SIEMENS

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ADVIA® 1800
ADVIA® 2400
Chemistry Systems

Potassium (K)

	Current Revision and Date[a]	Rev. K, 2019-11	
❙	**Product Name**	ADVIA® Chemistry Potassium (K) Electrode	REF 10309440 (073-0050-01)
	Systems	ADVIA 1800 Chemistry System ADVIA 2400 Chemistry System	
	Materials Required but Not Provided	ADVIA Chemistry ISE Buffer	REF 03463190 (2000-mL) REF 04997873 (3000-mL)
❙		ADVIA Chemistry ISE Serum Standard Set ADVIA Chemistry ISE Urine Standard Set ADVIA Chemistry Reference Electrode Commercially available controls	REF 00729777 (B03-4175-01) REF 06242535 (B03-4176-01) REF 10309465 (073-0653-01)
	Specimen Types	Human serum, plasma (lithium heparin), urine	
	Assay Principle	Ion Selective Electrode (ISE), diluted	
	Assay Range	Serum: 1.0–10.0 mEq/L (1.0–10.0 mmol/L) Plasma: 1.0–10.0 mEq/L (1.0–10.0 mmol/L) Urine: 3.0–300 mEq/L (3.0–300 mmol/L)	
❙	**Electrode Storage**	2–32°C	
	Electrode On-System Stability	Up to 30,000 samples, for 90 days from the time the ADVIA Chemistry K electrode is placed on the system, or until the expiration date on the electrode box, whichever occurs first.	

[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 determination of potassium in human serum, plasma (lithium heparin), and urine on ADVIA® Chemistry systems. Such measurements are used to monitor electrolyte balance in the diagnosis and treatment of primary aldosteronism, metabolic alkalosis, diarrhea, severe vomiting, diuretic administration, diabetic ketoacidosis, and other diseases.

Summary and Explanation

The ADVIA Chemistry Potassium (K) assay is based on an indirect potentiometric procedure using an ion selective electrode (ISE). The potassium ion selective electrode responds selectively to potassium ions according to the Nernst equation.[1]

Principles of the Procedure

The sample is mixed with ISE buffer, thereby providing a constant pH and a constant ionic strength solution. As the buffered sample is moved through the ion selective electrode, changes in the electrical potential take place. These electrical potential changes are measured against the potential of a reference electrode to derive the correct analog value for the sample.

Warnings and Precautions

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

H317, H350 **P201, P280, P261, P308+P313, P302+P352, P501**	**Danger!** May cause an allergic skin reaction. May cause cancer. Obtain special instructions before use. Wear protective gloves/protective clothing/eye protection/face protection. Avoid breathing vapors. IF exposed or concerned: Get medical advice/attention. IF ON SKIN: Wash with plenty of soap and water. Dispose of contents and container in accordance with all local, regional, and national regulations. **Contains:** Formaldehyde; ADVIA Chemistry ISE Buffer, ADVIA Chemistry ISE Baseline Solution

H350 **P201, P280, P261, P308+P313, P501**	**Danger!** May cause cancer. Obtain special instructions before use. Wear protective gloves/protective clothing/eye protection/face protection. Avoid breathing vapors. IF exposed or concerned: Get medical advice/attention. Dispose of contents and container in accordance with all local, regional, and national regulations. **Contains:** Formaldehyde; ADVIA Chemistry ISE Standard Set Serum, ADVIA Chemistry ISE Standard Set Urine

H412 **P273, P501**	Harmful to aquatic life with long lasting effects. Avoid release to the environment. Dispose of contents and container in accordance with all local, regional, and national regulations. **Contains:** Silver chloride; ADVIA Chemistry ISE Reference Electrode

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.

Storing and Stability

Unopened electrodes are stable until the expiration date printed on the product label when stored at 2–32°C.

Unopened ISE-related system solutions are stable until the expiration date printed on the product label when stored at 5–25°C.

Specimen Collection and Handling

Siemens Healthcare Diagnostics validated serum, plasma (lithium heparin), and urine for the ADVIA Chemistry K assay.

