SIEMENS Healthineers

Thyroid Stimulating Hormone 3-Ultra Master Curve Material (TSH3-UL MCM)

Current Revision and Date[a]	Rev. 01, 2017-05
Product Name	Atellica IM Thyroid Stimulating Hormone 3-Ultra Master Curve Material (TSH3-UL MCM)
Abbreviated Product Name	Atellica IM TSH3-UL MCM
	10 x 2.0 mL master curve material MCM 1 · 10 REF 10995705 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.

Intended Use

The Atellica™ IM Thyroid Stimulating Hormone 3-Ultra Master Curve Material (TSH3-UL MCM) is for *in vitro* diagnostic use for evaluating the Atellica™ IM TSH3-UL 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]
2.0 mL/vial; lyophilized After reconstitution, thyroid-stimulating hormone (human); equine serum; sodium azide (< 0.1%); amphotericin B; 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.com/healthineers.

H302+H312, H412
P280, P273, P301+P312, P302+P312, P501

WARNING
Harmful if swallowed or in contact with skin. Harmful to aquatic life with long lasting effects.
Wear protective gloves/protective clothing/eye protection/face protection. Avoid release to the environment. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. IF ON SKIN: Call a POISON CENTER or doctor/ physician if you feel unwell. Dispose of contents and container in accordance with all local, regional, and national regulations.
Contains: Sodium azide

CAUTION POTENTIAL BIOHAZARD
Contains human source material. Each donation of human blood or blood component was tested by FDA-approved methods for the presence of antibodies to human immunodeficiency virus type 1 (HIV-1) and type 2 (HIV-2), as well as for hepatitis B surface antigen (HBsAg) and antibody to hepatitis C virus (HCV). The test results were negative (not repeatedly reactive). No test offers complete assurance that these or other infectious agents are absent; this material should be handled using good laboratory practices and universal precautions.[1–3]

CAUTION
This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

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 2.0 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 TSH3-UL 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

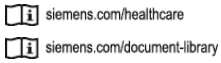
For customer support, contact your local technical support provider or distributor.
siemens.com/healthineers

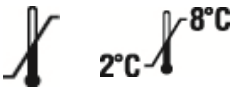
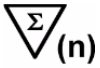
References

1. Centers for Disease Control. Perspectives in disease prevention and health promotion update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in healthcare settings. MMWR. 1988;37(24):377–382, 387–388.
2. Clinical and Laboratory Standards Institute. *Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document GP44-A4.
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 and Description
	Consult instructions for use
	Version of instructions for use
	Internet URL address to access the electronic instructions for use
	Revision
	Biological risks Potential biological risks are associated with the medical device.
	Corrosive
	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

Symbol	Symbol Title and Description
	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
	*In vitro* diagnostic medical device
	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.
	Mixing of substances Mix product before use.
	Reconstitute and mix lyophilized product before use.
	Target
	Interval
	Legal Manufacturer
	Authorized Representative in the European Community

Symbol	Symbol Title and Description
	Use-by date Use by the designated date.
	Batch code
	Catalog number
	Recycle
	Printed with soy ink
	CE Mark
	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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