SIEMENS

ADVIA® Chemistry
Systems

Enzyme 3 Calibrator (ENZ 3 CAL)

Current Revision and Date[a]	Rev. 03, 2021-11	
Product Name	ADVIA Chemistry Enzyme 3 Calibrator (ENZ 3 CAL)	REF 10916059
Abbreviated Product Name	ADVIA Chemistry ENZ 3 CAL	
Materials Provided	6 x 2.0 mL ENZ 3 CAL ENZ 3 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

ADVIA® Chemistry Enzyme 3 Calibrator is intended for *in vitro* diagnostic use in the calibration of the ADVIA Chemistry Creatine Kinase (CK_L) assay on the ADVIA Chemistry systems.

Material Description

Material Description	Storage	Stability[a]
ADVIA Chemistry ENZ 3 CAL 2.0 mL/vial Human serum albumin (5%) and preservatives with lot-specific concentrations of creatine kinase MM (human heart)	Unopened at -25--15°C Opened at 2–8°C	Until expiration date on product 30 days

[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.

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]

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

Once the cap is removed, the calibrator is stable for 30 days when vial is recapped immediately after use 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 calibrators using the following steps:

1. Thaw the calibrators at room temperature for 30–45 minutes.

   Note Do not thaw in a water bath or in water above 25°C.

2. Gently invert the calibrator vials at least 10 times to ensure that the contents are thoroughly mixed.

   Note Do not vortex.

   Note Multilevel dilution is performed automatically by the ADVIA Chemistry systems using isotonic saline (0.9%).

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.

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

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	Symbol	Symbol Title
	Manufacturer		Authorized representative in the European Community
	Use-by date		Batch code
	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		Revision
	*In vitro* diagnostic medical device		Unique Device Identifier
	Prescription device (US only)		CE Marking
	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

Symbol	Symbol Title	Symbol	Symbol Title
	Recycle		Caution
	Biological risks		Document face up[a]
	Common Units		International System of Units
YYYY-MM-DD	Date format (year-month-day)	**YYYY-MM**	Date format (year-month)
	Reconstitution volume		Calibrator lot value
	Quality control 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