SIEMENS Healthineers

A-LYTE Integrated Multisensor (IMT Na K Cl)

Current Revision and Date[a]	Rev. 07, 2024-06	
Product Name	A-LYTE Integrated Multisensor (IMT Na K Cl)	REF 11099315 (60,000 tests)
Abbreviated Product Name	IMT Na K Cl	
Test Name/ID	Na K Cl	
Systems	Atellica CH Analyzer	
Materials Required but Not Provided	A-LYTE IMT Standard A	REF 11099304
	A-LYTE IMT Standard B + Salt Bridge	REF 11099306
	A-LYTE IMT Diluent	REF 11099305
	A-LYTE IMT Dilution Check	REF 11099325
Optional Materials	A-LYTE IMT Cleaner	REF 11556782
Specimen Types	Serum, plasma (lithium heparin) and urine	
Sample Volume	25 µL	
Measuring Interval	**Sodium** Serum/plasma: 50–200 mmol/L (mEq/L) Urine: 10–300 mmol/L (mEq/L) **Potassium** Serum/plasma: 1–10 mmol/L (mEq/L) Urine: 2–300 mmol/L (mEq/L) **Chloride** Serum/plasma: 50–200 mmol/L (mEq/L) Urine: 20–330 mmol/L (mEq/L)	

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

CE 0197

Intended Use

The A-LYTE® Integrated Multisensor (IMT Na K Cl) is for *in vitro* diagnostic use in the quantitative determination of sodium, potassium and chloride (Na, K, Cl) in human serum, plasma (lithium heparin) and urine using the Atellica® CH Analyzer. Measurements of sodium obtained by this device are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance. Measurements of potassium obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Summary and Explanation

The methods for measurement of electrolytes include flame photometry, spectrophotometry and direct or indirect ion selective electrode potentiometry.

The A-LYTE Na, K, and Cl assays use indirect Integrated Multisensor Technology (IMT). There are four electrodes used to measure electrolytes. Three of these electrodes are ion-selective for sodium, potassium and chloride. A reference electrode is also incorporated in the multisensor.

Principles of the Procedure

A diluted sample (1:10 with A-LYTE IMT Diluent (IMT Diluent)) is positioned in the sensor and Na+, K+ or Cl- ions establish equilibrium with the electrode surface. A potential is generated proportional to the logarithm of the analyte activity in the sample. The electrical potential generated on a sample is compared to the electrical potential generated on a standard solution, and the concentration of the desired ions is calculated by use of the Nernst equation.[1]

Reagents

Material Description	Storage	Stability[a]
A-LYTE IMT Na K Cl	Unopened at 2–8°C	Until expiration date on product
4 multisensors per carton	Onboard per multisensor	14 days or 5000 samples

[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-healthineers.com.

The summary of safety and performance for this *in vitro* diagnostic medical device is available to the public in the European database on medical devices (EUDAMED) when this database is available and the information has been uploaded by the Notified Body. The web address of the EUDAMED public website is: https://ec.europa.eu/tools/eudamed.

To avoid potential instrument damage or possible erroneous results caused by microbial contamination, do not refill or reuse the IMT system calibration (standard) fluid containers. Use of any calibration fluids not manufactured by Siemens Healthcare Diagnostics Inc. could void the sensor warranty. A waste container is provided with the instrument. The used waste container holds human body fluids which may be potentially infectious; handle with appropriate care to avoid skin contact and ingestion.

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.

Storage and Stability

Unopened multisensors 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

The A-LYTE IMT Na K Cl multisensor is stable onboard the system for 14 days or 5000 samples per multisensor. Discard multisensor 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, plasma (lithium heparin) and urine are the recommended sample types for these assays.

Commercial standard solutions prepared for flame emission photometers should not be used since viscosity adjusters and wetting agents may affect electrode performance.

For urine manual dilutions refer to the *Extended Measuring Interval* section.

