SIEMENS Healthineers

B-Type Natriuretic Peptide Quality Control (BNP QC)

Current Revision and Date[a]	Rev. 03, 2022-04
Product Name	Atellica IM B-Type Natriuretic Peptide Quality Control (BNP QC)
Abbreviated Product Name	Atellica IM BNP QC
	3 x 2.0 mL quality control level 1 CONTROL 1 REF 10995475 3 x 2.0 mL quality control level 2 CONTROL 2 3 x 2.0 mL quality control level 3 CONTROL 3 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.

CE 0197

Intended Use

The Atellica® IM B-Type Natriuretic Peptide Quality Control (BNP QC) is for *in vitro* diagnostic use in monitoring the precision and the accuracy of the Atellica IM BNP assay using the Atellica® IM Analyzer.

Material Description

Material Description	Storage	Stability[a]
Atellica IM BNP QC 2.0 mL/vial; lyophilized After reconstitution, various levels of synthetic human BNP; lyophilized buffered sodium caseinate; sodium azide (< 0.1%)	Lyophilized at 2–8°C	Until expiration date on product
	Reconstituted at 2–8°C	5 days
	Reconstituted at ≤ -20°C	60 days; thaw 1 time
	Reconstituted 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.

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.

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.

H311, H302, H412	**Danger!**
P264, P280, P273, P312, P361+P364, P501	Toxic in contact with skin. Harmful if swallowed. Harmful to aquatic life with long lasting effects. Wash hands thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. Avoid release to the environment. Call a POISON CENTER or doctor/physician if you feel unwell. Take off immediately all contaminated clothing and wash it before reuse. Dispose of contents and container in accordance with all local, regional, and national regulations. **Contains:** sodium azide (Atellica IM BNP QC)

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. Lyophilized quality control materials are stable until the expiration date on the product when stored at 2–8°C. Reconstituted quality control materials are stable for 5 days at 2–8°C. Freeze reconstituted product at ≤ -20°C for up to 60 days; thaw only 1 time. Reconstituted quality control materials are stable for 8 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 Quality Control

Perform the quality control procedure at least once during each day 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

Prepare quality control material using the following steps:

1. Add 2.0 mL of special reagent water into each vial using a precision pipet. Replace cap.

   Note For information about special reagent water requirements, 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.
4. For extended storage, aliquot and seal tightly. Store reconstituted material according to stability limits specified in *Storage and Stability*. Do not store in a frost-free freezer.

   Note Before using frozen quality control material, allow the material to completely thaw. Gently mix and invert the material to ensure homogeneity. Use immediately and discard any remaining material. Perform only one procedure per aliquot.

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 range for the system or within your range, 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 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 intervals and ranges 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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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]		Authorized representative in the European Community	5.1.2[a]
	Use-by date	5.1.4[a]		Authorized representative in Switzerland	Proprietary
	Catalog number	5.1.6[a]		Batch code	5.1.5[a]
	Consult Instructions for Use	5.4.3[a]		Contains sufficient for <n> tests	5.5.5[a]
	Internet URL address to access the electronic instructions for use	Proprietary		Version of Instructions for Use	Proprietary
	*In vitro* diagnostic medical device	5.5.1[a]		Revision	Proprietary
	Prescription device (US only)	FDA[b]		Unique Device Identifier	5.7.10[c]
	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

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
	Document face up[f]	1952[e]		Handheld barcode scanner	Proprietary
	Target	Proprietary		Mixing of substances	5657[g]
CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.	Proprietary		Interval	Proprietary
MATERIAL ID	Unique material identification number	Proprietary	MATERIAL	Material	Proprietary
CONTROL TYPE	Type of control	Proprietary	CONTROL NAME	Name of control	Proprietary
CONTROL LOT VAL	Quality control lot value	Proprietary	CAL LOT VAL	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

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