SIEMENS Healthineers

Microalbumin_2 (µALB_2)

Current Revision and Date[a]	Rev. 03, 2019-06	
Product Name	Atellica CH Microalbumin_2 (µALB_2)	REF 11097610 (840 tests)
Abbreviated Product Name	Atellica CH µALB_2	
Test Name/ID	µALB_2	
Systems	Atellica CH Analyzer	
Materials Required but Not Provided	Atellica CH µALB_2 CAL	REF 11099435
Specimen Types	Urine	
Sample Volume	13.7 µL	
Measuring Interval	0.3–38.0 mg/dL (3–380 mg/L)	

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

CE

Intended Use

The Atellica® CH Microalbumin_2 (µALB_2) assay is for *in vitro* diagnostic use in the quantitative determination of albumin in human urine using the Atellica® CH Analyzer. Such measurements are used in the diagnosis and treatment of microalbuminuria and are helpful for the detection and treatment of patients at risk from renal disease.

Summary and Explanation

The Atellica CH Microalbumin_2 (µALB_2) assay is based on the work of Fielding and Hellsing, and it measures very small levels of albumin in urine samples. Albumin is a plasma protein that is responsible for much of the osmotic force of the blood. In a healthy population, only a small amount of albumin (up to 30 mg/day) is excreted in the urine.[1-4]

Elevated levels of urinary albumin indicate a high probability of damage of the glomerular filtration capacity of the kidney. During the progression of renal disease in type I diabetes mellitus, stage III or incipient nephropathy is characterized by the elevation in urinary albumin. Elevated results in urinary albumin may also be associated with hypertension, some lipid abnormalities, and several immune disorders as well as other conditions such as vigorous exercise, blood in the urine, urinary tract infection, dehydration, and some drugs.

Principles of the Procedure

The Atellica CH µALB_2 assay is a PEG-enhanced immunoturbidimetric assay. A sample containing human albumin is suitably diluted and then reacted with specific antiserum to form a precipitate that can be measured turbidimetrically at 340/596 nm. By constructing a standard curve from the absorbencies of standards, the albumin concentration of the sample is determined.

Reagents

Material Description	Storage	Stability[a]
Atellica CH µALB_2	Unopened at 2–8°C	Until expiration date on product
Pack 1 (P1)	Onboard per well	30 days
Well 1 (W1) Reagent 1 (R1) 14.0 mL Polyethylene glycol (6%); sodium azide (0.09%)		
Well 2 (W2) Reagent 1 (R1) 14.0 mL Polyethylene glycol (6%); sodium azide (0.09%)		
Pack 2 (P2)		
Well 1 (W1) Reagent 2 (R2) 4.3 mL Antihuman albumin (goat); sodium azide (0.09%)		
Well 2 (W2) Reagent 2 (R2) 4.3 mL Antihuman albumin (goat); sodium azide (0.09%)		

[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.

CAUTION

This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

Contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent buildup of azides. Disposal into drain systems must be in compliance with prevailing regulatory requirements.

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 30 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

Urine is the recommended sample type for this assay.

Collecting the Specimen

- Observe universal precautions when collecting specimens. Handle all specimens as if they are capable of transmitting disease.[5]
- Normal procedures for collecting and storing urine may be used for samples to be analyzed for this assay.[4,6]

Storing the Specimen

Specimens may be stored for up to 14 days at 2–8°C or stored frozen for up to 5 months at -20°C.[7]

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 13.7 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.[8]

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
11097610	**Pack 1 (P1)** Well 1 (W1) 14.0 mL of Atellica CH µALB_2 Reagent 1 Well 2 (W2) 14.0 mL of Atellica CH µALB_2 Reagent 1 **Pack 2 (P2)** Well 1 (W1) 4.3 mL of Atellica CH µALB_2 Reagent 2 Well 2 (W2) 4.3 mL of Atellica CH µALB_2 Reagent 2	4 x 210

Materials Required but Not Provided

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

REF	Description	
	Atellica CH Analyzer[a]	
11099435	Atellica CH µALB_2 CAL (calibrator)	1 x 2.0 mL calibrator level 2 CAL 2 1 x 2.0 mL calibrator level 3 CAL 3 1 x 2.0 mL calibrator level 4 CAL 4 1 x 2.0 mL calibrator level 5 CAL 5 1 x 2.0 mL calibrator level 6 CAL 6 Calibrator lot-specific value sheet CAL LOT VAL
	Commercially available quality control materials	

