

TLi[®] System



User Manual

IMPORTANT: Read the entire manual before operating the TLI_{IQ}® System.



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AW-22463-001 Rev. 002

If this equipment is used in a manner not specified by the manufacturer, then the protection provided by the equipment may be impaired.

FCC Notice:

This equipment has been tested and found to comply with the limits of a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.

- Increase the separation between the equipment and receiver.

- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

- Consult the dealer or an experienced radio/television technician for help.

FCC Warning:

Changes or modification not expressly approved by the manufacturer responsible for compliance could void the user's authority to operate the equipment.

Note: The use of a non-shielded interface cable with this equipment is prohibited.

CE Notice:

This equipment has been tested and found to be in compliance with the following standards per the IVD Directive:

EN61326-1	Electrical Equipment for Measurement, Control and Laboratory Use
EN55011	Radiated and Conducted Emissions
EN61010-1	Safety Requirements
EN61000-3-2	Harmonic Emissions
EN61000-3-3	Voltage Fluctuations
EN61000-4-2	Electrostatic Discharge
EN61000-4-4	Electrical Fast Transients
EN61000-4-5	Voltage Surges
EN61000-4-6	Conducted Immunity
EN61000-4-11	Voltage Interrupts

Disposal of Electrical & Electronic Equipment

Waste Electrical and Electronic Equipment (WEEE)

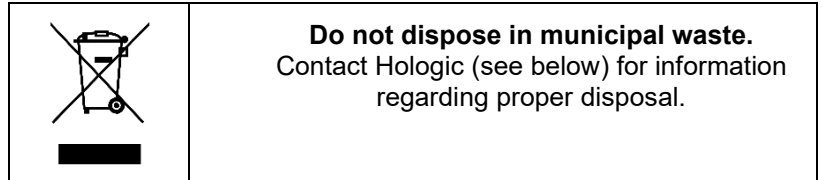
Hologic is dedicated to meeting country specific requirements associated with the environmentally sound treatment of our products. Our objective is to reduce the waste arising from our electrical and electronic equipment. Hologic realizes the benefits of subjecting such WEEE equipment to potential reuse, treatment, recycling or recovery to minimize the amount of hazardous substances entering the environment.

Your Responsibility

As a Hologic customer, you are responsible for ensuring that devices marked with the symbol shown below are not placed into the municipal waste system unless authorized to do so by the authorities in your area. Please contact Hologic (see below) prior to disposing any electrical equipment provided by Hologic.

Symbol Used on the Instrument

The following symbol is used on this instrument:



Reclamation

Hologic will provide for the collection and proper reclamation of electrical devices we provide to our customers. Hologic strives to reuse Hologic devices, subassemblies, and components whenever possible. When reuse is not appropriate, Hologic will ensure the waste material is properly disposed of.

Hologic Contact Information






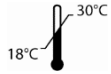
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FAX: 1-508-263-2967

Symbols Used on the Instrument

The following symbols are used on this instrument:

SYMBOL	TITLE	DEFINITION	STANDARD
	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
	Manufacturer	Indicates the medical device manufacturer.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.1
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified NOTE: Synonyms for "batch code" are "lot number" and "batch number".	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.5

SYMBOL**TITLE****DEFINITION****STANDARD**

Temperature Limit,
Store between
18°C and 30°C

Indicates the temperature limits 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



Catalog Number

Indicates the manufacturer's catalog
number so that the medical device can be
identified NOTE: Synonyms for "catalogue
number" are "reference number" and
"reorder number".

ISO 15223-1 Medical devices—Symbols to be used
with medical device labeling and information to be
supplied, Section 5.1.6



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



Serial number

Indicates the manufacturer's serial number
so that a specific medical device can be
identified.

ISO 15223-1 Medical devices—Symbols to be used
with medical device labeling and information to be
supplied, Section 5.1.7



Consult Instructions
For Use

Indicates the need for the user to consult
the instructions for use.

ISO 15223-1 Medical devices—Symbols to be used
with medical device labeling and information to be
supplied, Section 5.4.3

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SECTION I – INTRODUCTION



For *In Vitro* Diagnostic Use Only
To be used by trained laboratory personnel

INTENDED USE

The Hologic TLI_Q[®] System is intended to be used in conjunction with the Rapid fFN Cassette, the Rapid fFN Control Kit, and the TLI_Q QCette[®] for the detection of fetal fibronectin in cervicovaginal secretions. Refer to the directional insert for the Rapid fFN Cassette for detailed intended use information.

