowest amount of analyte in a sample at which the within-run precision is ≤ 10%. The LoQ of the AlbP assay is 0.4 g/dL (4 g/L), based on 225 determinations.

Assay results obtained at individual laboratories may vary from the data presented.

Precision

Precision was determined in accordance with CLSI Document EP05-A3.[12] Samples were assayed on an Atellica CH Analyzer in duplicate in 2 runs per day for at least 20 days (N ≥ 80 for each sample). The following results were obtained:

			Repeatability		Within-Lab Precision	
Sample Type	**N**	**Mean g/dL (g/L)**	**SD[a] g/dL (g/L)**	**CV[b] (%)**	**SD[a] g/dL (g/L)**	**CV[b] (%)**
Serum QC	84	2.7 (27)	0.03 (0.32)	1.17	0.03 (0.32)	1.17
Serum QC	80	3.6 (36)	0.04 (0.39)	1.07	0.05 (0.51)	1.42
Serum QC	84	7.1 (71)	0.05 (0.52)	0.73	0.07 (0.73)	1.02
Serum Pool	80	3.3 (33)	0.04 (0.41)	1.37	0.06 (0.64)	1.79

[a] Standard deviation.
[b] Coefficient of variation.

Assay results obtained at individual laboratories may vary from the data presented.

Assay Comparison

The Atellica CH AlbP assay is designed to have a correlation coefficient of > 0.96 and a slope of 1.00 ± 0.99 compared to ADVIA Chemistry 1800 ALBP. Assay comparison was determined using the Deming linear regression model in accordance with CLSI Document EP09-A3.[13] The following results were obtained:

Specimen	**Comparative Assay (x)**	**Regression Equation**	**Sample Interval**	**N[a]**	**r[b]**
Serum	ADVIA Chemistry 1800 ALBP	y = 0.99x + 0.01 g/dL (y = 0.99x + 0.1 g/L)	0.9–7.9 g/dL (9–79 g/L)	130	0.996

[a] Number of samples tested.
[b] Correlation coefficient.

The agreement of the assay may vary depending on the study design, comparative assay, and sample population. Assay results obtained at individual laboratories may vary from the data presented.

Specimen Equivalency

Specimen equivalency was determined using the Deming linear regression model in accordance with CLSI Document EP09-A3.[13] The following results were obtained:

Specimen (y)	**Reference Specimen (x)**	**Regression Equation**	**Sample Interval**	**N[a]**	**r[b]**
Lithium heparin plasma	Serum	y = 1.02x - 0.01 g/dL (y = 1.02x - 0.1 g/L)	0.5–6.4 g/dL (5.0–64 g/L)	59	0.99
EDTA plasma	Serum	y = 1.01x - 0.01 g/dL (y = 1.01x - 0.1 g/L)	0.5–6.4 g/dL (5.0–64 g/L)	59	0.99

[a] Number of samples tested.
[b] Correlation coefficient.

Agreement of the specimen types may vary depending on the study design and sample population used. Assay results obtained at individual laboratories may vary from the data presented.

Hemolysis, Icterus, and Lipemia (HIL)

The Atellica CH AlbP assay is designed to have ≤ 10% interference from hemoglobin, bilirubin, and lipemia. Interfering substances at the levels indicated in the table below were tested in accordance with CLSI Document EP07-A2 using the Atellica CH AlbP assay.[14]

Bias is the difference in the results between the control sample (does not contain the interferent) and the test sample (contains the interferent) expressed in percent. Bias > 10% is considered interference. Analyte results should not be corrected based on this bias.

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration g/dL (g/L)	Percent Bias[a]
Hemoglobin	600 mg/dL (0.37 mmol/L) 600 mg/dL (0.37 mmol/L)	3.2 (32) 4.8 (48)	8.2 3.3
Bilirubin, conjugated	30 mg/dL (513 µmol/L) 30 mg/dL (513 µmol/L)	3.1 (31) 4.7 (47)	-1.9 -1.3
Bilirubin, unconjugated	30 mg/dL (513 µmol/L) 30 mg/dL (513 µmol/L)	3.3 (33) 5.0 (50)	-0.6 0.4
Lipemia (Intralipid®)	500 mg/dL (5.65 mmol/L) 500 mg/dL (5.65 mmol/L)	3.2 (32) 4.8 (48)	7.5 5.8

[a] Analyte results should not be corrected based on this bias.

