

Urinary/Cerebrospinal Fluid Protein Calibrator (UCFP CAL)

Current Revision and Date^a	Rev. 01, 2023-02
Product Name	Atellica CH Urinary/Cerebrospinal Fluid Protein Calibrator (UCFP CAL)
Abbreviated Product Name	Atellica CH UCFP CAL
	2 x 4.0 mL calibrator level 2 CAL 2 REF 11099339 2 x 4.0 mL calibrator level 3 CAL 3 2 x 4.0 mL calibrator level 4 CAL 4 2 x 4.0 mL calibrator level 5 CAL 5 2 x 4.0 mL calibrator level 6 CAL 6 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.



Intended Use

The Atellica® CH Urinary/Cerebrospinal Fluid Protein Calibrator (UCFP CAL) is for *in vitro* diagnostic use in calibrating the UCFP 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 UCFP CAL 4.0 mL/vial Saline solution containing human serum albumin and IgG; reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	Unopened at 2–8°C Opened at 2–8°C	Until expiration date on product 60 days

^a Refer to *Storage and Stability*.

Warnings and Precautions

For *in vitro* diagnostic use.

For Professional Use.

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](https://www.siemens-healthineers.com).



H317, H412
P280, P273,
P302+P352,
P333+P313,
P362+P364, P501

Warning!

May cause an allergic skin reaction. Harmful to aquatic life with long lasting effects.

Wear protective gloves/protective clothing/eye protection/face protection. Avoid release to the environment. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. Dispose of contents and container in accordance with all local, regional, and national regulations.

Contains: reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)



Warning! Potential Biohazard

Contains human source material.

Caution: All products containing human source material should be treated as potentially infectious. Source material from human blood from which this product was derived was found negative when tested in accordance with current FDA required tests described in 21 CFR 610.40(a) and (b). No known test methods can offer assurance that products derived from human sources will not transmit infectious agents; this material should be handled using good laboratory practices and universal precautions.

The Packaging of This Product Contains Dry Natural Rubber.

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.

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."

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

Calibrators are liquid and ready to use.

Allow to equilibrate to room temperature and mix thoroughly before use.

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
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 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













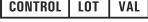

For customer support, contact your local technical support provider or distributor.

siemens-healthineers.com

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title	Symbol	Symbol Title		
	Manufacturer	<table border="1"><tr><td>EC</td><td>REP</td></tr></table>	EC	REP	Authorized representative in the European Community
EC	REP				
	Use-by date	<table border="1"><tr><td>CH</td><td>REP</td></tr></table>	CH	REP	Authorized representative in Switzerland
CH	REP				
<table border="1"><tr><td>REF</td></tr></table>	REF	Catalog number	<table border="1"><tr><td>LOT</td></tr></table>	LOT	Batch code
REF					
LOT					
	Consult Instructions for Use		Contains sufficient for <n> tests		
	Internet URL address to access the electronic instructions for use		Version of Instructions for Use		
<table border="1"><tr><td>IVD</td></tr></table>	IVD	<i>In vitro</i> diagnostic medical device	Rev. <table border="1"><tr><td>REVISION</td></tr></table>	REVISION	Revision
IVD					
REVISION					
RxOnly	Prescription device (US only)	<table border="1"><tr><td>UDI</td></tr></table>	UDI	Unique Device Identifier	
UDI					
	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
	Common Units		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
	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.		Interval
	Unique material identification number		Material
	Type of control		Name of control
	Quality control lot value		Calibrator lot value


^a Indicates Assay-eNote

Legal Information

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