SIEMENS Healthineers

Albumin (Alb)

Current Revision and Date[a]	Rev. 03, 2022-05	
Product Name	Atellica CH Albumin (Alb)	REF 11097590 (6800 tests)
Abbreviated Product Name	Atellica CH Alb	
Test Name/ID	Alb	
Systems	Atellica CI Analyzer	
Materials Required but Not Provided	Atellica CH CHEM CAL	REF 11099411
Specimen Types	Serum and plasma (lithium heparin)	
Sample Volume	2 µL	
Measuring Interval	1.0–6.0 g/dL (10–60 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 (Alb) assay is for *in vitro* diagnostic use in the quantitative determination of albumin in human serum and plasma (lithium heparin) using the Atellica® CI Analyzer. Such measurements are used in the diagnosis and treatment of chronic inflammatory diseases, collagen diseases, and liver and kidney disorders.

Summary and Explanation

The Atellica CH Albumin (Alb) assay is based on the method of Doumas, Watson, and Biggs and uses bromocresol green solution (BCG) as a binding dye.[1]

Principles of the Procedure

Serum or plasma albumin quantitatively binds to BCG to form an albumin-BCG complex that is measured as an endpoint reaction at 596/694 nm.

Reaction Equation

$$\text{BCG} + \text{Albumin} \xrightarrow{\text{pH 4.2}} \text{BCG Albumin complex}$$

Reagents

Material Description	Storage	Stability[a]
Atellica CH Alb	Unopened at 15–25°C	Until expiration date on product
Pack 1 (P1)	Onboard per well	90 days
Well 1 (W1) Reagent 1 (R1) 19.4 mL Bromocresol green (1.0 mmol/L); preservative		
Well 2 (W2) Reagent 1 (R1) 19.4 mL Bromocresol green (1.0 mmol/L); preservative		

[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.

H318	**Danger!**
P280,	Causes serious eye damage.
P305+P351+P338,	Wear protective gloves/protective clothing/eye protection/face protection.
P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.
	Contains: succinic acid

Contains 2-methyl-2H-isothiazol-3-one hydrochloride. May produce an allergic reaction.

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

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 15–25°C.

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

Onboard Stability

Discard reagents at the end of the onboard stability interval.

For details about product onboard stability, refer to *Reagents*.

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

Specimen Collection and Handling

Serum and plasma (lithium heparin) 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.[2]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[3]
- Follow the instructions provided with your specimen collection device for use and processing.[4]
- Allow blood specimens to clot completely before centrifugation.[5]
- Keep tubes capped at all times.[5]

Storing the Specimen

Specimens may be stored for up to 3 days at 2–8°C or stored frozen for up to 60 days at -20°C.[6]

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 2 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.[5]

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
11097590	**Pack 1 (P1)** Well 1 (W1) 19.4 mL of Atellica CH Alb Reagent 1 Well 2 (W2) 19.4 mL of Atellica CH Alb Reagent 1	4 x 1700

Materials Required but Not Provided

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

REF	Description	
	Atellica CI Analyzer[a]	
11099411	Atellica CH CHEM CAL (calibrator)	12 x 3.0 mL calibrator CAL Calibrator lot-specific value sheet CAL LOT VAL
	Commercially available quality control materials	

[a] Additional system fluids are required to operate the system. 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 80 µL of special reagent water into a reaction cuvette.
3. Dispenses 2 µL of pre-diluted sample into a reaction cuvette.
4. Mixes and incubates the mixture at 37°C.
5. Measures the absorbance after Reagent 1 addition.
6. Reports results.

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

Test Duration: 10 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 Alb assay, use Atellica CH CHEM 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	97
Pack Calibration	90

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 Alb assay, use at least two levels (low and high) of the appropriate quality control material of known analyte concentration. For assistance in identifying a quality control material, refer to the *Atellica CH Quality Control Material Supplement* available on siemens-healthineers.com.

For the assigned values, refer to the lot-specific value sheet provided.

Additional quality control material can be used at the discretion of the laboratory. Use the quality control material in accordance with the quality control instructions for use.

In addition, perform quality control:

- Following a valid calibration.
- With use of a new lot of reagent.
- When troubleshooting test results that do not match clinical conditions or symptoms.

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

Acceptable performance is achieved when the analyte values obtained are within the expected control interval for the system, as indicated by the manufacturer of the control material or within the interval determined by an internal laboratory quality control procedure.

