SIEMENS Healthineers

NT-proBNP Master Curve Material (PBNP MCM)

Current Revision and Date[a]	Rev. 03, 2022-10
Product Name	Atellica IM NT-proBNP Master Curve Material (PBNP MCM)
Abbreviated Product Name	Atellica IM PBNP MCM
	7 x 1.0 mL master curve material MCM 1 – 7 REF 11200590 Master curve material lot-specific value sheet MCM LOT VAL
Systems	Atellica IM Analyzer

[a] A vertical bar in the margin indicates a technical update to the previous version.

CE 0197

Intended Use

The Atellica® IM NT-proBNP (PBNP) Master Curve Material is for *in vitro* diagnostic use in the verification of calibration and reportable range of the Atellica® IM PBNP assay.

Material Description

The Atellica IM PBNP assay is standardized using internal standards. The Atellica IM PBNP master curve material is traceable to this standardization.

Material Description	Storage	Stability[a]
MCM 1: 1.0 mL/vial Bovine serum albumin with preservatives	Lyophilized at 2–8°C	Until expiration date on product
	Reconstituted at 2–8°C	24 hours
	Reconstituted at ≤ -20°C	Reconstituted: 30 days
	Reconstituted at room temperature	5 hours
MCM 2–7: 1.0 mL/vial Various levels of synthetic human NT-proBNP in bovine serum albumin with preservatives	Lyophilized at 2–8°C	Until expiration date on product
	Reconstituted at 2–8°C	24 hours
	Reconstituted at ≤ -20°C	Reconstituted: 30 days
	Reconstituted at room temperature	5 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.

H317, H412	**Warning!**
P261, P280, P273, P302+P352, P333+P313, P362+P364, P501	May cause an allergic skin reaction. Harmful to aquatic life with long lasting effects. Avoid breathing dust. 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) (Atellica IM PBNP MCM)

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.

Storage and Stability

Lyophilized material is stable until the expiration date on the product when stored at 2–8°C. Reconstituted material is stable for 24 hours at 2–8°C or 5 hours at room temperature.

Freeze reconstituted product at ≤ -20°C for up to 30 days.

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

Preparing the Master Curve Material

Prepare the master curve material using the following steps:

1. Add 1.0 mL of special reagent water into each vial using a volumetric or precision pipet. Replace cap.

   Note For information about special reagent water, 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.

Note Master curve material greater than the assay's measuring interval should be diluted with Atellica IM PBNP MCM level 1 to within the measuring interval of the assay.

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

Scheduling the Master Curve Material

For instructions about how to perform measuring interval verification, refer to the online help.

- Gently mix each vial and dispense a sufficient volume of each level into the appropriate sample cup.

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

- Do not pour the material back into the vials after testing because evaporation can occur, which may affect performance.
- Dispose of material remaining in the sample cups after 5 hours.
- Do not refill sample cups when the contents are depleted. If required, dispense fresh material into a new sample cup.

Evaluating the Results

Refer to the Atellica IM PBNP MCM lot-specific value sheet MCM LOT VAL for the assigned values. The assigned values represent the acceptable results for master curve material tested singly as unknown samples. Each level is expected to be within its assigned MCM interval. When evaluating results that are outside of the acceptable interval, use the same criteria used when evaluating patient and quality control results.

Master curve material is not intended for use as routine quality control material or as calibration material.

The results obtained depend on several factors. Erroneous results can occur from causes such as improper storage, inadequate mixing, reconstitution errors, or sample handling errors.

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

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
	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]
CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.	Proprietary		Interval	Proprietary
MATERIAL ID	Unique material identification number	Proprietary	MATERIAL	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

Atellica is a trademark of Siemens Healthineers.

© 2017–2022 Siemens Healthineers. All rights reserved.

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