SIEMENS Healthineers

Anti-Hepatitis B surface Antigen 2 Quality Control (aHBs2 QC)

Current Revision and Date[a]	Rev. 02, 2019-09
Product Name	Atellica IM Anti-Hepatitis B surface Antigen 2 Quality Control (aHBs2 QC)
Abbreviated Product Name	Atellica IM aHBs2 QC
	2 x 10.0 mL negative quality control CONTROL - REF 10995454 2 x 10.0 mL positive quality control CONTROL + Quality control lot-specific value sheet CONTROL LOT VAL
Systems	Atellica IM Analyzer

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

WARNING

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

Intended Use

The Atellica® IM Anti-Hepatitis B surface Antigen 2 Quality Control (aHBs2 QC) is for *in vitro* diagnostic use in monitoring the performance of the Atellica IM aHBs2 assay using the Atellica® IM Analyzer. The performance of the anti-HBs2 quality control material has not been established with any other anti-HBs assay.

Material Description

Material Description	Storage	Stability[a]
Atellica IM aHBs2 QC 10.0 mL/vial Processed human plasma negative and positive for antibodies to HBsAg; preservatives	At 2–8°C	Until expiration date on product
	At room temperature	8 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.

For Prescription Use Only.

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	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. **Contains:** 2-methyl-2H-isothiazol-3-one

CAUTION POTENTIAL BIOHAZARD

Contains human source material. The negative control 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]

The positive control was tested by FDA-approved methods and found to be nonreactive for antibody to HCV and antibody to HIV-1 and HIV-2. The positive control contains human plasma that is reactive for HBsAg.

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 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 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 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 aHBs2 quality control material has not been established with any other anti-HBs 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.

The following information pertains to limitations of the assay:

- Do not return any quality control materials back into the vials after testing because evaporation and contamination can occur, which may affect results.
- Do not refill sample cups when the contents are depleted. If required, dispense fresh quality control materials.

Technical Assistance

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

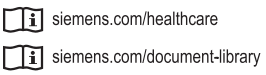
siemens.com/healthineers

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
	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.
	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

Symbol	Symbol Title and Description
	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
	*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

Symbol	Symbol Title and Description
EC REP	Authorized Representative in the European Community
	Use-by date Use by the designated date.
LOT	Batch code
REF	Catalog number
	Recycle
PRINTED WITH SOY INK	Printed with soy ink
CE	CE Mark
CE 0088	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

Atellica is a trademark of Siemens Healthcare Diagnostics.

All other trademarks and brands are the property of their respective owners.

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