HOLOGIC®

TLiQ® QCette® QC Device

REF 01175

For *In Vitro* Diagnostic Use Only
Store at room temperature (15° to 30°C / 59° to 86°F).
Do not freeze.

Rx only

For Professional Use 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.

RapidFN® for the TLiQ® System

TLiIQ® QCette® QC Device

INTERPRETATION OF RESULTS

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

The TLiIQ QCette is a Rapid fFN Cassette replica, containing a membrane with printed test and control lines, which is read by the TLiIQ 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 TLiIQ 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 run test patient samples until an acceptable result is obtained from the QCette.

TECHNICAL SERVICE AND ORDERING INFORMATION

USA/CANADA ONLY
Tel: 1-800-442-9892
Fax: 1-508-263-2956

ALL OTHER COUNTRIES
Tel: +1-508-263-2900
For additional contact information, go to www.ffntest.com

TLiQ® QCette® QC Device

Following is an explanation of the symbols that may appear on your product.

Symbol	Title	Description	Standard information
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.4.4
	*In vitro* diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.5.1
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.5
	Temperature limit	Indicates the upper and lower limit of temperature to which the medical device can be safely exposed.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.3.7
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.6
	Manufacturer	Indicates the medical device manufacturer, as defined in the EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.1

Hologic, Inc. • 1240 Elko Drive • Sunnyvale, CA • 94089-2212 • USA
1-800-442-9892• +1 (508) 263-2900 • www.hologic.com