SIEMENS

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ADVIA® 1800
ADVIA® 2400
Chemistry Systems

Microalbumin_2 (µALB_2)

Current Revision and Date[a]	Rev. H, 2020-02		
Product Name	ADVIA® Chemistry Microalbumin_2 (µALB_2) Reagents		REF 03051194
Systems	ADVIA 1800 Chemistry System ADVIA 2400 Chemistry System		
Materials Required but Not Provided	ADVIA Chemistry Microalbumin_2 Calibrators Reagent container adapters Commercially available controls		REF 06487733
Specimen Types	Human urine		
Assay Principle	Polyethylene glycol (PEG) enhanced immunoturbidimetric		
Assay Range	Urine: 0.3–(38.0–42.0) mg/dL (3–(380–420) mg/L)		
Reagent Storage	2–8°C		
Reagent On-System Stability		Without Reagent Container Inserts	With Reagent Container Inserts
	ADVIA 1800	60 days	60 days
	ADVIA 2400	40 days	45 days
Reagent Code	74090		

[a] In Rev. G or later, a vertical bar in the margin indicates a technical update to the previous version.

Intended Use

For *in vitro* diagnostic use in the quantitative measurement of microalbumin in human urine on ADVIA® Chemistry systems. 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 ADVIA Chemistry 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.[1,2,3,4]

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-1 diabetes mellitus, stage-3 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 ADVIA Chemistry µALB_2 assay is a polyethylene glycol (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 nm. By constructing a standard curve from the absorbancies of standards, the albumin concentration of the sample is determined.

Reagents

Reagent	Description	Storage	Reagent Stability		
REF 03051194	**ADVIA Chemistry Microalbumin_2 (µALB_2) Reagents**				
Microalbumin_2 Reagent 1 µALB_2 R1	20 mL in 20-mL containers Polyethylene glycol (6%) NaN_3 (0.09%)	2–8°C	**Unopened:** Stable until the expiration date on product.		
			On-system:	With Reagent Container Inserts	Without Reagent Container Inserts
			ADVIA 1800	60 days	60 days
			ADVIA 2400	45 days	40 days
Microalbumin_2 Reagent 2 µALB_2 R2	4.3 mL in 20-mL containers Anti-human albumin (goat) (lot specific) NaN_3 (0.09%)	2–8°C	**Unopened:** Stable until the expiration date on product.		
			On-system:	With Reagent Container Inserts	Without Reagent Container Inserts
			ADVIA 1800	60 days	60 days
			ADVIA 2400	45 days	40 days

Warnings and Precautions

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

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 the 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.

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

For *in vitro* diagnostic use.

Preparing Reagents

All reagents are liquid and ready to use.

Before use, gently invert the capped reagent to disrupt bubbles and ensure homogeneity. If bubbles still exist or foam is present, use a clean transfer pipette to aspirate them from the reagent container prior to use.

Storing and Stability

Unopened reagents are stable until the expiration date printed on the product label when stored at 2–8°C. Do not freeze reagents.

Specimen Collection and Handling

Siemens Healthcare Diagnostics validated urine for the ADVIA Chemistry µALB_2 assay.

The purpose of handling and storage information is to provide guidance to users. 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.

Collecting the Specimen

Follow these guidelines for specimens used for this assay:

- Collect the urine as a 24-hour, timed, or random midstream sample (spot collection) in a clean, unused glass or plastic collection container.
- Preservatives are not recommended for this method.

Storing the Specimen

Follow these guidelines for specimens used for this assay:

- For timed specimens or 24-hour specimens, use fresh specimens whenever possible.
- Specimens are stable for 14 days at 4°C or for up to 5 months at -70°C. Avoid repeated freeze-thaw cycles.[3]
- Mix stored specimens adequately. Centrifuge prior to testing.

Procedure

Materials Provided

The following materials are provided:

Item	Contents	Number of Tests
REF 03051194	Reagent 1: 4 × 20-mL containers Reagent 2: 4 × 20-mL containers	4 × 105 ADVIA 1800 4 × 130 ADVIA 2400

Materials Required but Not Provided

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

Item	Description
REF 06487733	ADVIA Chemistry Microalbumin_2 Calibrators
REF 02404085	20-mL reagent container adapter for 40-mL slot (ADVIA 1800)
REF 00771668	20-mL reagent container adapter for 70-mL slot (ADVIA 2400)
	Commercially available control materials

Optional Materials

The following materials may be used to perform this assay, but are not provided:

Item	Description
REF 02991886	Reagent container insert

Assay Procedure

Sampling, reagent delivery, mixing, and processing are automatically performed by the ADVIA Chemistry system.

