SIEMENS Healthineers

Intact Parathyroid Hormone Quality Control (PTH QC)

Current Revision and Date[a]	Rev. 02, 2019-09
Product Name	Atellica IM Intact Parathyroid Hormone Quality Control (PTH QC)
Abbreviated Product Name	Atellica IM PTH QC
	2 x 1.0 mL quality control level 1 CONTROL 1 REF 10995626 2 x 1.0 mL quality control level 2 CONTROL 2 2 x 1.0 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.

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Intended Use

The Atellica™ IM Intact Parathyroid Hormone Quality Control (PTH QC) is for *in vitro* diagnostic use in monitoring the precision and the accuracy of the Atellica IM PTH assay using the Atellica™ IM Analyzer.

Material Description

Material Description	Storage	Stability[a]
Atellica IM PTH QC 1.0 mL/vial; lyophilized After reconstitution, various levels of intact PTH synthetic peptide; buffered saline; human EDTA plasma (10%); serine protease inhibitor; surfactants; preservatives	Lyophilized at 2–8°C	Until expiration date on product
	Reconstituted at 2–8°C	4 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.com/healthineers.

H411 Toxic to aquatic life with long lasting effects.
P273, P391, P501 Avoid release to the environment. Collect spillage. Dispose of contents and container in accordance with all local, regional, and national regulations.
Contains: 2-methyl-2H-isothiazol-3-one.

Contains: 2-methyl-2H-isothiazol-3-one. May produce an allergic reaction.
(Atellica IM PTH QC)

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 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 4 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 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

Prepare quality control material using the following steps:

1. Add 1.0 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.

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

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

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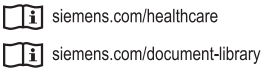
References

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

Symbol	Symbol Title and Description
	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
	*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

Symbol	Symbol Title and Description
	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)
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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