

To be used by trained medical personnel only

The Hologic TLiQ® QCette® is a quality control device used to monitor the performance of the TLiQ® Analyzer.

#### INTENDED USE

The TLiQ QCette is a quality control device used to verify that the TLiQ Analyzer performs within specification. The QCette Setup software determines a value for the QCette. Daily quality control data collected from the QCette are automatically compared to this setup value to verify analyzer performance.

#### PRECAUTIONS AND WARNINGS

1. For *in vitro* diagnostic use only.
2. Do not use the QCette if it is damaged.

#### STORAGE AND STABILITY

The 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. If properly stored, the QCette should last an indefinite period of time.

#### MATERIALS REQUIRED BUT NOT PROVIDED

TLiQ Analyzer, Printer, and User Manual

#### PROCEDURE

##### Initial TLiQ QCette Setup

**Note:** Setup is performed once for the QCette received with the TLiQ System.

1. From the Main Menu, select CHANGE SETUP.
2. Select QCette SETUP from the SETUP menu and enter the information requested until the analyzer prompts to insert QCette. Insert QCette and press enter. Setup of the QCette will take approximately 15 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 TLiQ System User Manual for details.**

##### Daily TLiQ QCette Use

**Note:** Daily running of the QCette is a quality control method for analyzer performance.

1. From the Main Menu, select DAILY QC.
2. Enter the information requested until the analyzer prompts to insert QCette. Insert QCette and press enter. 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, SYSTEM FAIL, or INVALID.

#### INTERPRETATION OF RESULTS

The TLiQ QCette is a daily quality control test to verify that the performance of the TLiQ Analyzer is within specification.

The TLiQ QCette is a Rapid fFN Cassette replica, containing a membrane with printed test and control lines, which is read by the TLiQ Analyzer. Three different levels of response are measured with this QC device:

1. **High Level:** The blue line at the procedural control position, which is in the high positive range, must be above a minimum threshold value for QC to pass.
2. **Low Level:** The blue printed line at the test line position is in the cutoff range. This line is measured and compared with a value established during instrument setup and must be within 5% of that value for QC to pass.
3. **Negative:** The white space between the blue lines is measured and should always be in the negative range for QC to pass.

A "PASS" result indicates that the daily QCette value is within the specification determined at setup. A "FAIL" result indicates that the daily QCette value is outside the specification determined at setup.

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 TLiQ 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.

The TLiQ QCette is covered by U.S. patent number Des. 432,244.

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#### TECHNICAL SERVICE AND ORDERING INFORMATION

##### USA/CANADA ONLY

Tel: 1-888-PRETERM  
(1-888-773-8376)

Fax: 1-508-263-2956

##### ALL OTHER COUNTRIES

Tel: +1-508-263-2900

For additional contact information, go to  
[www.ffntest.com](http://www.ffntest.com)



Caution, consult accompanying documents



Store between 15° and 30°C



In vitro diagnostic medical device



Catalogue number



Use by



Do not reuse



Batch code



Manufacturer



Authorized Representative in the European Community