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]
- Collect 24-hour urine without additives. Store refrigerated during collection.[6]

Storing the Specimen

Sodium, potassium and chloride in serum, plasma and urine may be stored for up to 7 days at 2–8°C or stored frozen for up to 30 days at -20°C.[7]

Twenty-four hour urine collection for sodium, potassium, and chloride should be made without addition of preservatives.[1] Store refrigerated at 2–8°C or frozen for delayed analysis.[1]

Thawed or 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 25 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
11099315	**Carton** A-LYTE IMT Na K Cl	4 x 5000 (per analyte) 4 x 15,000 (counting Na, K and Cl)

Materials Required but Not Provided

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

REF	Description
	Atellica CH Analyzer[a, b]
11099304	A-LYTE IMT Standard A
11099306	A-LYTE IMT Standard B + Salt Bridge
11099305	A-LYTE IMT Diluent
11099325	A-LYTE IMT Dilution Check
	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.

[b] Additional system fluids are required to operate the system: A-LYTE IMT Dilution Check, A-LYTE IMT Standard A, A-LYTE IMT Diluent, and A-LYTE IMT Standard B + Salt Bridge. For system fluid instructions for use, refer to the Document Library.

Optional Materials

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

REF	Description	
11556782	A-LYTE IMT Cleaner	6 x 2.5 mL vials

Assay Procedure

The system automatically performs the following steps:

1. Dispenses 25 µL of primary sample, 75 µL of A-LYTE IMT Diluent and 150 µL of special reagent water.
2. Measures the potential of each ion selective electrode (sodium, potassium, and chloride) against the reference electrode.
3. Reports results.

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

Test Duration: 18 seconds (serum/plasma), 27 seconds (urine)

Preparing the System

Refer to the Operators Guide.

Performing Calibration

For calibration of the A-LYTE IMT Na K Cl, the system performs a two point automatic calibration in duplicate every 4 hours. In addition, the system will routinely perform a one point calibration check with each sample measurement.

Auto-calibration occurs after power-on, with the changing of A-LYTE IMT Standard A, A-LYTE IMT Standard B + Salt Bridge, or a sensor and when the system software is reset. Calibration can be initiated at any time a sample is not being run.

Calibration Frequency

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

- When indicated by quality control results.
- After major maintenance or service, if indicated by quality control results.

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 A-LYTE IMT Na K Cl assays, 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. 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:

- With use of a new multisensor.
- 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 mmol/L (common units) or mEq/L (SI units) using the Nernst equation.[1]

Conversion formula: 1 mmol/L = 1 mEq/L

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

Dilutions

A verification of the system dilution ratio, using A-LYTE IMT Dilution Check (REF 11099325), should be performed with the instrument preventative maintenance procedure or if indicated by quality control results.

Interpretation of Results

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

Limitations

Avoid hemolyzed samples for potassium. Hemolyzed samples may give incorrect elevated potassium. Intracellular potassium concentration is 30–50 times greater than that of extracellular serum or plasma.

Samples exposed to benzalkonium salts present in certain blood catheter devices will cause falsely elevated sodium and potassium measurements.[8]

Iron at 1 g/dL increases the potassium result in serum/plasma at 2.69 mmol/L (2.69 mEq/L) by 17% and 4.54 mmol/L (4.54 mEq/L) by 11%.

Citrate at 1 g/dL decreases the chloride result in serum/plasma at 82.4 mmol/L (82.4 mEq/L) by -12%.

Fluoride at 1 g/dL increases the chloride result in serum/plasma at 81.7 mmol/L (81.7 mEq/L) by 40% and 101 mmol/L (101 mEq/L) by 55%.

Iodine at 50 mg/dL increases the chloride result in serum/plasma at 82.2 mmol/L (82.2 mEq/L) by 16%.

Bromide at 200 mg/dL increases the chloride result in serum/plasma at 82.1 mmol/L (82.1 mEq/L) by 55% and 101 mmol/L (101 mEq/L) by 36%.

Salicylate at 50 mg/dL increases the chloride result in serum/plasma at 98.5 mmol/L (98.5 mEq/L) by 11% and 101 mmol/L (101 mEq/L) by 12%.

Ibuprofen at 500 mg/dL increases chloride results in urine at 47.2 mmol/L (47.2 mEq/L) by 18%.

