SIEMENS Healthineers

# Carcinoembryonic Master Curve Material (CEA MCM)

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| **Current Revision and Date**[a] | Rev. 02, 2022-10 |
| **Product Name** | Atellica IM Carcinoembryonic Master Curve Material (CEA MCM) |
| **Abbreviated Product Name** | Atellica IM CEA MCM |
| | 6 x 1.0 mL master curve material MCM 1–6 REF 10995526<br>Master curve material lot-specific value sheet MCM LOT VAL |
| **Systems** | Atellica IM Analyzer |

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

## Intended Use

The Atellica® IM Carcinoembryonic Master Curve Material (CEA MCM) is for *in vitro* diagnostic use for evaluating the Atellica® IM CEA assay. This material is intended to be run singly as unknown samples after a two-point calibration has been performed on the system.

## Material Description

| Material Description | Storage | Stability[a] |
|---|---|---|
| 1.0 mL/vial; lyophilized<br>After reconstitution, various levels of carcinoembryonic antigen; human serum; sodium azide (< 0.1%); preservatives | Lyophilized at 2–8°C | Until expiration date on product |
| | Reconstituted at 2–8°C | 28 days |
| | Reconstituted at room temperature | 4 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-healthineers.com.

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| **H412** | Harmful to aquatic life with long lasting effects. |
| **P273, P501** | Avoid release to the environment. Dispose of contents and container in accordance with all local, regional, and national regulations.<br>**Contains:** Sodium azide |

**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]

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.

## 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 28 days at 2–8°C or 4 hours at room temperature.

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** 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.

- Allow the master curve material to come to room temperature.
- 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 4 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 CEA 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 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.

siemens-healthineers.com

# 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] | 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] | Σ | Contains sufficient for <n> tests | 5.5.5[a] |
| < .../eifu > | Internet URL address to access the electronic instructions for use | Proprietary | Rev. XX | Version of Instructions for Use | Proprietary |
| IVD | *In vitro* diagnostic medical device | 5.5.1[a] | Rev. REVISION | Revision | Proprietary |
| **RxOnly** | Prescription device (US only) | FDA[b] | UDI | Unique Device Identifier | 5.7.10[c] |

| Symbol | Symbol Title | Source | Symbol | Symbol Title | Source |
|---|---|---|---|---|---|
|  | 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 |
|  | Type of control | Proprietary |  | Name of control | Proprietary |
|  | Quality control lot value | Proprietary |  | 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

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