Assay results obtained at individual laboratories may vary from the data presented.

Standardization

The Atellica CH AlbP assay is traceable to ERM DA470k Reference Material.[15]

Assigned values for calibrators are traceable to this standardization.[7]

Technical Assistance

For customer support, contact your local technical support provider or distributor.

siemens.com/healthineers

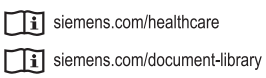
References

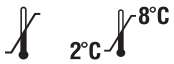
1. Carter P. Ultramicroestimation of human serum albumin: Binding of the cationic dye, 5,5'-dibromo-o-cresolsulfonphthalein. *Microchem J*. 1970;15:531–9.
2. Louderback A, Measley AH, Taylor NA. A new dye-binder technique using bromocresol purple for determination of albumin in serum. *Clin Chem*. 1968;14:793–4.
3. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document M29-A4.
4. Clinical and Laboratory Standards Institute. *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Sixth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2007. CLSI Document GP41-A6.
5. Clinical and Laboratory Standards Institute. *Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard—Sixth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document GP39-A6.
6. Clinical and Laboratory Standards Institute. *Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document GP44-A4.
7. Data on file at Siemens Healthcare Diagnostics.

8. Young DS. *Effects of Drugs on Clinical Laboratory Tests*. 5th ed. Washington, DC: AACC Press; 2000.
9. Clinical and Laboratory Standards Institute. *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document EP28-A3c.
10. Willey DA, Savory J, Lansky F. *An Evaluation of a Revised Albumin Method for the aca® Discrete Clinical Analyzer*. Wilmington, DE: Du Pont Company; 1982.
11. Clinical and Laboratory Standards Institute. *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2012. CLSI Document EP17-A2.
12. Clinical and Laboratory Standards Institute. *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document EP05-A3.
13. Clinical and Laboratory Standards Institute. *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2013. CLSI Document EP09-A3.
14. Clinical and Laboratory Standards Institute. *Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2005. CLSI Document EP07-A2.
15. Zegers I, Schreiber W, Sheldon J, et al. Certification of Proteins in the Human Serum - Certified Reference Material ERM-DA470k/IFCC. JRC46604. OPOCE; 2008. doi:10.2787/63869.

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title and Description
	Consult instructions for use
	Version of instructions for use
	Internet URL address to access the electronic instructions for use
	Revision
	Caution Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device.
	Biological risks Potential biological risks are associated with the medical device.
	Corrosive
	Dangerous to environment

Symbol	Symbol Title and Description
	Irritant Oral, dermal, or inhalation hazard
	Inhalation hazard Respiratory or internal health
	Flammable Flammable to extremely flammable
	Oxidizing
	Explosive
	Toxic
	Compressed gas
	Keep away from sunlight Prevent exposure to sunlight and heat.
	Up Store in an upright position.
	Do not freeze
	Temperature limit Upper and lower limits of temperature indicators are adjacent to the upper and lower horizontal lines.
	Handheld barcode scanner
	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests Total number of IVD tests the system can perform with the IVD kit reagents appears adjacent to the symbol.
RxOnly	Prescription device (US only) Applies only to United States-registered IVD assays. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.
	Mixing of substances Mix product before use.

Symbol	Symbol Title and Description
	Reconstitute and mix lyophilized product before use.
	Target
	Interval
	Legal Manufacturer
	Authorized Representative in the European Community
	Use-by date Use by the designated date.
	Batch code
	Catalog number
	Recycle
	Printed with soy ink
	CE Mark
	CE Mark with notified body ID number Notified body ID number can vary.
YYYY-MM-DD	Date format (year-month-day)
	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.
	Common Units
	International System of Units
	Material
	Unique material identification number
	Name of control
	Type of control

Legal Information

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