Ofloxacin at 90 mg/dL decreases chloride results in urine at 55.8 mmol/L (55.8 mEq/L) by -11%.

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

As with any chemical reaction, you must be alert to the possible effect 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

Reference Interval

A reference interval for healthy adults was established in accordance with CLSI Document EP28-A3c and verified on the Atellica CH Analyzer.[9,10]

Specimen Type	Analyte	Reference Interval Common Units (SI Units)
Serum	Na K Cl	136–145 mmol/L (136–145 mEq/L) 3.5–5.1 mmol/L (3.5–5.1 mEq/L) 98–107 mmol/L (98–107 mEq/L)
Plasma	Na K Cl	136–145 mmol/L (136–145 mEq/L) 3.4–4.5 mmol/L (3.4–4.5 mEq/L) 98–107 mmol/L (98–107 mEq/L)
Urine	Na K Cl	40–220 mmol/24 hr (40–220 mEq/24 hr) 25–125 mmol/24 hr (25–125 mEq/24 hr) 110–250 mmol/24 hr (110–250 mEq/24 hr)

Anion Gap (AG): 5–15 mmol/L (mEq/L)

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

Analyte	Serum/Plasma mmol/L (mEq/L)	Urine mmol/L (mEq/L)
Sodium	50–200 (50–200)	10–300 (10–300)
Potassium	1–10 (1–10)	2–300 (2–300)
Chloride	50–200 (50–200)	20–330 (20–330)

This is the range of analyte values that can be measured directly on the specimen without any dilution or pretreatment that is not part of the usual analytical process. The assays are linear across this range of analyte values.

Urine samples with results in excess of $Na^+ > 300$ mmol/L (mEq/L), $K^+ > 300$ mmol/L (mEq/L), or $Cl^- > 330$ mmol/L (mEq/L) should be repeated with a dilution.

Extended Measuring Interval

Manual urine dilution

1. Dilute 1 part urine with 1 part special reagent water.
2. Enter manual dilution factor of 2.
3. Reassay.
4. Resulting readout is corrected for dilutions.

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

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.[11]

The Na assay is designed to have a limit of quantitation (LoQ) ≤ 50 mmol/L (50 mEq/L) with ≤ 20% total error for serum and plasma, and ≤ 10 mmol/L (10 mEq/L) with ≤ 30% total error for urine. The K assay is designed to have a LoQ ≤ 1 mmol/L (1 mEq/L) with ≤ 20% total error for serum and plasma, and ≤ 2 mmol/L (2 mEq/L) with < 30% total error for urine. The Cl assay is designed to have a LoQ ≤ 50 mmol/L (50 mEq/L) with ≤ 20% total error for serum and plasma, and ≤ 20 mmol/L (20 mEq/L) with ≤ 30% total error for urine.

LoQ

Sample Type	Assay	Limit of Quantitation (LoQ) mmol/L (mEq/L)	Determinations	Total Analytical Error Limit (%)[a]
Serum and plasma	Na	42.4 (42.4)	120	≤ 20
Urine	Na	5.35 (5.35)	120	≤ 30
Serum and plasma	K	0.429 (0.429)	120	≤ 20
Urine	K	1.03 (1.03)	120	≤ 30
Serum and plasma	Cl	38.3 (38.3)	120	≤ 20
Urine	Cl	15.8 (15.8)	120	≤ 30

[a] Calculated using the Westgard model.

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 20 days (N ≥ 80 for each sample). The following results were obtained:

Sodium (Na)

			Repeatability		Within-Lab Precision	
Sample Type	N	Mean mmol/L (mEq/L)	SD[a] mmol/L (mEq/L)	CV[b] (%)	SD mmol/L (mEq/L)	CV (%)
Serum Pool	80	73.6 (73.6)	0.36 (0.36)	0.5	0.60 (0.60)	0.8
Serum QC	80	116 (116)	0.69 (0.69)	0.6	1.19 (1.19)	1.0

