PeriLynx™ QCette

Instructions for Use
For *in vitro* diagnostic use only.
Store at room temperature
(15° to 30°C / 59° to 86°F).
Do not freeze.

PeriLynx™ QCette®

REF PRD-04007

For near-patient testing. To be used by trained medical personnel only

The Hologic PeriLynx QCette is an instrument verification device used to monitor the performance of the PeriLynx™ Analyzer.

INTENDED USE

The PeriLynx QCette is an instrument verification device used to verify that the PeriLynx Analyzer performs within specification. The QCette Setup software determines reference values for the QCette. Daily data collected from the QCette are automatically compared to the reference values to verify analyzer performance.

PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only.

STORAGE AND STABILITY

The PeriLynx QCette should be stored at room temperature (15° to 30°C / 59° to 86°F) in the container provided. Do not store in the cassette insertion site of the analyzer. Do not use the QCette unless it is clean and free of lint or moisture.

MATERIALS REQUIRED BUT NOT PROVIDED

PeriLynx Analyzer, Printer, and User Manual

PROCEDURE

PeriLynx QCette Setup

Note: Setup is initially required for the QCette upon receipt of the PeriLynx™ System and upon receipt of a new QCette.

1. From the Main Menu, select Adjust Settings
2. Select QCette Setup from the Adjust Settings menu and enter the information requested until the analyzer prompts to insert QCette. The QCette ID must be entered using the touch screen. Insert QCette and press Next. Setup of the QCette will take approximately 10 minutes.
3. Upon completion, the analyzer will display either SETUP COMPLETE or SETUP ERROR. Setup Error indicates that the performance criteria of the analyzer have not been established. See the Troubleshooting section of the PeriLynx System User Manual for details.

Daily PeriLynx QCette Use

Note: Daily running of the QCette is an instrument verification method for analyzer performance.

1. From the Main Menu, select Run QCette QC.
2. Enter the information requested until the analyzer prompts to insert QCette. The QCette ID must be entered using the touch screen. Insert QCette and press Next. Analysis of the QCette will take approximately 2–3 minutes.
3. The result for the QCette will be displayed on the analyzer display screen and automatically printed as SYSTEM: PASS or SYSTEM: FAIL.

INTERPRETATION OF RESULTS

The PeriLynx QCette is an internal daily instrument verification test to verify that the performance of the PeriLynx Analyzer is within specification.

The PeriLynx QCette is a cassette replica, containing a membrane with printed test and control lines, which is read by the analyzer. Two different levels of response are measured with this QC device:

1. QCette Level 1: The blue printed line at the test line position is read by the analyzer and converted into a value. This value is compared with the value established during QCette Setup and must be within 5% of that value for QC to pass.
2. QCette Level 2: The blue printed line at the control line position is read by the analyzer and converted into a value. This value is compared with the value established during QCette Setup and must be within 5% of that value for QC to pass.

A "SYSTEM: PASS" result indicates that the daily QCette Level 1 and Level 2 values are within the specification determined at setup. A "SYSTEM: FAIL" result indicates that one or both of the daily QCette values are outside the specification determined at setup. A "PASS" or "FAIL" result for each QCette level and the numeric value are also reported. If the QCette fails, ensure that it is clean and free of lint or moisture, and repeat the test. If there is dirt or lint on the QCette, a "canned air" product may be used. If the problem persists, see the PeriLynx System User Manual for further details, or contact Hologic for technical assistance.

QUALITY CONTROL PROCEDURES

Current Good Laboratory Practice includes the periodic use of controls to monitor assay performance. The QCette is recommended for use in monitoring the performance of the analyzer. The recommended frequency of use of the QCette is at least once every 24 hours, or whenever there is uncertainty about the analyzer. Do not test patient samples until an acceptable result is obtained from the QCette.

TECHNICAL SERVICE AND ORDERING INFORMATION

For country-specific Technical Support and Customer Service email address and telephone number, visit www.hologic.com/support.

In case of serious incident, please notify the Manufacturer and Competent Authority in your region

REVISION HISTORY

Part Number	Date	Description
AW-26293 Rev.001	02-2022	• Created PeriLynx Qcette Instructions for Use AW-26293-001 Rev.001 based on AW-22410-001 Rev.001 for regulatory compliance with IVDR • Removed reference to 'quality control device'. Updated contact information including: EC Rep authority, Australian sponsor details, and technical support information.
Rev. 002	06-2022	• Removed '10Q' from the title

Consult instructions for use

IVD In vitro diagnostic medical device

REF Catalogue Number

For near patient testing

EC REP Authorized Representative in the European Community

15°C 30°C Store between 15° and 30°C

Manufacturer

HOLOGIC®

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CE