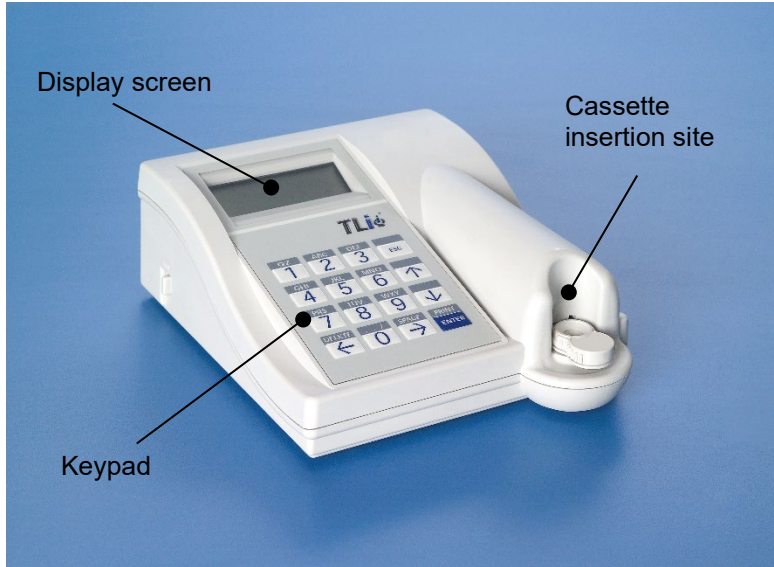
GENERAL DESCRIPTION

The TLI_Q[®] Analyzer is an electronic optical reflectance device that converts a colorimetric reaction from a cassette into a digitized format. The data are analyzed using multiple parameters, including a comparison of sample data to calibration data. The analyzer provides one of three possible patient test results: Positive, Negative, or Invalid.

The result is positive if the signal intensity derived from the patient sample is greater than or equal to the reference calibration value specified by the calibration code. The result is negative if the signal intensity derived from the patient sample is less than the reference calibration value specified by the calibration code. The result is reported as invalid if specific internal test criteria have not been met.

COMPONENTS OF THE ANALYZER

The major components of the analyzer are the display screen, the keypad, and the cassette insertion site.

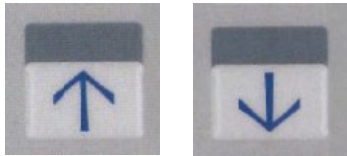




KEYPAD

Numeric – Use keypad to enter numerical characters from **0 to 9**.

Alpha – Use keypad to enter alpha characters from **A to Z**.



KEYPAD FUNCTIONS

(Vertical Scroll)

Alpha characters - Use ↑ ↓ to navigate through the alphanumeric keys when selecting an alpha character.

Scrolling through Data Records - Use ↑ ↓ when scrolling through data records in ACCESS DATA mode.

Menu Screens - Some menus require up to three screens to display all of the options. Use ↑ ↓ to go to the next or previous screen of the menu.



(Left Arrow Key)

Previous Page - Use ← to go to the previous page within a data record.

Delete - Use **DELETE** to delete characters to the left of the cursor.



(Right Arrow Key)

Next Page - Use → to go to the next page within a data record.

Space - Use **SPACE** to enter a space in the position of the cursor.



(Print/Enter Key)

Accept/Confirm - Press **ENTER** to accept or confirm an entry in any data entry field.

Print - Press **PRINT** to print a data record.

This print function is only active when a data record is on the display screen.



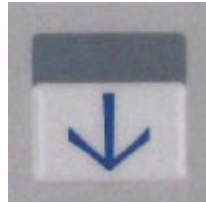
(Escape Key)

Press **ESC** to return to the most recent Menu screen, unless otherwise specified. If **ESC** is pressed in any screen requiring data entry, all entries will revert to the previous setting.

KEYPAD ENTRIES

Entries of **numerical characters** require pressing the appropriate numeric key.

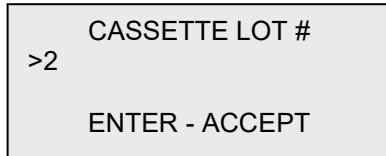
Entries of **alpha characters** require pressing the numeric key containing the alpha character and the ↑ or ↓ arrows (scroll keys).



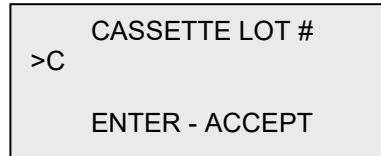
Example - to enter Cassette Lot Number **C9123**.

1 - Press **2**. Use ↑ arrow until **C** appears on the display screen.

NOTE: The ↑ arrow will scroll repetitively through the characters **2-A-B-C**. The ↓ arrow will scroll repetitively through the characters **2-C-B-A**.