[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 urine, dispenses 50 µL of primary sample and 200 µL of Atellica CH Diluent into a dilution cuvette.
2. Dispenses 80 µL of Reagent 1 into a reaction cuvette.
3. Measures the absorbance after Reagent 1 addition.
4. Dispenses 13.7 µL of pre-diluted sample into a reaction cuvette.
5. Measures the absorbance after sample addition.
6. Dispenses 10 µL of Reagent 2 into a reaction cuvette.
7. Mixes and incubates the mixture at 37°C.
8. Measures the absorbance.
9. Reports results.

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 µALB_2 assay, use Atellica CH µALB_2 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	180
Pack Calibration	30
Reagent Onboard Stability	30

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 µALB_2 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 mg/dL (common units) or mg/L (SI units), depending on the units defined when setting up the assay.

Conversion formula: mg/dL x 10.0 = mg/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 μALB_2 assay is limited to the detection of microalbumin in human urine.

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 microalbumin is < 30 mg/day for adults.[4]

Note Use the following equation to convert the reported microalbumin value in mg/dL to mg/day:

reported microalbumin mg/day = 24-hour urine volume (dL/day) x system-reported microalbumin concentration (mg/dL)

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 μALB_2 assay provides results from 0.3 mg/dL (3 mg/L) to 38.0 mg/dL (380 mg/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 380 mg/dL (3800 mg/L) for urine. 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.[10] The assay is designed to have a limit of blank (LoB) ≤ 0.3 mg/dL (≤ 3 mg/L) and limit of detection (LoD) ≤ 0.3 mg/dL (≤ 3 mg/L).

The LoD corresponds to the lowest concentration of microalbumin that can be detected with a probability of 95%. The LoD for the Atellica CH µALB_2 assay is 0.1 mg/dL (1 mg/L), and was determined using 135 determinations, with 60 blank and 75 low level replicates, and a LoB of 0.0 mg/dL (0 mg/L).

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

Precision

Precision was determined in accordance with CLSI Document EP05-A3.[11] Samples were assayed on an Atellica CH Analyzer in duplicate in 2 runs per day for 20 days (N ≥ 80 for each sample). The following results were obtained:

			Repeatability		Designed to be ≤	Within-Lab Precision		Designed to be ≤
Sample Type	N	Mean mg/dL (mg/L)	SD[a] mg/dL (mg/L)	CV[b] (%)	CV (%)	SD mg/dL (mg/L)	CV (%)	CV (%)
Urine QC	80	3.0 (30)	0.04 (0.4)	1.4	5.0	0.11 (1.1)	3.6	7.0
Urine QC	80	5.9 (59)	0.06 (0.6)	1.0	5.0	0.14 (1.4)	2.4	7.0
Urine Pool	80	29.2 (292)	0.29 (2.9)	1.0	5.0	0.58 (5.8)	2.0	7.0
Urine Pool	80	40.9 (409)	0.48 (4.8)	1.2	5.0	0.58 (5.8)	1.4	7.0

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

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

Assay Comparison

The Atellica CH µALB_2 assay is designed to have a correlation coefficient of ≥ 0.950 and a slope of 1.0 ± 0.10 compared to ADVIA® Chemistry µALB_2. Assay comparison was determined using the Deming linear regression model in accordance with CLSI Document EP09-A3.[12] The following results were obtained:

Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N[a]	r[b]
Urine	ADVIA Chemistry µALB_2	y = 1.05x + 0.1 mg/dL (y = 1.05x + 1.0 mg/L)	0.3–41.5 mg/dL (3–415 mg/L)	112	0.999

[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.