Follow these guidelines for specimens used for this assay:

- Serum and plasma can be collected using recommended procedures for collection of diagnostic blood specimens by venipuncture.[2] Follow the instructions provided with your specimen collection device for use and processing.[3]
- Complete clot formation should take place before centrifugation.
- 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.[4]
- Specimens should be free of particulate matter.
- Specimens should be as fresh as possible.
- The use of hemolyzed samples should be avoided.

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.

Procedure

Materials Provided

The following materials are provided:

Item	Description	Storage	Stability
REF 10309440 (073-0050-01) 	**ADVIA® Chemistry Potassium (K) Electrode**	2–32°C	**Unopened:** Stable until the expiration date on product. **On-system:** Up to 30,000 samples or 90 days after installation of the electode

Materials Required but Not Provided

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

Item	Description	Storage	Stability
REF 10309465 (073-0653-01) 	**ADVIA Chemistry Reference Electrode**	2–32°C	**Unopened:** Stable until the expiration date on product. **On-system:** Up to 30,000 samples or 90 days after installation of the electrode
REF 03463190	**ADVIA Chemistry ISE Buffer** 2000-mL Formaldehyde (0.5%) Triethanolamine (< 5.0%) Sodium (1-mmol/L) Potassium (0.05 mmol/L) Chloride (1-mmol/L) Buffers Preservative	5–25°C	**Unopened:** Stable until the expiration date on product. **On-system:** 30 days

Item	Description	Storage	Stability
REF 04997873	**ADVIA Chemistry ISE Buffer** (ADVIA 1800/2400) 3000-mL Formaldehyde (0.5%) Triethanolamine (< 5.0%) Sodium (1-mmol/L) Potassium (0.05 mmol/L) Chloride (1-mmol/L) Buffers Preservative	5–25°C	**Unopened:** Stable until the expiration date on product. **On-system:** 30 days
REF 00729777 (B03-4175-01)	**ADVIA Chemistry ISE Serum Standard Set**		
ISE Serum Low Standard SER L	100-mL Formaldehyde (0.1%) Na+ (130 mmol/L) K+ (3.5 mmol/L) Cl- (85 mmol/L) Preservative	5–25°C	**Unopened:** Stable until the expiration date on product. Open-bottle stability: 60 days
ISE Serum High Standard SER H	100-mL Formaldehyde (0.1%) Na+ (160 mmol/L) K+ (6 mmol/L) Cl- (120 mmol/L) Preservative	5–25°C	**Unopened:** Stable until the expiration date on product. Open-bottle stability: 60 days
REF 06242535 (B03-4176-01)	**ADVIA Chemistry ISE Urine Standard Set**		
ISE Urine Low Standard UR L	100-mL Formaldehyde (0.1%) Na+ (50 mmol/L) K+ (10 mmol/L) Cl- (50 mmol/L) Preservative	5–25°C	**Unopened:** Stable until the expiration date on product. Open-bottle stability: 60 days
ISE Urine High Standard UR H	100-mL Formaldehyde (0.1%) Na+ (200 mmol/L) K+ (100 mmol/L) Cl- (180 mmol/L) Preservative	5–25°C	**Unopened:** Stable until the expiration date on product. Open-bottle stability: 60 days
	Commercially available controls		

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

Refer to the *Materials Provided* table and the *Materials Required but Not Provided* table for on-system and open-bottle stability.

Do not use solutions beyond their expiration dates.

Electrode Warranty

The potassium electrode (REF 10309440; 073-0050-01) is warranted for use up to 30,000 samples, for 3 months from the time the electrode is placed on the system, or until the expiration date stamped on the electrode box, whichever occurs first.

The reference electrode (REF 10309465; 073-0653-01) is warranted for use up to 30,000 samples, for 3 months from the time the electrode is placed on the system, or until the expiration date stamped on the electrode box, whichever occurs first.

This warranty is not applicable to dialysis samples, samples left at room temperature longer than 24 hours after blood collection, or samples that are decomposed.