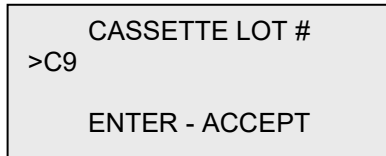


CASSETTE LOT #
>2
ENTER - ACCEPT



CASSETTE LOT #
>C
ENTER - ACCEPT

2 - Press **9**.



CASSETTE LOT #
>C9
ENTER - ACCEPT

3 - Press each subsequent number **1, 2, 3**.

```
CASSETTE LOT #  
>C912_  
  
ENTER - ACCEPT
```

4 - Press **ENTER** after all entries have been made.

```
CASSETTE LOT #  
>C9123  
  
ENTER - ACCEPT
```

Example - to enter Patient Name **ABE**

1 - Press **2**. Use ↑ or ↓ arrow until **A** appears on the display screen.

PATIENT ID
>2
ENTER - ACCEPT

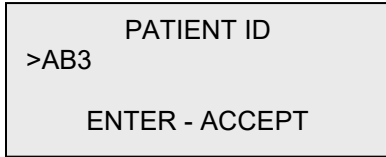
PATIENT ID
>A
ENTER - ACCEPT

2 - Press **2** again. Use ↑ or ↓ arrow until **B** appears on the display screen.

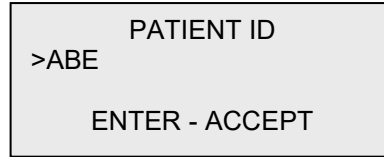
PATIENT ID
>A2
ENTER - ACCEPT

PATIENT ID
>AB
ENTER - ACCEPT

3 - Press **3** to enter the next letter. Use \uparrow or \downarrow arrow until **E** appears on the display screen.



PATIENT ID
>AB3
ENTER - ACCEPT



PATIENT ID
>ABE
ENTER - ACCEPT

4 - Press **ENTER** after all entries have been made.

CASSETTE INSERTION SITE

The Cassette Insertion Site contains a slightly concave trough designed to capture any fluids that may have been spilled while applying sample to the Rapid fFN Cassette. This area of the instrument should be cleaned regularly (see Section 5).



DISPLAYED/PRINTED RESULTS

Each test result is displayed on the analyzer display screen. A test result requires three screens to display all of the data associated with the result. With AUTOPRINT ON, the test result is automatically printed. Each printed result requires one printer label. Results can be printed from any data record screen either immediately after a test or in DATA ACCESS mode.

The printer labels must be the labels available from Hologic. Printer errors may occur if the wrong labels are used.

Example: Displayed/Printed Results of Calibration Record

Displayed

```
FETAL FIBRONECTIN
09:08 AM      04/15/16
SYSTEM CALIBRATED
USER:XXXXXXXXXX→
```

```
CAL CODE:DH37
CASSETTE LN:J4047
ANALYZER ID:AD000
ESC-MAIN MENU ←
```

Printed

```
HOLOGIC® TLi™
-----
RAPID FFN CALIBRATION
SYSTEM CALIBRATED
TIME:09:08a DATE:04/15/16
-----
USER:JOHN SMITH
CASSETTE LOT:J4047
CALIBRATION CODE:DH37
ANALYZER ID:AD000
```


Example: Displayed/Printed Results of TLi_Q QCette®

Displayed

```
QCette
09:13 AM      04/15/16
SYSTEM: PASS
USER:XXXXXXXXXX →
```

```
CAL CODE:FG56
QCette SN:010279
ANALYZER ID:AD000
ESC-MAIN MENU ←
```

Printed

```
-----
HOLOGIC® TLi™
-----
      TLi QCette
TIME:09:13a DATE:04/15/16
-----
SYSTEM: PASS
-----
USER:JOHN SMITH
SERIAL#:010279
ANALYZER ID:AD000
```

