SIEMENS Healthineers

A-LYTE IMT System Fluids

Current Revision and Date[a]	Rev. 05, 2022-09		
Product Name	A-LYTE IMT Dilution Check	6 x 2 mL	REF 11099325
	A-LYTE IMT Standard A	2 x 1.5 L	REF 11099304
	A-LYTE IMT Diluent	2 x 1.5 L	REF 11099305
	A-LYTE IMT Standard B + Salt Bridge	Standard B: 2 x 250 mL Salt Bridge: 2 x 125 mL	REF 11099306
	A-LYTE IMT Cleaner	6 x 2.5 mL	REF 11556782
Systems	Atellica CH Analyzer		

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

CE

A-LYTE IMT Dilution Check (IMT Dilution Check)

Intended Use

The A-LYTE® IMT Dilution Check is for *in vitro* diagnostic use to monitor and adjust the dilution ratio for the IMT Na K Cl assays on the Atellica® CH Analyzer.

Reagents

Material Description	Storage	Stability[a]
A-LYTE IMT Dilution Check 2 mL Sodium chloride (0.63%); potassium chloride (0.03%); sodium bicarbonate (0.15%); sodium carbonate (0.07%)	Unopened at 2–30°C	Until expiration date on product

[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.

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 IMT Dilution Check is stable until the expiration date on the product when stored at 2–30°C.

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

Preparing the Reagents

All system fluids are liquid and ready to use.

A-LYTE IMT Standard A (IMT Standard A)

Intended Use

The A-LYTE® IMT Standard A is for *in vitro* diagnostic use in calibrating Na, K, and Cl assays using the Atellica® CH Analyzer.

Reagents

Material Description	Storage	Stability[a]
A-LYTE IMT Standard A 1.5 L Phosphate buffer; sodium chloride (10 mmol/L); potassium chloride (0.4 mmol/L); sodium bicarbonate (4.0 mmol/L); bovine serum albumin (0.01%); preservatives	Unopened at 2–30°C Onboard	Until expiration date on product 30 days

[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.

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 IMT Standard A is stable until the expiration date on the product when stored at 2–30°C.

IMT Standard A is stable onboard the system for 30 days when used on the Atellica CH Analyzer. Discard system fluids at the end of the onboard stability interval.

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

Preparing the Reagents

All system fluids are liquid and ready to use. Ensure that the system has sufficient system fluids. For information about loading system fluids, refer to the online help.

A-LYTE IMT Diluent (IMT Diluent)

Intended Use

The A-LYTE® IMT Diluent is for *in vitro* diagnostic use in diluting IMT samples using the Atellica® CH Analyzer.

Reagents

Material Description	Storage	Stability[a]
A-LYTE IMT Diluent 1.5 L Phosphate buffer; bovine serum albumin (0.01%); preservatives	Unopened at 2–30°C Onboard	Until expiration date on product 90 days

[a] Refer to *Storage and Stability*.

Warnings and Precautions

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For Professional Use.

CAUTION

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H302+H312
P280, P270,
P301+P312,
P302+P312, P501

Warning!
Harmful if swallowed or in contact with skin.
Wear protective gloves/protective clothing/eye protection/face protection. Do no eat, drink or smoke when using this product. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. IF ON SKIN: Call a POISON CENTER or doctor/physician if you feel unwell. Dispose of contents and container in accordance with all local, regional, and national regulations.
Contains: Tetramethylammonium hydroxide

CAUTION

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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 IMT Diluent is stable until the expiration date on the product when stored at 2–30°C.

IMT Diluent is stable onboard the system for 90 days. Discard system fluids at the end of the onboard stability interval.

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

Preparing the Reagents

All system fluids are liquid and ready to use. Ensure that the system has sufficient system fluids. For information about loading system fluids, refer to the online help.

A-LYTE IMT Standard B + Salt Bridge (IMT Standard B + Salt Bridge)

Intended Use

The A-LYTE® IMT Standard B + Salt Bridge is for *in vitro* diagnostic use in calibrating Na, K, and Cl assays using the Atellica® CH Analyzer.

Reagents

Material Description	Storage	Stability[a]
A-LYTE IMT Standard B + Salt Bridge	Unopened at 2–30°C	Until expiration date on product
Standard B 250 mL Phosphate buffer; sodium chloride (7.0 mmol/L); potassium chloride (6.0 mmol/L); lithium chloride (3.0 mmol/L); bovine serum albumin (0.01%); preservatives	Onboard per well	30 days
Salt Bridge 125 mL Potassium chloride (120 mmol/L); bovine serum albumin (0.01%); preservatives		

[a] Refer to *Storage and Stability*.

Warnings and Precautions

For *in vitro* diagnostic use.

For Professional Use.

CAUTION

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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.

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 IMT Standard B + Salt Bridge is stable until the expiration date on the product when stored at 2–30°C.

IMT Standard B + Salt Bridge is stable onboard the system for 30 days when used on the Atellica CH Analyzer. Discard system fluids at the end of the onboard stability interval.

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

Preparing the Reagents

All system fluids are liquid and ready to use. Ensure that the system has sufficient system fluids. For information about loading system fluids, refer to the online help.

A-LYTE IMT Cleaner (IMT Cleaner)

Intended Use

The A-LYTE® IMT Cleaner is for *in vitro* diagnostic use in cleaning the IMT subsystem using an Atellica® chemistry analyzer.

Reagents

Material Description	Storage	Stability[a]
A-LYTE IMT Cleaner 2.5 mL HEPES Buffer; bovine serum albumin (5.96%); amylase (human saliva) (<0.01%); gamma-glutamyl transpeptidase (bovine kidney) (<0.01%); lipase (porcine pancreas) (<0.01%); pseudo-cholinesterase (horse serum) (<0.01%); lactate dehydrogenase (chicken heart) (<0.01%); preservatives	Unopened at 2–8°C Opened and recapped at 2–8°C	Until expiration date on product 30 days

[a] Refer to *Storage and Stability*.

Warnings and Precautions

For *in vitro* diagnostic use.

For Professional Use.

CAUTION

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

Warning! Potential Biohazard

Contains human source material.

Caution: No known test method can ensure that products derived from human source materials will not transmit infection. These materials should be handled using good laboratory practices and universal precautions.[1-3]

CAUTION

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

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 IMT Cleaner is stable until the expiration date on the product when stored at 2–8°C.

Once cap is removed, IMT Cleaner is stable for 30 days when recapped immediately after use and stored at 2–8°C.

Newly opened IMT Cleaner stored onboard the Atellica Sample Handler is stable for 30 days.

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

Preparing the Reagents

All system fluids are liquid and ready to use. For information about loading system fluids, refer to the system operating instructions.

Technical Assistance

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

siemens.com/healthineers

References

1. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009.
2. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
3. 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.

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.

Symbol	Symbol Title and Description
	Corrosive
	Dangerous to environment
	Irritant Oral, dermal, or inhalation hazard
	Inhalation hazard Respiratory or internal health
	Flammable Flammable to extremely flammable
	Oxidizing
	Explosive
	Toxic
	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
	*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.

Symbol	Symbol Title and Description
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
	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

Symbol	Symbol Title and Description
CONTROL NAME	Name of control
CONTROL TYPE	Type of control

Legal Information

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