

Urinary/Cerebrospinal Fluid Protein Calibrator (UCFP CAL)

Current Revision and Date ^a	Rev. 01, 2019-10
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

^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 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 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.



**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.
















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Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title and Description	
	Consult instructions for use	
 Rev. 01	Version of instructions for use	
 siemens.com/healthcare	Internet URL address to access the electronic instructions for use	
 siemens.com/document-library		
Rev. <table border="1" data-bbox="339 1018 442 1054"><tr><td>REVISION</td></tr></table>	REVISION	Revision
REVISION		
	Caution Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device.	
	Biological risks Potential biological risks are associated with the medical device.	
	Corrosive	
	Dangerous to environment	
	Irritant Oral, dermal, or inhalation hazard	
	Inhalation hazard Respiratory or internal health	
	Flammable Flammable to extremely flammable	

Symbol	Symbol Title and Description
	Oxidizing
	Explosive
	Toxic
	Compressed gas
	Keep away from sunlight Prevent exposure to sunlight and heat.
	Up Store in an upright position.
	Do not freeze
	Temperature limit Upper and lower limits of temperature indicators are adjacent to the upper and lower horizontal lines.
	Handheld barcode scanner
	<i>In vitro</i> diagnostic medical device
	Contains sufficient for <n> tests Total number of IVD tests the system can perform with the IVD kit reagents appears adjacent to the symbol.
RxOnly	Prescription device (US only) Applies only to United States-registered IVD assays. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.
	Mixing of substances Mix product before use.
	Reconstitute and mix lyophilized product before use.
	Target
	Interval
	Legal Manufacturer

Symbol	Symbol Title and Description
	Authorized Representative in the European Community
	Use-by date Use by the designated date.
	Batch code
	Catalog number
	Recycle
	Printed with soy ink
	CE Mark
	CE Mark with notified body ID number Notified body ID number can vary.
YYYY-MM-DD	Date format (year-month-day)
	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.
	Common Units
	International System of Units
	Material
	Unique material identification number
	Name of control
	Type of control

Legal Information

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