SIEMENS Healthineers

Chemistry Calibrator (CHEM CAL)

Current Revision and Date[a]	Rev. 07, 2022-04	
Product Name	Atellica CH Chemistry Calibrator (CHEM CAL)	
Abbreviated Product Name	Atellica CH CHEM CAL	
	12 x 3.0 mL calibrator CAL Calibrator lot-specific value sheet CAL LOT VAL	REF 11099411
Systems	Atellica CH Analyzer	

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

CE

Intended Use

The Atellica® CH Chemistry Calibrator (CHEM CAL) is for *in vitro* diagnostic use in calibrating the chemistry assays: Alb, Ca, CA_2, Chol_2, Crea_2, DBil_2, ECre_2, ECre3, ECreJ, GluH_3, GluO, Iron_2, Iron3, Li, LITH_2, Mg, IP, TBil_2, TP, TP_2, Trig, Trig_2, UA, UN, and UN_c using the Atellica® CH 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 CHEM CAL Lyophilized; reconstituted to 3.0 mL/vial Analytes for assays listed in *Intended Use*; bovine serum; preservative	Unopened at 2–8°C	Until expiration date on product Refer to the instructions below entitled, *Calibrating Glucose Assays*, for guidelines.
	Reconstituted at 2–8°C	48 hours (except for total and direct bilirubin, which are stable for 8 hours when capped and stored at 2–8°C)

[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

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

Protect the product from heat and light sources. Unopened calibrators are stable until the expiration date on the product when stored at 2–8°C. Reconstituted calibrators are stable at 2–8°C for 48 hours (except for total and direct bilirubin, which are stable for 8 hours when capped and stored at 2–8°C).

Note The normal degradation of glucose is approximately 2% per year.

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

Prepare calibrators using the following steps:

1. Shake to break up lyophilized cake.
2. Open each vial carefully.
3. Using a precision pipet, add exactly 3.0 mL of deionized water into the vial. Replace the stopper.
4. Follow step 4a or 4b, whichever is applicable.
    a. Manually mix by inverting 10 times every 10 minutes for a period of 30 minutes, or until reconstitution is complete.
    b. Mechanically mix on a rotary mixer for 30 minutes, or until reconstitution is complete.
5. Prior to use, mix by inversion at least 5 times to ensure homogeneity.
6. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

Calibrating Glucose Assays (GluH_3, GluO)

The glucose calibrator value changes over time. The Atellica CH Analyzer automatically adjusts the glucose value every 6 months based on the normal degradation rate of glucose of approximately 2% per year. The calibrator lot expiration date and initial glucose value should be entered onto the analyzer from the lot-specific value sheet CAL LOT VAL provided with the calibrator materials.

Calibration Procedure

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.

siemens-healthineers.com

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title	Symbol	Symbol Title
	Manufacturer	EC REP	Authorized representative in the European Community
	Use-by date	CH REP	Authorized representative in Switzerland
REF	Catalog number	LOT	Batch code
	Consult Instructions for Use	Σ	Contains sufficient for <n> tests
< .../eifu >	Internet URL address to access the electronic instructions for use	Rev. XX	Version of Instructions for Use
IVD	*In vitro* diagnostic medical device	Rev. REVISION	Revision
RxOnly	Prescription device (US only)	UDI	Unique Device Identifier
CE XXXX	CE Marking with Notified Body	CE	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