			Repeatability		Within-Lab Precision	
Sample Type	**N**	**Mean mmol/L (mEq/L)**	**SD[a] mmol/L (mEq/L)**	**CV[b] (%)**	**SD mmol/L (mEq/L)**	**CV (%)**
Serum QC	80	143 (143)	0.84 (0.84)	0.6	1.41 (1.41)	1.0
Serum QC	80	156 (156)	0.82 (0.82)	0.5	1.36 (1.36)	0.9
Urine Pool	80	32.2 (32.2)	0.33 (0.33)	1.0	0.50 (0.50)	1.5
Urine QC	80	80.3 (80.3)	0.52 (0.52)	0.6	0.83 (0.83)	1.0
Urine QC	80	177 (177)	1.23 (1.23)	0.7	1.85 (1.85)	1.0
Urine Pool	80	284 (2.84)	1.7 (1.7)	0.6	3.17 (3.17)	1.1

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

Potassium (K)

			Repeatability		Within-Lab Precision	
Sample Type	**N**	**Mean mmol/L (mEq/L)**	**SD[a] mmol/L (mEq/L)**	**CV[b] (%)**	**SD mmol/L (mEq/L)**	**CV (%)**
Serum QC	80	2.64 (2.64)	0.01 (0.01)	0.4	0.03 (0.03)	1.0
Serum QC	80	3.95 (3.95)	0.02 (0.02)	0.5	0.03 (0.03)	0.9
Serum Pool	80	5.92 (5.92)	0.03 (0.03)	0.5	0.04 (0.04)	0.8
Serum QC	80	7.39 (7.39)	0.04 (0.04)	0.5	0.06 (0.06)	0.8
Urine QC	80	31.2 (31.2)	0.15 (0.15)	0.5	0.30 (0.30)	0.9
Urine QC	80	73.7 (73.7)	0.39 (0.39)	0.5	0.69 (0.69)	0.9
Urine Pool	80	258 (258)	2.01 (2.01)	0.8	2.95 (2.95)	1.1

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

Chloride (Cl)

			Repeatability		Within-Lab Precision	
Sample Type	**N**	**Mean mmol/L (mEq/L)**	**SD[a] mmol/L (mEq/L)**	**CV[b] (%)**	**SD mmol/L (mEq/L)**	**CV (%)**
Serum QC	80	78.1 (78.1)	0.73 (0.73)	0.9	1.15 (1.15)	1.5
Serum QC	80	102 (102)	0.83 (0.83)	0.8	1.05 (1.05)	1.0
Serum QC	80	114 (114)	0.78 (0.78)	0.7	0.99 (0.99)	0.9
Serum Pool	80	189 (189)	1.01 (1.01)	0.5	1.30 (1.30)	0.7
Urine Pool	80	42.7 (42.7)	0.26 (0.26)	0.6	0.71 (0.71)	1.7
Urine QC	80	99.7 (99.7)	0.65 (0.65)	0.6	0.97 (0.97)	1.0

			Repeatability		Within-Lab Precision	
Sample Type	N	Mean mmol/L (mEq/L)	SD[a] mmol/L (mEq/L)	CV[b] (%)	SD mmol/L (mEq/L)	CV (%)
Urine QC	80	194 (194)	0.99 (0.99)	0.5	1.76 (1.76)	0.9
Urine Pool	80	280 (280)	1.23 (1.23)	0.4	2.16 (2.16)	0.8

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

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

Based on internal testing, the overall reproducibility is estimated to be ≤ 2.0% CV for Na serum samples tested, ≤ 1.4% CV for K serum samples tested and ≤ 3.0% CV for Cl serum samples tested and includes multiple reagent lots, instruments, days, and replicates.[7] Performance of the assay at individual laboratories may vary.

