SIEMENS Healthineers

Alkaline Phosphatase_2 Calibrator (ALP_2 CAL)

Current Revision and Date[a]	Rev. 03, 2022-11
Product Name	Atellica CH Alkaline Phosphatase_2 Calibrator (ALP_2 CAL)
Abbreviated Product Name	Atellica CH ALP_2 CAL
	6 x 1.0 mL calibrator CAL REF 11099316 Calibrator lot-specific value sheet CAL LOT VAL
Systems	Atellica CH Analyzer Atellica CI Analyzer

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

CE

Intended Use

The Atellica® CH Alkaline Phosphatase_2 Calibrator (ALP_2 CAL) is for *in vitro* diagnostic use in calibrating the ALP_2c assay using an Atellica® chemistry analyzer.

Material Description

For the assigned values, refer to the calibrator lot-specific value sheet CAL LOT VAL provided. The assigned values are traceable to the standardization of the assay.

Material Description	Storage	Stability[a]
Atellica CH ALP_2 CAL 1.0 mL/vial Human serum albumin; alkaline phosphatase (porcine kidney)	Unopened at 2–8°C	Until expiration date on product
	Opened at 2–8°C	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-healthineers.com.

CAUTION POTENTIAL BIOHAZARD

Contains human source material. Each donation of human blood or blood component was tested by FDA-approved methods for the presence of antibodies to human immunodeficiency virus type 1 (HIV-1) and type 2 (HIV-2), as well as for hepatitis B surface antigen (HBsAg) and antibody to hepatitis C virus (HCV). The test results were negative (not repeatedly reactive). No test offers complete assurance that these or other infectious agents are absent; this material 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.

Note For information about calibrator preparation, refer to *Preparing the Calibrators*.

Storage and Stability

Unopened calibrators are stable until the expiration date on the product when stored at 2–8°C. Opened stability is 30 days when recapped immediately after use and stored at 2–8°C.

For information about storage and stability of materials in the Cal-QC tube storage area, refer to the supplementary document "Atellica Sample Handler Calibrator and QC Storage and Stability."

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

Performing Calibration

Calibration Frequency

Follow government regulations or accreditation requirements for calibration frequency. Individual laboratory quality control programs and procedures may require more frequent calibration.

For information about calibration frequency, refer to the assay instructions for use.

Preparing the Calibrators

Calibrators are liquid and ready to use.

Calibration Procedure

Dilution is performed automatically by the analyzer using the Atellica CH Diluent as Level 1 and the Atellica CH ALP_2 CAL for Level 2.

Use the following lot-specific materials to perform calibration:

- For the calibrator definitions, refer to the lot-specific value sheet CAL LOT VAL provided with the calibrator materials.
- Generate lot-specific barcode labels to use with the calibrator samples, if necessary.

For instructions about how to perform the calibration procedure, refer to the online help.

Technical Assistance

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

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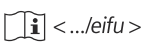
References

1. Centers for Disease Control. Perspectives in disease prevention and health promotion update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in healthcare settings. *MMWR*. 1988;37(24):377–382, 387–388.
2. 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.
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	Symbol	Symbol Title
	Manufacturer		Authorized representative in the European Community
	Use-by date		Authorized representative in Switzerland
	Catalog number		Batch code
	Consult Instructions for Use		Contains sufficient for <n> tests
 <*.../eifu*>	Internet URL address to access the electronic instructions for use		Version of Instructions for Use
	*In vitro* diagnostic medical device		Revision
RxOnly	Prescription device (US only)		Unique Device Identifier
	CE Marking with Notified Body		CE Marking
	Temperature limit		Keep away from sunlight
	Upper limit of temperature		Lower limit of temperature
	Do not re-use		Do not freeze
	Recycle		This way up
	Biological risks		Caution

Symbol	Symbol Title	Symbol	Symbol Title
UNITS | C	Common Units	UNITS | SI	International System of Units
YYYY-MM-DD	Date format (year-month-day)	YYYY-MM	Date format (year-month)
	Document face up[a]		Handheld barcode scanner
	Target		Mixing of substances
CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.		Interval
MATERIAL ID	Unique material identification number	MATERIAL	Material
CONTROL TYPE	Type of control	CONTROL NAME	Name of control
CONTROL | LOT | VAL	Quality control lot value	CAL | LOT | VAL	Calibrator lot value

[a] Indicates Assay-eNote

Legal Information

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

Siemens Healthineers Headquarters
Siemens Healthcare GmbH
Henkestraße 127
91052 Erlangen
Germany
Phone: +49 9131 84-0
siemens-healthineers.com