For detailed information on performing the procedure, refer to the system operating instructions.

Preparing the System

For detailed information on preparing the system, refer to the system operating instructions.

Preparing the Samples

Before placing samples on the system, ensure that samples have the following characteristics:

- Samples are free of fibrin or other particulate matter.
- Samples are free of bubbles.

On-System Stability

	Stability without Reagent Container Insert	Stability with Reagent Container Insert
ADVIA 1800	60 days	60 days
ADVIA 2400	40 days	45 days

Do not use reagents beyond the expiration date.

Performing Calibration

To calibrate the ADVIA Chemistry μALB_2 assay, use the ADVIA Chemistry Microalbumin_2 Calibrators, REF 06487733.

Enter the lot-specific calibrator values that are provided with each lot of calibrator. Perform the calibration as described in the calibrator instructions for use.

Calibration Frequency

	Minimum Calibration Frequency without Reagent Container Insert	Minimum Calibration Frequency with Reagent Container Insert
ADVIA 1800	60 days	60 days
ADVIA 2400	14 days	45 days

Calibrate the assay after the following events:

- When the reagent lot number changes
- When a reagent pack is replaced by a new reagent pack with the same lot number, and the previous reagent pack was recalibrated during use
- When a reagent pack is replaced by a new reagent pack with the same lot number, and an additional reagent blank was run on the previous reagent pack during use
- After replacing critical optical or hydraulic components
- When indicated by quality control procedures

Individual laboratory quality control programs and procedures may require more frequent calibration.

Reagent Blank (RBL) Frequency

The ADVIA Chemistry system measures the RBL during assay calibration.

Note Use deionized water as the sample for the RBL in the ADVIA Chemistry µALB_2 assay.

Performing Quality Control

Follow government regulations or accreditation requirements for quality control frequency.

At least once each day of use, analyze 2 levels (low and high) of a commercially available quality control (QC) material with known microalbumin concentrations.

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.

The actual frequency of control in a laboratory is based on many factors, such as workflow, system experience, and government regulation. Each laboratory should evaluate the controls based on the frequency established by their laboratory guidelines.

Also, assay controls under the following conditions:

- Whenever you use a new reagent lot
- Following any system maintenance, cleaning, or troubleshooting procedure
- After performing a new calibration or an additional reagent blank

Follow your laboratory internal QC procedures if the results obtained are outside acceptable limits.

Taking Corrective Action

If the quality control results do not fall within the expected control range or within the laboratory's established values, do not report results. Take the following actions:

1. Determine and correct the cause of the unacceptable control results:
   a. Verify that the assay was performed according to the instructions for use.
   b. Verify that the materials are not expired.
   c. Verify that required maintenance was performed.
   d. Rerun the assay with fresh quality control samples, and confirm that quality control results are within acceptable limits before running patient samples.
   e. If the quality control results are not within acceptable limits, recalibrate the assay, and repeat the prior step.
   f. If necessary, contact your local technical support provider or distributor for assistance.
2. After corrective action is complete, repeat required testing of patient samples before reporting results.

Perform corrective actions in accordance with your established laboratory protocol.

Results

Calculation of Results

The system calculates and reports results based on the absorbance measurements of the test sample during the test, and of the calibrator(s) from calibration.

The instrument calculates the concentration of microalbumin in mg/dL (common units) or mg/L (Sl units).

Conversion factor: mg/dL × 10 = mg/L

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

A number of substances cause physiological changes in urine analyte concentrations. A comprehensive discussion of possible interfering substances, their urine 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.[5]

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.

Expected Values

The expected value for microalbumin is < 30 mg/day for urine.[4]

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

reported μALB mg/day = 24-hour urine volume (dL/day) × system-reported μALB concentration (mg/dL)

Siemens provides this information for reference. As with all *in vitro* diagnostic assays, each laboratory should determine its own reference ranges for the diagnostic evaluation of patient results. Consider these values as a guideline only.