Assay Comparison

The A-LYTE Na assay is designed to have a a slope of 1.0 ± 0.05 compared to ADVIA® Chemistry Na for serum and urine specimens. The A-LYTE K assay is designed to have a slope of 1.0 ± 0.07 compared to ADVIA Chemistry K for serum specimens, and a slope of 1.0 ± 0.05 compared to ADVIA Chemistry K for urine specimens. The A-LYTE Cl assay is designed to have a a slope of 1.0 ± 0.05 compared to ADVIA Chemistry Cl for serum and urine specimens. Assay comparison was determined using the Passing and Bablok 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 Na	y = 1.00x - 2.00 mmol/L (y = 1.00x - 2.00 mEq/L)	101–197 mmol/L (101–197 mEq/L)	106	0.995
Urine	ADVIA Chemistry 1800 Na	y = 1.01x + 0.97 mmol/L (y = 1.01x + 0.97 mEq/L)	12–283 mmol/L (12–283 mEq/L)	101	1.000
Serum	ADVIA Chemistry 1800 K	y = 0.99x - 0.04 mmol/L (y = 0.99x - 0.04 mEq/L)	1.50–9.90 mmol/L (1.50–9.90 mEq/L)	103	1.000
Urine	ADVIA Chemistry 1800 K	y = 1.03x - 0.67 mmol/L (y = 1.03x - 0.67 mEq/L)	3.7–280.9 mmol/L (3.7–280.9 mEq/L)	105	0.998
Serum	ADVIA Chemistry 1800 Cl	y = 1.00x + 0.00 mmol/L (y = 1.00x + 0.00 mEq/L)	59–191 mmol/L (59–191 mEq/L)	108	0.998
Urine	ADVIA Chemistry 1800 Cl	y = 0.99x - 0.28 mmol/L (y = 0.99x - 0.28 mEq/L)	19–321 mmol/L (19–321 mEq/L)	102	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.

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:

Assay	Specimen (y)	Reference Specimen (x)	Regression Equation	Sample Interval	N[a]	r[b]
Na	Lithium heparin plasma	Serum	y = 0.99x + 0.52 mmol/L (y = 0.99x + 0.52 mEq/L)	94.6–198 mmol/L (94.6–198 mEq/L)	50	0.997
K[c]	Lithium heparin plasma	Serum	y = 0.93x + 0.01 mmol/L (y = 0.93x + 0.01 mEq/L)	1.37–9.94 mmol/L (1.37–9.94 mEq/L)	50	0.980
Cl	Lithium heparin plasma	Serum	y = 0.99x + 0.52 mmol/L (y = 0.99x + 0.52 mEq/L)	64.4–163 mmol/L (64.4–163 mEq/L)	50	0.997

[a] Number of samples tested.

[b] Correlation coefficient.

[c] It is documented in the literature that potassium concentrations in plasma specimens can be lower than in serum specimens as a consequence of platelet rupture during coagulation. The extent of the potential difference is dependent on the platelet count in the specimen. The lower potassium reference intervals for plasma specimens compared to serum specimens reflect this known occurrence.

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 A-LYTE IMT Na K Cl multisensor was evaluated for 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 A-LYTE IMT Na K Cl multisensor.[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.

Serum/Plasma Interference - Sodium (Na)

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration mmol/L (mEq/L)	Percent Bias
Hemoglobin	750 mg/dL (0.47 mmol/L)	123 (123)	2
	750 mg/dL (0.47 mmol/L)	137 (137)	2
Bilirubin, conjugated	60 mg/dL (1026 µmol/L)	122 (122)	2
	60 mg/dL (1026 µmol/L)	136 (136)	2
Bilirubin, unconjugated	60 mg/dL (1026 µmol/L)	127 (127)	0
	60 mg/dL (1026 µmol/L)	142 (142)	-1
Lipemia (Intralipid®)	3000 mg/dL (33.9 mmol/L)	129 (129)	-1
	3000 mg/dL (33.9 mmol/L)	149 (149)	-1

Serum/Plasma Interference - Potassium (K)

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration mmol/L (mEq/L)	Percent Bias
Bilirubin, conjugated	60 mg/dL (1026 µmol/L)	2.72 (2.72)	-1
	60 mg/dL (1026 µmol/L)	4.62 (4.62)	-1
Bilirubin, unconjugated	60 mg/dL (1026 µmol/L)	2.73 (2.73)	-1
	60 mg/dL (1026 µmol/L)	4.61 (4.61)	0
Lipemia (Intralipid®)	3000 mg/dL (33.9 mmol/L)	2.87 (2.87)	4
	3000 mg/dL (33.9 mmol/L)	4.84 (4.84)	2

