SIEMENS

ADVIA® Chemistry
Systems

Chemistry Calibrator (CHEM CAL)

Current Revision and Date[a]	Rev. 04, 2021-11	
Product Name	Siemens Chemistry Calibrator (CHEM CAL)	REF 09784096 (T03-1291-62)
Abbreviated Product Name	Siemens CHEM CAL	
Materials Provided	12 x 0.28 g CHEM CAL CHEM CAL Calibrator lot-specific value sheet	
Systems	ADVIA Chemistry Systems	

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

CE

Intended Use

For *in vitro* diagnostic use in the calibration of chemistry assays on ADVIA® Chemistry systems.

Material Description

Material Description	Storage	Stability[a]
Siemens CHEM CAL Lyophilized; reconstituted to 3.0 mL/vial (in deionized H_2O) Lyophilized bovine serum; analytes; preservative	Unopened at 2-8°C	Until expiration date on product **Note** The normal degradation of glucose is approximately 2% per year. Refer to *Calibrating Glucose Assays (GLUH_3, GLUH_c, GLUO, GLUO_c)*.
	Reconstituted at 2–8°C	48 hours
	Reconstituted at room temperature	8 hours

[a] Refer to *Storage and Stability*.

For lot-specific values, refer to the lot-specific value sheet included with the calibrator kit.

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

Store all calibrators in an upright position, away from light and heat. Do not use products beyond the expiration date printed on the product labeling.

Opened calibrators are stable for 48 hours when capped and stored at 2–8°C (except for total and direct bilirubin, which are stable for 8 hours when capped and stored at 2–8°C).

For details about product material description, storage, and stability, refer to *Material Description*.

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 the calibrator using the following steps:

1. Shake to break up lyophilized cake. Remove the metal seal and open the vial.
2. Use a volumetric pipette to add exactly 3.0 mL of deionized water into the vial. Replace the stopper.
3. Follow step 3a or 3b, whichever is applicable.
    a. Manually mix by inverting the vial 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.
4. Prior to use, mix by inversion at least 5 times to ensure homogeneity.
5. Refer to the assay instructions for use for performing a calibration on the system.
6. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

Calibration Procedure

Use the following lot-specific materials to perform calibration:

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

Calibrating Glucose Assays (GLUH_3, GLUH_c, GLUO, GLUO_c)

The glucose calibrator value changes over time. To accommodate this, refer to the document included in the Siemens Chemistry Calibrator kit entitled, *Assigned Calibrator Values for ADVIA Chemistry Systems*.

There are five date-adjusted levels provided for the ADVIA Chemistry glucose assays listed above. Use the calibrator value for the year and month (yyyy/mm) immediately preceding date of use. Then change the calibrator value according to the dates and values provided in the document.

For example: When using the calibrator between January 1 and June 30, use the January value. For calibrations after June 30, use the July value.

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.

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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	LOT	Batch code
REF	Catalog number		Contains sufficient for <n> tests
	Consult Instructions for Use		Version of Instructions for Use
	Internet URL address to access the electronic instructions for use	Rev. REVISION	Revision
IVD	*In vitro* diagnostic medical device	UDI	Unique Device Identifier
RxOnly	Prescription device (US only)	CE	CE Marking

Symbol	Symbol Title	Symbol	Symbol Title
CE XXXX	CE Marking with Notified Body		Keep away from sunlight
	Temperature limit		Lower limit of temperature
	Upper limit of temperature		Do not freeze
	Do not re-use		This way up
	Recycle		Caution
	Biological risks		Document face up[a]
UNITS C	Common Units	UNITS SI	International System of Units
YYYY-MM-DD	Date format (year-month-day)	YYYY-MM	Date format (year-month)
	Reconstitution volume	CAL LOT VAL	Calibrator lot value
CONTROL LOT VAL	Quality control lot value		

[a] Indicates Assay-eNote

Legal Information

US Pats 4,339,533; 4,438,302

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