Performance Characteristics

Analytical Measuring Range

The analytical range is from 0.3 mg/dL (3 mg/L), to the ADVIA Chemistry Microalbumin_2 Calibrator - Level 5, which varies from 38.0–42.0 mg/dL (380–420 mg/L).

Results that are below the assay range are flagged **L**. You should report the test result as < 0.3 mg/dL (< 3 mg/L).

Results that are above the assay range are flagged **H**.

Extended Measuring Range

Siemens has validated an automatic rerun condition for this assay that extends the reportable range to 380 mg/dL (3800 mg/L). You may configure the system to trigger automatic reruns.

Prozone Effect

A prozone effect was not demonstrated for analyte concentrations up to 20,000 mg/dL (200,000 mg/L).

Precision

The precision of the ADVIA Chemistry μALB_2 assay was analyzed as described in CLSI protocol EP05-A2.[7] Each sample was assayed 2 times per run, 2 runs per day, for at least 10 days.

ADVIA 1650/1800

		Repeatability (Within-Run)		Within-Lab (Total)	
Specimen Type	**Mean**	**SD[a]**	**CV[b] (%)**	**SD**	**CV (%)**
Common Units (mg/dL)					
Pool 1	2.9	0.06	2.1	0.10	3.3
Pool 2	29.3	0.34	1.2	0.49	1.7
Control 1	1.9	0.08	4.1	0.12	6.1
Control 2	9.1	0.16	1.8	0.23	2.5
SI Units (mg/L)					
Pool 1	29	0.6	2.1	1.0	3.3
Pool 2	293	3.4	1.2	4.9	1.7
Control 1	19	0.8	4.1	1.2	6.1
Control 2	91	1.6	1.8	2.3	2.5

[a] SD = standard deviation

[b] CV = coefficient of variation

ADVIA 2400

Specimen Type	Mean	Repeatability (Within-Run) SD[a]	Repeatability (Within-Run) CV[b] (%)	Within-Lab (Total) SD	Within-Lab (Total) CV (%)
Common Units (mg/dL)					
Pool 1	2.8	0.05	1.6	0.08	2.9
Pool 2	28.8	0.24	0.8	0.28	1.0
Control 1	1.7	0.04	2.1	0.07	3.8
Control 2	8.9	0.08	0.9	0.10	1.1
SI Units (mg/L)					
Pool 1	28	0.5	1.6	0.8	2.9
Pool 2	288	2.4	0.8	2.8	1.0
Control 1	17	0.4	2.1	0.7	3.8
Control 2	89	0.8	0.9	1.0	1.1

[a] SD = standard deviation
[b] CV = coefficient of variation

Actual results will vary depending on the study design, and on the sample and sample population used. Results obtained at individual laboratories may vary from the data provided.

Accuracy / Method Comparison

The performance of the ADVIA Chemistry μALB_2 assay (y) was compared with the performance of the comparison assay on the indicated system (x).

ADVIA 1650/1800

Specimen Type	Comparison Assay (x)	N	Regression Equation	Sy.x	r	Sample Range
Urine	ADVIA 1650/1800 μALB	98	y = 0.99x - 0.1 y = 0.99x - 0.7	0.1 1.2	0.999 0.999	0.6–16.8 mg/dL 6–168 mg/L

ADVIA 2400

Specimen Type	Comparison Assay (x)	N	Regression Equation	Sy.x	r	Sample Range
Urine	ADVIA 1650/1800 μALB_2	95	y = 0.97x - 0.0 y = 0.97x - 0.0	0.4 3.5	0.997 0.997	0.6–16.7 mg/dL 6–167 mg/L
Urine	ADVIA 2400 μALB	97	y = 1.00x - 0.2 y = 1.00x - 2.4	0.6 6.4	0.991 0.991	0.5–17.1 mg/dL 5–171 mg/L

The correlation of the assay may vary depending on the study design, comparable method, and sample population. Results obtained at individual laboratories may vary from the data provided.

Interferences

Siemens tested the following potential interferents with a urine pool of approximately 3 mg/dL (30 mg/L) albumin, and found the results shown below.