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.

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 Alb assay is limited to the detection of albumin in human serum and plasma (lithium heparin).

Expected Values

Reference Interval

A reference interval for healthy adults was established in accordance with CLSI Document EP28-A3c and verified by analysis for the Atellica CI Analyzer.[7]

The reference interval for albumin is 3.2–4.8 g/dL (32–48 g/L) for adults. These data were established on the ADVIA® Chemistry system.[6]

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.[7]

Performance Characteristics

Measuring Interval

The Atellica CH Alb assay is linear from 1.0–6.0 g/dL (10–60 g/L). The system flags all values that are outside the specified measuring interval.

Extended Measuring Interval

An automatic repeat condition for this assay extends the measuring interval to 12.0 g/dL (120 g/L) for serum and plasma. You may configure the system to trigger an automatic repeat. Automatic repeat results will be flagged **Autorepeat**.

Detection Capability

Detection capability was determined in accordance with CLSI Document EP17-A2.[8] The assay is designed to have a limit of blank (LoB) ≤ limit of detection (LoD) and LoD ≤ 1.0 g/dL (≤ 10 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 Alb assay is 0.0 g/dL (0 g/L), and was determined using 405 determinations, with 180 blank and 225 low level replicates, and a LoB of 0.0 g/dL (0 g/L). All samples were assayed n = 5 using 3 reagent lots, over a period of 3 days.

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

Precision

The Repeatability precision of the assay is designed to have the following characteristics:

- CV ≤ 3.0% at 1.6–6.0 g/dL

The Within-Laboratory precision of the assay is designed to have the following characteristics:

- CV ≤ 5.0% at 1.6–6.0 g/dL

Precision was determined in accordance with CLSI Document EP05-A3.[9] Samples were assayed on an Atellica CI 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-Laboratory 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 1	80	2.1 (21)	0.04 (0.4)	1.9	0.05 (0.5)	2.4
Serum 1	80	2.5 (25)	0.03 (0.3)	1.2	0.07 (0.7)	2.8
Serum QC 2	80	3.6 (36)	0.04 (0.4)	1.1	0.07 (0.7)	1.9
Serum 2	80	5.4 (54)	0.05 (0.5)	0.9	0.10 (1.0)	1.9

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

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

Reproducibility

The assay is designed to have the following reproducibility:

- Serum/plasma: CV ≤ 6.0% at 1.6–6.0 g/dL

Reproducibility was determined in accordance with CLSI Document EP05-A3.[9] Samples were assayed n=5 in 1 run for 5 days using 3 instruments and 3 reagent lots. The data were analyzed to calculate the following components of precision: repeatability, between-day, between-lot, between-instrument, and reproducibility (total). The following results were obtained:

			Repeatability		Between-Day		Between-Instrument		Between-Lot		Total Reproducibility	
Sample	**N[a]**	**Mean g/dL (g/L)**	**SD[b] g/dL (g/L)**	**CV[c] (%)**	**SD g/dL (g/L)**	**CV (%)**	**SD g/dL (g/L)**	**CV (%)**	**SD g/dL (g/L)**	**CV (%)**	**SD g/dL (g/L)**	**CV (%)**
Serum 1	225	2.5 (25)	0.04 (0.4)	1.6	0.02 (0.2)	0.8	0.02 (0.2)	0.8	0.05 (0.5)	2.0	0.07 (0.7)	2.8
Serum 2	225	5.4 (54)	0.05 (0.5)	0.9	0.05 (0.5)	0.9	0.07 (0.7)	1.3	0.00 (0.0)	0.0	0.09 (0.9)	1.7
Serum QC 1	225	3.6 (36)	0.04 (0.4)	1.1	0.03 (0.3)	0.8	0.03 (0.3)	0.8	0.02 (0.2)	0.6	0.06 (0.6)	1.7

[a] Number of results.
[b] Standard deviation.
[c] Coefficient of variation.