Serum/Plasma Interference - Chloride (Cl)

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration mmol/L (mEq/L)	Percent Bias
Hemoglobin	750 mg/dL (0.47 mmol/L)	84.1 (84.1)	3
	750 mg/dL (0.47 mmol/L)	100 (100)	3
Bilirubin, conjugated	60 mg/dL (1026 µmol/L)	83.4 (83.4)	1
	60 mg/dL (1026 µmol/L)	99.6 (99.6)	1
Bilirubin, unconjugated	60 mg/dL (1026 µmol/L)	84.6 (84.6)	0
	60 mg/dL (1026 µmol/L)	100 (100)	0
Lipemia (Intralipid®)	3000 mg/dL (33.9 mmol/L)	87.0 (87.0)	-1
	3000 mg/dL (33.9 mmol/L)	105 (105)	-1
Salicylate	30 mg/dL (2.16 mmol/L)	87.0 (87.0)	7
	30 mg/dL (2.16 mmol/L)	103 (103)	3

Urine Interference - Sodium (Na)

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration mmol/L (mEq/L)	Percent Bias
Hemoglobin	500 mg/dL (0.31 mmol/L)	53.1 (53.1)	-9
	500 mg/dL (0.31 mmol/L)	191 (191)	-2
Bilirubin, conjugated	60 mg/dL (1026 µmol/L)	45.2 (45.2)	3
	60 mg/dL (1026 µmol/L)	182 (182)	1
Bilirubin, unconjugated	60 mg/dL (1026 µmol/L)	45.0 (45.0)	0
	60 mg/dL (1026 µmol/L)	182 (182)	-1
Lipemia (Intralipid®)	2000 mg/dL (22.6 mmol/L)	45.1 (45.1)	-1
	2000 mg/dL (22.6 mmol/L)	183 (183)	1

Urine Interference - Potassium (K)

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration mmol/L (mEq/L)	Percent Bias
Hemoglobin	500 mg/dL (0.31 mmol/L)	23.6 (23.6)	6
	500 mg/dL (0.31 mmol/L)	200 (200)	1
Bilirubin, conjugated	60 mg/dL (1026 µmol/L)	23.5 (23.5)	-1
	60 mg/dL (1026 µmol/L)	198 (198)	0
Bilirubin, unconjugated	60 mg/dL (1026 µmol/L)	23.5 (23.5)	0
	60 mg/dL (1026 µmol/L)	199 (199)	0
Lipemia (Intralipid®)	2000 mg/dL (22.6 mmol/L)	23.5 (23.5)	1
	2000 mg/dL (22.6 mmol/L)	199 (199)	2

Urine Interference - Chloride (Cl)

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration mmol/L (mEq/L)	Percent Bias
Hemoglobin	500 mg/dL (0.31 mmol/L)	54.7 (54.7)	-6
	500 mg/dL (0.31 mmol/L)	199 (199)	-1
Bilirubin, conjugated	60 mg/dL (1026 µmol/L)	47.3 (47.3)	2
	60 mg/dL (1026 µmol/L)	190 (190)	1
Bilirubin, unconjugated	60 mg/dL (1026 µmol/L)	47.7 (47.7)	0
	60 mg/dL (1026 µmol/L)	192 (192)	-1
Lipemia (Intralipid®)	2000 mg/dL (22.6 mmol/L)	48.1 (48.1)	3
	2000 mg/dL (22.6 mmol/L)	200 (200)	-1

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

Non-Interfering Substances

The following substances do not interfere with the A-LYTE IMT Na K Cl multisensor when present in urine at the concentrations indicated in the table below. Bias due to these substances is ≤ 10%. The Na and Cl assay interferences were tested with urine pools at approximately 50 mmol/L and 200 mmol/L of Na and Cl. The K assay interference was tested with urine pools at approximately 25 mmol/L and 200 mmol/L of K.

