

Cyclosporine Calibrator (CsA CAL)

Current Revision and Date ^a	Rev. 02, 2019-08
Product Name	Atellica IM Cyclosporine Calibrator (CsA CAL)
Abbreviated Product Name	Atellica IM CsA CAL
	2 x 2.0 mL low calibrator CAL L REF 10995549
	2 x 2.0 mL high calibrator CAL H
	Calibrator lot-specific value sheet CAL 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 Cyclosporine Calibrator (CsA CAL) is for *in vitro* diagnostic use in calibrating the Atellica IM CsA assay using the Atellica™ IM Analyzer.

Material Description

For the assigned values, refer to the calibrator lot-specific value sheet CAL LOT VAL provided. The assigned values are traceable to the standardization of the assay. For additional information, refer to the assay instructions for use.

Material Description	Storage	Stability ^a
Atellica IM CsA CAL 2.0 mL/vial Low or high levels of cyclosporine; human serum; detergents; glycerol; anti-foam; preservatives	Unopened at 2–8°C	Until expiration date on product
	Opened at 2–8°C	21 weeks
	At room temperature	4 hours
	Atellica™ Sample Handler ^b	

^a Refer to *Storage and Stability*.

^b Refer to the supplementary document "Atellica Sample Handler Calibrator and QC Storage and Stability" for information about storage and stability of materials in the Cal-QC tube storage area.

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.com/healthineers.

H412 P273, P501	Harmful to aquatic life with long lasting effects. Avoid release to the environment. Dispose of contents and container in accordance with all local, regional, and national regulations. Contains: 2-methyl-2H-isothiazol-3-one
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**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

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.

Note For information about calibrator preparation, refer to *Preparing the Calibrators*.

Storage and Stability

Store calibrators in an upright position. Unopened calibrators are stable until the expiration date on the product when stored at 2–8°C. Opened calibrators are stable for 21 weeks at 2–8°C. Calibrators are stable for 4 hours at room temperature.

Refer to the supplementary document "Atellica Sample Handler Calibrator and QC Storage and Stability" for information about storage and stability of materials in the Cal-QC tube storage area.

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

Performing Calibration

Calibration Frequency

For information about calibration frequency, refer to the assay instructions for use.

Preparing the Calibrators

Calibrators are liquid and ready to use. Gently mix and invert the vials to ensure homogeneity of the material.

Calibration Procedure

The product is provided in dropper vials. Each dispensed drop is approximately 50 µL.

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

Use the following lot-specific materials to perform calibration:

- For the master curve and assay test definitions, refer to the lot-specific master curve and test definition sheet **MC TDEF** provided with the assay reagents.
- For the calibrator definitions, refer to the lot-specific value sheet **CAL LOT VAL** provided with the calibrator materials.
- Generate lot-specific barcode labels to use with the calibrator samples.

For instructions about how to perform the calibration procedure, refer to the online help.

Technical Assistance

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






siemens.com/healthineers


References



















- 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.
- 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.
- 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
 Rev. 01	Version of instructions for use
 siemens.com/healthcare	Internet URL address to access the electronic instructions for use
 siemens.com/document-library	
Rev. REVISION	Revision
	Caution Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device.

Symbol	Symbol Title and Description
	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
	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
	<i>In vitro</i> diagnostic medical device

Symbol	Symbol Title and Description
	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
	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)
	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.
	Common Units
	International System of Units
	Material


Symbol	Symbol Title and Description
MATERIAL ID	Unique material identification number
CONTROL NAME	Name of control
CONTROL TYPE	Type of control

Legal Information

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