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

Assay Comparison

The performance of the Atellica CH Alb assay on the Atellica CI Analyzer (y) was compared with the performance of the comparison assay on the indicated system (x) and is designed to have a correlation coefficient of > 0.950 and a slope of 1.00 ± 0.05. Assay comparison was determined using the Deming linear regression model in accordance with CLSI Document EP09c.[10] The following results were obtained:

Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N[a]	r[b]
Serum	ADVIA® Chemistry ALB on ADVIA 1800 Chemistry System	y = 1.00x + 0.0 g/dL (y = 1.0x + 0 g/L)	1.1–5.9 g/dL (11–59 g/L)	100	0.996
Serum	Atellica CH Alb on Atellica CH Analyzer	y = 1.02x + 0.0 g/dL (y = 1.02x + 0 g/L)	1.2–5.8 g/dL (12–58 g/L)	206	0.994

[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 EP09c.[10] The following results were obtained:

Specimen (y)	Reference Specimen (x)	Regression Equation	Sample Interval	N[a]	r[b]
Lithium heparin plasma	Serum	y = 1.00 + 0.03 g/dL (y = 1.00 + 0.3 g/L)	1.8–5.2 g/dL (18–52 g/L)	59	0.97

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

These data were generated on the Atellica CH Analyzer with assay reaction conditions that are equivalent to those on the Atellica CI Analyzer. 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.

Interferences

Hemolysis, Icterus, and Lipemia (HIL)

The Atellica CH Alb 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 Alb assay.[11]

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
Hemoglobin	400 mg/dL (0.25 mmol/L) 600 mg/dL (0.37 mmol/L)	3.4 (34) 4.8 (48)	10 9
Bilirubin, conjugated	30 mg/dL (513 µmol/L) 30 mg/dL (513 µmol/L)	3.3 (33) 4.7 (47)	-2 0

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration g/dL (g/L)	Percent Bias
Bilirubin, unconjugated	30 mg/dL (513 µmol/L) 30 mg/dL (513 µmol/L)	3.5 (35) 4.9 (49)	-2 0
Lipemia (Intralipid®)	1000 mg/dL (11.3 mmol/L) 1000 mg/dL (11.3 mmol/L)	3.4 (34) 4.8 (48)	7 3

These data were generated on the Atellica CH Analyzer with assay reaction conditions that are equivalent to those on the Atellica CI Analyzer. Assay results obtained at individual laboratories may vary from the data presented.

Standardization

The Atellica CH Alb assay is traceable to a BCG reference method, which uses SRM 927 reference materials from the National Institute of Standards and Technology (NIST).

Assigned values for calibrators are traceable to this standardization.[6]

Technical Assistance

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

siemens.com/healthineers

References

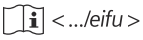
1. Doumas BT, Biggs HG. Determination of serum albumin. In: Cooper CA, ed. *Standard Methods of Clinical Chemistry.* New York, NY: Academic Press, Inc.; 1972:175.
2. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document M29-A4.
3. 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.
4. 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.
5. 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.
6. Data on file at Siemens Healthcare Diagnostics.
7. 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.
8. 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.
9. 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.

10. 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; 2018. CLSI Document EP09c-ed3.

11. 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.

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title	Symbol	Symbol Title
	Manufacturer		Authorized representative in the European Community
	Use-by date		Authorized representative in Switzerland
	Catalog number		Batch code
	Consult Instructions for Use		Contains sufficient for <n> tests
	Internet URL address to access the electronic instructions for use		Version of Instructions for Use
	*In vitro* diagnostic medical device		Revision
RxOnly	Prescription device (US only)		Unique Device Identifier
	CE Marking with Notified Body		CE Marking
	Temperature limit		Keep away from sunlight
	Upper limit of temperature		Lower limit of temperature
	Do not re-use		Do not freeze
	Recycle		This way up
	Biological risks		Caution
	Common Units		International System of Units
YYYY-MM-DD	Date format (year-month-day)	**YYYY-MM**	Date format (year-month)
	Document face up[a]		Handheld barcode scanner

Symbol	Symbol Title	Symbol	Symbol Title
	Target		Mixing of substances
CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.		Interval
MATERIAL ID	Unique material identification number	MATERIAL	Material
CONTROL TYPE	Type of control	CONTROL NAME	Name of control
CONTROL LOT VAL	Quality control lot value	CAL LOT VAL	Calibrator lot value

[a] Indicates Assay-eNote

Legal Information

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591 USA

Siemens Healthineers Headquarters
Siemens Healthcare GmbH
Henkestraße 127
91052 Erlangen
Germany
Phone: +49 9131 84-0
siemens.com/healthineers