SIEMENS Healthineers

NT-proBNP Master Curve Material (PBNP MCM)

Current Revision and Date[a]	Rev. 02, 2021-07
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

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) are available on siemens.com/healthineers.

H317	**Warning!**
P280, P272, P302+P352, P333+P313, P363, P501	May cause an allergic skin reaction. Wear protective gloves/protective clothing/eye protection/face protection. Contaminated work clothing should not be allowed out of the workplace. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. Dispose of contents and container in accordance with all local, regional, and national regulations. **Contains:** reaction mass of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

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

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

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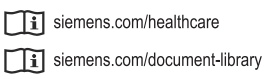
Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title and Description
	Consult instructions for use
	Version of instructions for use
	Internet URL address to access the electronic instructions for use
Rev. REVISION	Revision
	Biological risks Potential biological risks are associated with the medical device.
	Corrosive

Symbol	Symbol Title and Description
	Dangerous to environment
	Irritant Oral, dermal, or inhalation hazard
	Inhalation hazard Respiratory or internal health
	Flammable Flammable to extremely flammable
	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
IVD	*In vitro* diagnostic medical device
Σ (n)	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.

Symbol	Symbol Title and Description
	Mixing of substances Mix product before use.
	Reconstitute and mix lyophilized product before use.
	Target
	Interval
	Legal Manufacturer
EC REP	Authorized Representative in the European Community
	Use-by date Use by the designated date.
LOT	Batch code
REF	Catalog number
	Recycle
	Printed with soy ink
CE	CE Mark
CE 0088	CE Mark with notified body ID number Notified body ID number can vary.
YYYY-MM-DD	Date format (year-month-day)
CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.
UNITS C	Common Units
UNITS SI	International System of Units
MATERIAL	Material
MATERIAL ID	Unique material identification number
CONTROL NAME	Name of control
CONTROL TYPE	Type of control

Legal Information

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