Interferences

Hemolysis, Icterus, and Lipemia (HIL)

The Atellica CH µALB_2 assay is designed to have ≤ 10% interference from hemoglobin. Interfering substances at the levels indicated in the table below were tested in accordance with CLSI Document EP07-A2 using the Atellica CH µALB_2 assay.[13]

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 mg/dL (mg/L)	Percent Bias
Hemoglobin	500 mg/dL (0.31 mmol/L)	2.9 (29)	0
	500 mg/dL (0.31 mmol/L)	22.2 (222)	-2

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

Non-Interfering Substances

The following substances do not interfere with the Atellica CH µALB_2 assay when present in human urine at the concentrations indicated in the table below. Bias due to these substances is ≤ 10% at an analyte concentration of 3.0 mg/dL (30 mg/L).[14] These data were generated on the ADVIA Chemistry system with assay reaction conditions that are equivalent to those on the Atellica CH Analyzer.[14]

Substance	Substance Test Concentration Common Units (SI Units)	Percent Bias
Acetaminophen	100 mg/dL (0.66 mmol/L)	≤ 10%
Ascorbic Acid	500 mg/dL (28.4 mmol/L)	≤ 10%
Calcium	400 mg/dL (100 mmol/L)	≤ 10%
Citrate	500 mg/dL (26 mmol/L)	≤ 10%
Creatinine	500 mg/dL (44.2 mmol/L)	≤ 10%
Glucose	5000 mg/dL (277.5 mmol/L)	≤ 10%
Hippuric Acid	400 mg/dL (22.3 mmol/L)	≤ 10%
Inorganic Phosphorus	400 mg/dL (129.2 mmol/L)	≤ 10%
Magnesium	400 mg/dL (42.0 mmol/L)	≤ 10%
Oxalate	30 mg/dL (3.42 mmol/L)	≤ 10%
Potassium Chloride	1000 mg/dL (134.1 mmol/L)	≤ 10%
Salicylate	250 mg/dL (18.1 mmol/L)	≤ 10%
Sodium Chloride	2000 mg/dL (342.2 mmol/L)	≤ 10%
Urea Nitrogen	400 mg/dL (142.8 mmol/L)	≤ 10%
Uric Acid	100 mg/dL (5.9 mmol/L)	≤ 10%

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

High-Dose Hook Effect

High microalbumin levels can cause a paradoxical decrease in signal as a result of the high-dose hook effect. In the Atellica CH µALB_2 assay, microalbumin levels as high as 20,000 mg/dL (200,000 mg/L) will read > 38.0 mg/dL (> 380 mg/L).

Standardization

The Atellica CH µALB_2 assay standardization is traceable to an internal standard manufactured using highly purified material.

Assigned values for calibrators are traceable to this standardization.[14]

Technical Assistance

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

siemens.com/healthineers

References

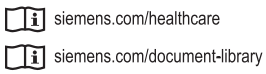
1. Fielding BA, Price DA, Houlton CA. Enzyme immunoassay for urinary albumin. *Clin Chem*. 1983;29:355–357.
2. Hellsing K. Influenced polymers on the antigen-antibody reaction in a continuous flow system. In: *Automated Immunoprecipitin Reactions*. Colloquium on AIP. Tarrytown, NY: Technicon Inst. Corp.; 1972:17, 798–9.
3. Burtis CA, Ashwood ER, Bruns DE. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics*. 4th ed. St. Louis, MO: Saunders; 2006:886-888.
4. Wu AHB, ed. *Tietz Clinical Guide to Laboratory Tests*. 4th ed. St. Louis, MO: Saunders; 2006:22-25,70,316.
5. 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.
6. Clinical and Laboratory Standards Institute. *Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Second Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2001. CLSI Document GP16-A2.
7. Burtis CA, Ashwood ER, Bruns DE. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics,* 4th ed. St. Louis, MO: Elsevier Saunders; 2006:886-888.
8. 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.
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. 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.
11. 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.
12. 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.

13. 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.

14. Data on file at Siemens Healthcare Diagnostics.

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
	Irritant Oral, dermal, or inhalation hazard
	Inhalation hazard Respiratory or internal health
	Flammable Flammable to extremely flammable
	Oxidizing
	Explosive
	Toxic

Symbol	Symbol Title and Description
	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
IVD	*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.
	Reconstitute and mix lyophilized product before use.
	Target
	Interval
	Legal Manufacturer
EC REP	Authorized Representative in the European Community
	Use-by date Use by the designated date.
LOT	Batch code
REF	Catalog number

Symbol	Symbol Title and Description
	Recycle
	Printed with soy ink
CE	CE Mark
CE 0088	CE Mark with notified body ID number Notified body ID number can vary.
YYYY-MM-DD	Date format (year-month-day)
CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.
UNITS C	Common Units
UNITS SI	International System of Units
MATERIAL	Material
MATERIAL ID	Unique material identification number
CONTROL NAME	Name of control
CONTROL TYPE	Type of control

Legal Information

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