

# Hepatitis C Quality Control (aHCV QC)

Current Revision and Date <sup>a</sup>	Rev. 03, 2023-08
Product Name	Atellica IM Hepatitis C Quality Control (aHCV QC)
Abbreviated Product Name	Atellica IM aHCV QC
	2 x 7.0 mL negative quality control <span>CONTROL -</span> <span>REF</span> 10995457
	2 x 7.0 mL positive quality control <span>CONTROL +</span>
	Quality control lot-specific value sheet <span>CONTROL</span> <span>LOT</span> <span>VAL</span>
Systems	Atellica IM Analyzer

<sup>a</sup> A vertical bar in the page margin indicates technical content that differs from the previous version.



## Intended Use

The Atellica® IM Hepatitis C Quality Control (aHCV QC) is for *in vitro* diagnostic use in monitoring the performance of the Atellica IM aHCV assay using the Atellica® IM Analyzer.

## Material Description

Material Description	Storage	Stability <sup>a</sup>
<b>Atellica IM aHCV QC</b> 7.0 mL/vial Processed human plasma negative and positive for anti-HCV; sodium azide (< 0.1%); preservatives	At 2–8°C	Until expiration date on product
	At room temperature	8 hours
	Atellica® Sample Handler <sup>b</sup>	

<sup>a</sup> Refer to *Storage and Stability*.

<sup>b</sup> 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-healthineers.com](https://www.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>.



H317, H412  
P280, P273,  
P302+P352,  
P333+P313,  
P362+P364, P501

#### **Warning!**

May cause an allergic skin reaction. Harmful to aquatic life with long lasting effects.  
Wear protective gloves/protective clothing/eye protection/face protection.  
Avoid release to the environment. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. Dispose of contents and container in accordance with all local, regional, and national regulations.

**Contains:** reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (Atellica IM aHCV QC)



#### **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.<sup>1-3</sup>

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.

**Note** For information about quality control material preparation, refer to *Preparing the Quality Control Materials*.

## **Storage and Stability**

Store quality control materials in an upright position. Protect the product from heat and light sources. Quality control materials are stable until the expiration date on the product when stored at 2–8°C. Quality control materials are stable for 8 hours on the system at room temperature.

**Note** 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 Quality Control**

Perform the quality control procedure at least once during each work shift that samples are analyzed.

Follow government regulations or accreditation requirements for quality control frequency. Individual laboratory quality control programs and procedures may require more frequent quality control testing.

Test quality control samples after a successful calibration.

## Preparing the Quality Control Materials

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

**Note** Use quality control material within the stability limits specified in *Storage and Stability* and discard any remaining material.

## Quality Control 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 quality control:

- For the quality control (QC) definitions, refer to the lot-specific value sheet 

CONTROL	LOT	VAL
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 provided with the quality control materials.
- Generate lot-specific barcode labels to use with the quality control samples.

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

## Taking Corrective Action

If the quality control results do not fall within the assigned values, do not report results.

Perform corrective actions in accordance with established laboratory protocol. For suggested protocol, refer to the online help.

## Expected Values

For the assigned values, refer to the quality control lot-specific value sheet 

CONTROL	LOT	VAL
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 provided. A satisfactory level of performance is achieved when the analyte values obtained are within the expected control interval for the system or within your interval, as determined by an appropriate internal laboratory quality control scheme. Follow your laboratory's quality control procedures if the results obtained do not fall within the acceptable limits. For information about entering QC definitions, refer to the online help.

The assigned values are traceable to the standardization of the assay. For additional information, refer to the assay instructions for use.

## Limitations

The performance of the aHCV quality control material has not been established with any other anti-HCV assay.

The results obtained using quality control material depend on several factors. Erroneous results can occur from causes such as improper storage, inadequate mixing, reconstitution errors, or sample handling errors associated with system or assay procedures.

The assigned control values should be used as a guide in evaluating performance. The control targets and intervals should be adapted to each laboratory's individual requirements. Values obtained should fall within the established interval. Each laboratory should establish corrective measures if individual values fall outside the interval. Follow the applicable government regulations and local guidelines for quality control.

## 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.









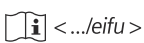

















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## References

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 <sup>a</sup>		Authorized representative in the European Community	5.1.2 <sup>a</sup>
	Use-by date	5.1.4 <sup>a</sup>		Authorized representative in Switzerland	Proprietary
	Catalog number	5.1.6 <sup>a</sup>		Batch code	5.1.5 <sup>a</sup>
	Consult Instructions for Use	5.4.3 <sup>a</sup>		Contains sufficient for <n> tests	5.5.5 <sup>a</sup>
	Internet URL address to access the electronic instructions for use	Proprietary		Version of Instructions for Use	Proprietary
	<i>In vitro</i> diagnostic medical device	5.5.1 <sup>a</sup>		Revision	Proprietary
	Prescription device (US only)	FDA <sup>b</sup>		Unique Device Identifier	5.7.10 <sup>c</sup>
	CE Marking with Notified Body	EU IVDR <sup>d</sup>		CE Marking	EU IVDR <sup>d</sup>
	Temperature limit	5.3.7 <sup>a</sup>		Keep away from sunlight	5.3.2 <sup>a</sup>
	Upper limit of temperature	5.3.6 <sup>a</sup>		Lower limit of temperature	5.3.5 <sup>a</sup>
	Do not re-use	5.4.2 <sup>a</sup>		Do not freeze	Proprietary
	Recycle	1135 <sup>e</sup>		This way up	0623 <sup>e</sup>
	Biological risks	5.4.1 <sup>a</sup>		Caution	5.4.4 <sup>a</sup>

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
	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 <sup>f</sup>	1952 <sup>e</sup>		Handheld barcode scanner	Proprietary
	Target	Proprietary		Mixing of substances	5657 <sup>g</sup>
	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

<sup>a</sup> International Standard Organization (ISO). ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied.

<sup>b</sup> Federal Register. Vol. 81, No 115. Wednesday, June 15, 2016. Rules and Regulations: 38911.

<sup>c</sup> ISO 15223-1:2020-04

<sup>d</sup> IVDR REGULATION (EU) 2017/746

<sup>e</sup> International Standard Organization (ISO). ISO 7000 Graphical symbols for use on equipment.

<sup>f</sup> Indicates Assay-eNote

<sup>g</sup> International Electrotechnical Commission (IEC). IEC 60417-1 Graphical symbols for use on equipment – Part 1: Overview and Application

## Legal Information

Atellica is a trademark of Siemens Healthineers.

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