Interferent	Interferent Level	Microalbumin Sample Concentration	Interference
Acetaminophen	100 mg/dL (0.66 mmol/L)	3.0 mg/dL (30 mg/L)	NSI[a]
Ascorbic Acid	500 mg/dL (28.4 mmol/L)	3.0 mg/dL (30 mg/L)	NSI
Calcium	400 mg/dL (100 mmol/L)	3.0 mg/dL (30 mg/L)	NSI
Citrate	500 mg/dL (26 mmol/L)	3.0 mg/dL (30 mg/L)	NSI
Creatinine	500 mg/dL (44.2 mmol/L)	3.0 mg/dL (30 mg/L)	NSI
Glucose	5000 mg/dL (277.5 mmol/L)	3.0 mg/dL (30 mg/L)	NSI
Hemoglobin	500 mg/dL (5.0 g/L)	3.0 mg/dL (30 mg/L)	NSI
Hippuric Acid	400 mg/dL (22.3 mmol/L)	3.0 mg/dL (30 mg/L)	NSI
Inorganic Phosphorous	400 mg/dL (129.2 mmol/L)	3.0 mg/dL (30 mg/L)	NSI
Magnesium	400 mg/dL (42.0 mmol/L)	3.0 mg/dL (30 mg/L)	NSI
Oxalate	30 mg/dL (3.42 mmol/L)	3.0 mg/dL (30 mg/L)	NSI
Potassium Chloride	1000 mg/dL (134.1 mmol/L)	3.0 mg/dL (30 mg/L)	NSI
Salicylate	250 mg/dL (18.1 mmol/L)	3.0 mg/dL (30 mg/L)	NSI
Sodium Chloride	2000 mg/dL (342.2 mmol/L)	3.0 mg/dL (30 mg/L)	NSI
Urea Nitrogen	400 mg/dL (142.8 mmol/L)	3.0 mg/dL (30 mg/L)	NSI
Uric Acid	100 mg/dL (5.9 mmol/L)	3.0 mg/dL (30 mg/L)	NSI

[a] NSI = No significant interference. A percentage effect ≥ 10% is considered a significant interference.

Actual results will vary depending on the study design, the levels of the potential interferences tested, and the samples used. Results obtained at individual laboratories may vary from the data provided.

Standardization

The ADVIA Chemistry μALB_2 assay is traceable to an internal standard manufactured using highly purified material. Currently, no reference standard for this method exists. Assigned values of ADVIA Chemistry Microalbumin_2 Calibrator are traceable to this standardization.

Technical Assistance

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

siemens.com/healthcare

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 edition. St. Louis, MO.: Elsevier Saunders; 2006:886-888.
4. Wu AHB, ed. *Tietz Clinical Guide to Laboratory Tests*, 4th ed. St. Louis, MO: WB Saunders Company; 2006:70.
5. Young DS. *Effects of Drugs on Clinical Laboratory Tests.* 5th ed. Washington, DC: AACC Press; 2000.
6. Clinical and Laboratory Standards Institute (formerly NCCLS). *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition.* CLSI document EP05-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2004.

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Definition	Symbol	Definition
IVD	*In vitro* diagnostic medical device	REF REF	Catalog number
	Legal manufacturer	EC REP	Authorized Representative in the European Community
CE	CE Mark	CE 0088	CE Mark with identification number of notified body
	Consult instructions for use		Biological risk
	Keep away from sunlight and heat		Temperature limitation
	Lower limit of temperature		Upper limit of temperature
	Do not freeze (> 0°C)		Up
	Use by	Σ (n)	Contains sufficient for (n) tests
	Recycle	PRINTED WITH SOY INK	Printed with soy ink
Rev.	Revision	YYYY-MM-DD	Date format (year-month-day)
LOT	Batch code	**RxOnly**	Prescription Device (US only)

Trademarks

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

Global Siemens Headquarters
Siemens AG
Wittelsbacherplatz 2
80333 Muenchen
Germany

Global Siemens Healthcare Headquarters
Siemens AG
Healthcare Sector
Henkestrasse 127
91052 Erlangen
Germany
Phone: +49 9131 84-0
siemens.com/healthcare

Global Division
Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591
USA
siemens.com/healthcare