SIEMENS Healthineers

CE 0197

ADVIA Centaur®
Immunoassay Systems

High-Sensitivity Troponin I (TNIH) Master Curve Material

Contents

REF	Contents	
10994776	5 vials of lyophilized Master Curve Material (MCM) Lot-specific value sheet	MCM 1 - 5

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

Intended Use

The ADVIA Centaur® High-Sensitivity Troponin I (TNIH) Master Curve Material is for *in vitro* diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur High-Sensitivity Troponin I (TNIH) assay.

Master Curve Material Description

The ADVIA Centaur TNIH MCM is for use with ADVIA Centaur systems. The ADVIA Centaur TNIH assay is standardized to an internal standard manufactured using human heart homogenate.

The ADVIA Centaur TNIH MCM may assist in documenting the verification of calibration and reportable range where required for compliance with local regulations.

Refer to the target ranges on the lot-specific value sheet for the acceptable range of each level.

Volume	Ingredients	Storage	Stability
1.0 mL/ vial	Human troponin I complex in a human serum base, with preservatives	2–8°C	**Lyophilized:** Stable until the expiration date on the vial label
		18–25°C	**Reconstituted:** 8 hours
			On-system: 4 hours

Warnings and Precautions

Safety data sheets (MSDS/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

WARNING! POTENTIAL BIOHAZARD

Contains human source material. No known test method can ensure that products derived from human source materials will not transmit infection. These materials should be handled using good laboratory practices and universal precautions.[1–3]

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.

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

For professional use.

For *in vitro* diagnostic use.

Preparing the Master Curve Material

Prepare the ADVIA Centaur TNIH MCM using the following steps:

1. Add 1.0 mL of reagent water into each MCM vial using a volumetric or precision pipet.
   Note For information about reagent water, refer to the system operating instructions.
2. Let the vials stand for 15–20 minutes at room temperature to allow the lyophilized material to dissolve.
3. Gently swirl and invert the vials until homogeneous.

Scheduling the Master Curve Material

CAUTION

Ensure that the test for the appropriate calibrator is scheduled before running the MCM.

Schedule the MCMs using the following steps:

1. Schedule the test for the calibrator as described in the assay instructions for use.
2. Schedule the MCM in order of increasing concentration:
   a. Add Level 1 to the worklist.
   b. Add Level 2 to the worklist.
   c. Continue until all levels are scheduled.
3. Label sample cups with the appropriate barcode labels for the calibrators.
4. Gently mix each vial of calibrator and MCM.
5. Dispense a sufficient volume of low and high calibrators into labeled sample cups.
6. Place the calibrators on the system.
7. Dispense a sufficient volume of each MCM level into the appropriate sample cup.
8. Place the MCM on the system from lowest concentration to highest concentration.
   Note Ensure that the assay reagents are loaded on the system.
9. Start the system, if required.

Expected Values

Refer to the ADVIA Centaur TNIH MCM lot-specific value sheet for the expected values. The assigned values were established using the ADVIA Centaur TNIH assay run on the ADVIA Centaur systems.

Evaluating the Results

The MCM target and ranges represent the acceptable results for master curve material tested singly as unknown samples. All levels are expected to be in the acceptable range.

When evaluating MCM results that are outside of the acceptable range, use the same criteria used when evaluating patient and quality control results. MCMs are not intended for use as routine quality control material or as calibration material.

Limitations

The following information pertains to limitations of the MCMs:

- Do not pour the MCM back into the vials after testing because evaporation can occur, which may affect performance.
- Dispose of any material remaining in the sample cups after 4 hours.
- Do not refill MCM sample cups when the contents are depleted. If required, dispense fresh MCM.

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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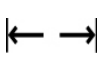
References

1. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009.
2. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.

3. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document M29-A4.

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]		Authorized representative in the European Community	5.1.2[a]
	Use-by date	5.1.4[a]		Authorized representative in Switzerland	Proprietary
	Catalog number	5.1.6[a]		Batch code	5.1.5[a]
	Consult Instructions for Use	5.4.3[a]		Contains sufficient for <n> tests	5.5.5[a]
	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[c]		Unique Device Identifier	5.7.10[b]
	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		Document face up[f]	1952[e]
YYYY-MM-DD	Date format (year-month-day)	N/A		International System of Units	Proprietary
	Target	Proprietary	YYYY-MM	Date format (year-month)	N/A
				Interval	Proprietary

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
	Handheld barcode scanner	Proprietary	CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.	Proprietary
LOT DTL	Lot details	Proprietary	MC DEF	Master Curve definition	Proprietary
CAL LOT VAL	Calibrator lot value	Proprietary	CONTROL LOT VAL	Quality control 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] ISO 15223-1:2020-04

[c] Federal Register. Vol. 81, No 115. Wednesday, June 15, 2016. Rules and Regulations: 38911.

[d] IVDR REGULATION (EU) 2017/746

[e] International Standard Organization (ISO). ISO 7000 Graphical symbols for use on equipment.

[f] Indicates Assay-eNote

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