Performing Calibration

To calibrate the ADVIA Chemistry K assay, use the ADVIA Chemistry ISE Serum Standard Set, REF 00729777 (B03-4175-01) and the ADVIA Chemistry ISE Urine Standard Set, REF 06242535 (B03-4176-01).

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

Calibration Frequency

Calibrate the assay every day.

Calibrate the assay after the following events:

- When the buffer lot number changes
- After replacing ISE electrodes 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

Not applicable

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 potassium 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 buffer lot
- Following any system maintenance, cleaning, or troubleshooting procedure
- After performing a new calibration

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 an indirect potentiometric measurement of the test sample during the test, and of the calibrator(s) from calibration.

The instrument calculates the concentration of potassium in mEq/L (common units) or mmol/L (SI units).

Conversion factor: mEq/L = mmol/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 serum, plasma, or urine analyte concentrations. A comprehensive discussion of possible interfering substances, their serum, plasma, or 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 reference ranges for potassium are listed in the following table.

Sample Type	Reference Range
Serum[6]	3.5–5.5 mEq/L (3.5–5.5 mmol/L)
Plasma (males)[7]	3.5–4.5 mEq/L (3.5–4.5 mmol/L)
Plasma (females)[7]	3.4–4.4 mEq/L (3.4–4.4 mmol/L)
Urine[7]	25–125 mEq/day (varies with diet) (25–125 mmol/day) (varies with diet)

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

This assay is linear from 1.0–10.0 mEq/L (1.0–10.0 mmol/L) for serum and plasma, and 3.0–300 mEq/L (3.0–300 mmol/L) for urine.

Results that are below the assay range are flagged **L**. You should report the test result as < 1.0 mEq/L (< 1.0 mmol/L) for serum and plasma, and < 3.0 mEq/L (< 3.0 mmol/L) for urine.

Results that are above the assay range are flagged **H**. You should report the test result as > 10.0 mEq/L (> 10.0 mmol/L) for serum and plasma, and as > 300 mEq/L (> 300 mmol/L) for urine.

Precision

The precision of the ADVIA Chemistry K assay was analyzed as described in CLSI protocol EP05-A2.[8] Each sample was assayed 2 times per run, at least 1 run per day, for at least 20 days.

ADVIA 1650

		Repeatability (Within-Run)		Within-Lab (Total)	
Specimen Type	**Mean**	**SD[a]**	**CV[b] (%)**	**SD**	**CV (%)**
Common Units (mEq/L) and SI Units (mmol/L)					
Serum	3.0	0.02	0.8	0.09	3.0
Serum	6.4	0.11	1.7	0.17	2.7
Urine	28.5	1.61	5.7	1.75	6.1
Urine	102.9	3.56	3.5	4.92	4.8

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

ADVIA 1800

		Repeatability (Within-Run)		Within-Lab (Total)	
Specimen Type	**Mean**	**SD[a]**	**CV[b] (%)**	**SD**	**CV (%)**
Common Units (mEq/L) and SI Units (mmol/L)					
Serum	3.0	0.03	0.9	0.04	1.4
Serum	5.8	0.06	0.5	0.052	0.9
Urine	31.4	0.16	0.5	0.29	0.9
Urine	99.8	0.30	0.3	1.10	1.1

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

ADVIA 2400

		Repeatability (Within-Run)		Within-Lab (Total)	
Specimen Type	**Mean**	**SD[a]**	**CV[b] (%)**	**SD**	**CV (%)**
Common Units (mEq/L) and SI Units (mmol/L)					
Serum	3.0	0.03	0.9	0.04	1.4
Serum	5.9	0.04	0.6	0.05	0.8
Urine	29.0	0.29	1.0	0.29	1.0
Urine	98.7	0.49	0.5	0.98	1.0

[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 K assay (y) was compared with the performance of the comparison assay on the indicated system (x).