Substance	Substance Test Concentration Common Units (SI Units)
Acetaminophen	200 mg/dL (13,200 µmol/L)
N-Acetyl cysteine	2 mg/dL (123 µmol/L)
Ascorbic acid	60 mg/dL (3408 µmol/L)
Sodium cefoxitin	660 mg/dL (15,453 µmol/L)
Gentamycin sulfate	10 mg/dL (21 µmol/L)

Substance	Substance Test Concentration Common Units (SI Units)
Ibuprofen	400 mg/dL (19.4 mmol/L)
Levodopa	100 mg/dL (5071 µmol/L)
Ofloxacin	80 mg/dL (2214 µmol/L)
Phenazopyridine	30 mg/dL (1407 µmol/L)
Tetracycline	15 mg/dL (312 µmol/L)
Low pH	pH 4
High pH	pH 8

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

Standardization

The A-LYTE Na assay is traceable to a flame emission spectrophotometry 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.

The A-LYTE K assay is traceable to a flame emission spectrophotometry 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.

The A-LYTE Cl assay is traceable to a coulometric 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.

Assay	N	Mean % Bias	Range mmol/L (mEq/L)
Na	25	-0.92	73.1–183.2 (73.1–183.2)
K	25	-2.29	2.22–8.97 (2.22–8.97)
Cl	25	0.00	55–148 (55–148)

Assigned values of A-LYTE IMT Standard A and A-LYTE IMT Standard B + Salt Bridge are traceable to this standardization.

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

Technical Assistance

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.

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

siemens-healthineers.com

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Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
	Manufacturer	5.1.1[a]		Authorized representative in the European Community	5.1.2[a]
	Use-by date	5.1.4[a]		Authorized representative in Switzerland	Proprietary
	Catalog number	5.1.6[a]		Batch code	5.1.5[a]
	Consult Instructions for Use	5.4.3[a]		Contains sufficient for <n> tests	5.5.5[a]
	Internet URL address to access the electronic instructions for use	Proprietary		Version of Instructions for Use	Proprietary

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
IVD	*In vitro* diagnostic medical device	5.5.1[a]	Rev. REVISION	Revision	Proprietary
RxOnly	Prescription device (US only)	FDA[b]	UDI	Unique Device Identifier	5.7.10[c]
CE XXXX	CE Marking with Notified Body	EU IVDR[d]	CE	CE Marking	EU IVDR[d]
	Temperature limit	5.3.7[a]		Keep away from sunlight	5.3.2[a]
	Upper limit of temperature	5.3.6[a]		Lower limit of temperature	5.3.5[a]
	Do not re-use	5.4.2[a]		Do not freeze	Proprietary
	Recycle	1135[e]		This way up	0623[e]
	Biological risks	5.4.1[a]		Caution	5.4.4[a]
UNITS C	Common Units	Proprietary	UNITS SI	International System of Units	Proprietary
YYYY-MM-DD	Date format (year-month-day)	N/A	**YYYY-MM**	Date format (year-month)	N/A
	Document face up[f]	1952[e]		Handheld barcode scanner	Proprietary
	Target	Proprietary		Mixing of substances	5657[g]
CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.	Proprietary		Interval	Proprietary
MATERIAL ID	Unique material identification number	Proprietary	MATERIAL	Material	Proprietary

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
CONTROL TYPE	Type of control	Proprietary	CONTROL NAME	Name of control	Proprietary
CONTROL LOT VAL	Quality control lot value	Proprietary	CAL LOT VAL	Calibrator lot value	Proprietary

[a] International Standard Organization (ISO). ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied.
[b] Federal Register. Vol. 81, No 115. Wednesday, June 15, 2016. Rules and Regulations: 38911.
[c] ISO 15223-1:2020-04
[d] IVDR REGULATION (EU) 2017/746
[e] International Standard Organization (ISO). ISO 7000 Graphical symbols for use on equipment.
[f] Indicates Assay-eNote
[g] International Electrotechnical Commission (IEC). IEC 60417-1 Graphical symbols for use on equipment – Part 1: Overview and Application

Legal Information

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