SIEMENS Healthineers

B-Type Natriuretic Peptide Calibrator (BNP CAL)

Current Revision and Date[a]	Rev. 03, 2022-04
Product Name	Atellica IM B-Type Natriuretic Peptide Calibrator (BNP CAL)
Abbreviated Product Name	Atellica IM BNP CAL
	2 x 2.0 mL low calibrator CAL | L — REF 10995473 2 x 2.0 mL high calibrator CAL | H Calibrator lot-specific value sheet CAL | LOT | VAL
Systems	Atellica IM Analyzer

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

CE 0197

Intended Use

The Atellica® IM B-Type Natriuretic Peptide Calibrator (BNP CAL) is for *in vitro* diagnostic use in calibrating the Atellica IM BNP assay using the Atellica® IM 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 internal standards manufactured using synthetic human BNP (amino acid 77–108). For additional information, refer to the assay instructions for use.

Material Description	Storage	Stability[a]
Atellica IM BNP CAL 2.0 mL/vial; lyophilized After reconstitution, low or high levels of synthetic human BNP; lyophilized buffered sodium caseinate; sodium azide (< 0.1%)	Lyophilized at 2–8°C	Until expiration date on product
	Reconstituted at 2–8°C	5 days
	Reconstituted at ≤ -20°C	60 days; thaw 1 time
	Reconstituted at room temperature	8 hours

[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.

The summary of safety and performance for this *in vitro* diagnostic medical device is available to the public in the European database on medical devices (EUDAMED) when this database is available and the information has been uploaded by the Notified Body. The web address of the EUDAMED public website is: https://ec.europa.eu/tools/eudamed.

H311, H302, H412 P264, P280, P273, P312, P361+P364, P501	**Danger!** Toxic in contact with skin. Harmful if swallowed. Harmful to aquatic life with long lasting effects. Wash hands thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. Avoid release to the environment. Call a POISON CENTER or doctor/physician if you feel unwell. Take off immediately all contaminated clothing and wash it before reuse. Dispose of contents and container in accordance with all local, regional, and national regulations. **Contains:** sodium azide (Atellica IM BNP CAL)

Contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent buildup of azides. Disposal into drain systems must be in compliance with prevailing regulatory requirements.

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 calibrators in an upright position. Lyophilized calibrators are stable until the expiration date on the product when stored at 2–8°C. Reconstituted calibrators are stable for 5 days at 2–8°C. Freeze reconstituted product at ≤ -20°C for up to 60 days; thaw only 1 time. Reconstituted calibrators are stable for 8 hours at room temperature.

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

Performing Calibration

Calibration Frequency

For information about calibration frequency, refer to the assay instructions for use.

Preparing the Calibrators

Prepare calibrators using the following steps:

1. Add 2.0 mL of special reagent water into each vial using a precision pipet. Replace cap.

   Note For information about special reagent water requirements, refer to the online help.

2. Let the vials stand for 15–20 minutes at room temperature to allow the lyophilized material to dissolve.
3. Gently mix and invert the vials to ensure homogeneity of the material.
4. For extended storage, aliquot and seal tightly. Store reconstituted material according to stability limits specified in *Storage and Stability*. Do not store in a frost-free freezer.

   Note Before using frozen calibrators, allow the material to completely thaw. Gently mix and invert the material to ensure homogeneity. Use immediately and discard any remaining material. Perform only one procedure per aliquot.

Note Use calibrators within the stability limits specified in*Storage and Stability* and discard any remaining material.

Calibration Procedure

The required sample volume for testing depends on several factors. For information about sample volume requirements, refer to the online help.

Use the following lot-specific materials to perform calibration:

- For the master curve and assay test definitions, refer to the lot-specific master curve and test definition sheet MC TDEF provided with the assay reagents.
- 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.

For instructions about how to perform the calibration procedure, refer to the online help.

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	Source	Symbol	Symbol Title	Source
	Manufacturer	5.1.1[a]	EC REP	Authorized representative in the European Community	5.1.2[a]
	Use-by date	5.1.4[a]	CH REP	Authorized representative in Switzerland	Proprietary
REF	Catalog number	5.1.6[a]	LOT	Batch code	5.1.5[a]
	Consult Instructions for Use	5.4.3[a]		Contains sufficient for <n> tests	5.5.5[a]

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
	Internet URL address to access the electronic instructions for use	Proprietary		Version of Instructions for Use	Proprietary
	*In vitro* diagnostic medical device	5.5.1[a]		Revision	Proprietary
RxOnly	Prescription device (US only)	FDA[b]		Unique Device Identifier	5.7.10[c]
	CE Marking with Notified Body	EU IVDR[d]		CE Marking	EU IVDR[d]
	Temperature limit	5.3.7[a]		Keep away from sunlight	5.3.2[a]
	Upper limit of temperature	5.3.6[a]		Lower limit of temperature	5.3.5[a]
	Do not re-use	5.4.2[a]		Do not freeze	Proprietary
	Recycle	1135[e]		This way up	0623[e]
	Biological risks	5.4.1[a]		Caution	5.4.4[a]
	Common Units	Proprietary		International System of Units	Proprietary
YYYY-MM-DD	Date format (year-month-day)	N/A	**YYYY-MM**	Date format (year-month)	N/A
	Document face up[f]	1952[e]		Handheld barcode scanner	Proprietary
	Target	Proprietary		Mixing of substances	5657[g]
	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.	Proprietary		Interval	Proprietary
	Unique material identification number	Proprietary		Material	Proprietary

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
CONTROL TYPE	Type of control	Proprietary	CONTROL NAME	Name of control	Proprietary
CONTROL LOT VAL	Quality control lot value	Proprietary	CAL LOT VAL	Calibrator lot value	Proprietary

[a] International Standard Organization (ISO). ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied.
[b] Federal Register. Vol. 81, No 115. Wednesday, June 15, 2016. Rules and Regulations: 38911.
[c] ISO 15223-1:2020-04
[d] IVDR REGULATION (EU) 2017/746
[e] International Standard Organization (ISO). ISO 7000 Graphical symbols for use on equipment.
[f] Indicates Assay-eNote
[g] International Electrotechnical Commission (IEC). IEC 60417-1 Graphical symbols for use on equipment – Part 1: Overview and Application

Legal Information

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