ADVIA 1650

Specimen Type	Comparison Assay (x)	N	Regression Equation	Sy.x	r	Sample Range
Serum	Technicon DAX®	156	y = 1.09x - 0.20	0.08	0.995	2.2–8.1 mEq/L (mmol/L)
Plasma[a]	ADVIA 1650 (serum)	49	y = 0.92x - 0.01	0.16	0.890	3.4–4.8 mEq/L (mmol/L)
Urine	Beckman CX3	99	y = 1.01x - 0.20	1.20	0.999	7.0–116.0 mEq/L (mmol/L)

[a] lithium heparin

ADVIA 1800

Specimen Type	Comparison Assay (x)	N	Regression Equation	Sy.x	r	Sample Range
Serum	ADVIA 1650	47	y = 0.99x + 0.11	0.07	0.999	1.0–10.0 mEq/L (mmol/L)
Urine	ADVIA 1650	31	y = 1.02x - 0.42	1.52	0.999	6.1–184.4 mEq/L (mmol/L)
Serum	Flame Photometer	47	y = 1.02x - 0.01	0.09	0.999	1.0–9.8 mEq/L (mmol/L)

ADVIA 2400

Specimen Type	Comparison Assay (x)	N	Regression Equation	Sy.x	r	Sample Range
Serum	ADVIA 1650	367	y = 0.99x + 0.09	0.07	0.995	2.0–7.3 mEq/L (mmol/L)
Urine	ADVIA 1650	92	y = 0.95x + 0.69	0.99	1.000	4.0–201 mEq/L (mmol/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 and found the results shown below.

ADVIA 1650/1800

Interferent	Interferent Level	Potassium Sample Concentration	Interference
Bilirubin (conjugated and unconjugated)	25 mg/dL (428 µmol/L)	3.3 mEq/L (mmol/L)	NSI[a]
Lipemia[b] (from triglycerides concentrate)	500 mg/dL (5.65 mmol/L)	3.3 mEq/L (mmol/L)	NSI

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

[b] SI units calculated as triolein

ADVIA 2400

Interferent	Interferent Level	Potassium Sample Concentration	Interference
Bilirubin (conjugated and unconjugated)	25 mg/dL (428 µmol/L)	4.1 mEq/L (mmol/L)	NSI[a]
Lipemia[b] (from triglycerides concentrate)	500 mg/dL (5.65 mmol/L)	4.0 mEq/L (mmol/L)	NSI

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

[b] SI units calculated as triolein

Avoid hemolyzed samples.

Note There is poor correlation between turbidity and triglyceride concentration in a lipemic sample.[9]

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 K assay is traceable to a flame photometric reference method, which uses reference materials from the National Institute of Standards and Technology (NIST) via patient sample correlation and is verified using NIST Reference Serum.

System	n	Mean Bias	Range
ADVIA 1800	47	-0.10	1.0–9.8 mmol/L
ADVIA 2400	50	-0.003	2.2–7.2 mmol/L

Assigned values of ADVIA Chemistry ISE Serum Standards and ADVIA Chemistry ISE Urine Standards are traceable to this standardization.

Technical Assistance

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

siemens.com/healthcare

References

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3. Clinical and Laboratory Standards Institute (formerly NCCLS). *Tubes and Additives for Venous Blood Specimen Collection: Approved Standard; Approved Guideline—Sixth Edition.* CLSI document GP39-A6. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.
4. Clinical and Laboratory Standards Institute (formerly NCCLS). *Procedures for the Handling and Processing of Blood Specimens; Approved Guideline—Fourth Edition.* CLSI document GP44-A4. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.
5. Young DS. *Effects of Drugs on Clinical Laboratory Tests.* 5th ed. Washington, DC: AACC Press; 2000.
6. Data on file at Siemens Healthcare Diagnostics.
7. Wu AHB, ed. *Tietz Clinical Guide to Laboratory Tests*, 4th ed. St. Louis, MO: WB Saunders Company; 2006:880-885.
8. 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.
9. Twomey PJ, Don-Wauchope AC, McCullough D. Unreliability of triglyceride measurement to predict turbidity induced interference. *J Clin Pathol.* 2003 Nov;56(11):861–862.

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

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