Example: Displayed/Printed Results of Negative Control Record

Displayed

FETAL FIBRONECTIN
10:41 AM 04/15/16
NEG CTL:M1032
RESULT:PASS →

INTERNAL CONTROLS
USER:XXXXXXXXXXXXXXXXX
ANALYZER: PASS
CASSETTE: PASS ← →

CAL CODE:DH37
CASSETTE LN:J4047
ANALYZER ID:AD000
ESC-MAIN MENU ←

Printed

HOLOGIC® TLi™

fFN NEGATIVE CTL RESULT
PASS
TIME:10:41a DATE:04/15/16

NEG CONTROL:M1032
USER:JOHN SMITH
CASSETTE LOT:J4047
CALIBRATION CODE:DH37
ANALYZER ID:AD000

INTERNAL CONTROLS
ANALYZER: PASS
CASSETTE: PASS

Example: Displayed/Printed Results of Patient Record

Displayed

FETAL FIBRONECTIN
11:41 AM 04/15/16
PT:XXXXXXXXXXXXXXXXXX
RESULT:POSITIVE →

USER:JOHN SMITH
INTERNAL CONTROLS
ANALYZER: PASS
CASSETTE: PASS ← →

CAL CODE:DH37
CASSETTE LN:J4047
ANALYZER ID:AD000
ESC-MAIN MENU ←

Printed

HOLOGIC® TLI™

RAPID fFN RESULT
POSITIVE
TIME:11:41a DATE:04/15/16

PATIENT:XXXXXXXXXX
USER:JOHN SMITH
CASSETTE LOT:J4047
CALIBRATION CODE:DH37
ANALYZER ID:AD000

INTERNAL CONTROLS
ANALYZER: PASS
CASSETTE: PASS

Example: Displayed/Printed Results of Test Counts Record

Displayed

FETAL FIBRONECTIN
TEST COUNTS
10:40 AM 04/15/16
ANALYZER:AD000 →

PATIENT:9
CONTROL:8
QCette:3 ←

Printed

HOLOGIC® TLi™

FETAL FIBRONECTIN (fFN)
TEST COUNT RECORD
TIME:10:40a DATE:06/07/16
ANALYZER ID:AD000

PATIENT: 9
LIQUID CTL: 8
QCette: 3

SPECIFICATIONS

Power Supply	UL 12 VDC listed power supply
Memory Capacity	50 Calibration Records 50 QCette Records 50 Control Records 50 Patient Records
Display	4 lines 20 characters per line alphanumeric 5 x 8 matrix Supertwist LCD Black characters with gray background
Keypad	3.5 x 4.5 inches tactile membrane alphanumeric keys

Dimensions	Length - 8.9 inches Width - 6.9 inches Height - 1.0 to 3.0 inches Weight - 1.2 pounds
Operating Temperature	18° to 30°C 64° to 86°F
A.C. Supply	120VAC / 60Hz / 16W or 220VAC / 50Hz / 16W
Input Connector	Coaxial power plug with positive center conductor
Output Connectors	9 pin male and 9 pin female data connectors

CAUTIONS AND WARNINGS

There are no known hazards associated with the TLi_{IQ} System when it is operated in accordance with the instructions in this manual. However, you should be aware of situations that can result in serious injury.



WARNING! Ensure that the analyzer power adapter is connected to a grounded AC electrical outlet that provides voltage and current specified by Hologic. Use of an incompatible power receptacle can cause shock and fire hazard.

CAUTION! Use only the power adapter supplied by Hologic. Use of an incompatible power adapter can damage the internal components.

CAUTION! Always turn off the power and unplug the power adapter before cleaning the exterior of the analyzer. Fluid can damage internal components. **DO NOT** clean the power adapter.

CAUTION! Extreme heat can damage the display and other electronic components.



WARNING! Never apply cleaning reagents by spray as the liquid may leak into the analyzer causing damage to the electrical components or possibly electrical shock to the user.

CAUTION! Do not immerse the analyzer in liquid. Fluid can damage internal components.

CAUTION! Do not clean the keypad with undiluted bleach solution or other solvents. Caustic cleaning solutions can damage the keypad.

CAUTION! Use appropriate laboratory procedures for handling biohazardous materials.

SECTION 2 – INSTALLATION

GENERAL

This section provides detailed installation instructions for the TLI_Q System. Follow installation steps carefully to insure proper installation and operation.

ENVIRONMENTAL FACTORS

The TLI_Q System has been designed to be safe under the following conditions: Indoor use; Altitudes up to 2000m; Maximum relative humidity of 80% for temperatures up to 31°C decreasing linearly to 50% relative humidity at 40°C; Main supply voltage fluctuations not to exceed $\pm 10\%$ of the nominal; transient overvoltages according to Installation Category and Pollution Degree 2. However, as with all electronic instruments, prolonged exposure to high temperature and humidity should be avoided. The operating temperature should be held relatively constant. The optimum operating temperature is 18° to 30°C (64° to 86°F). Before operating, allow the instrument to equilibrate to room temperature.

Place the instrument where it will not be subjected to extreme temperature variations (e.g., near open windows, ovens, hot plates, radiators, direct sunlight).

UNPACKING

TLiQ Analyzer

Carefully remove the analyzer and accessories from the shipping carton. Inspect the carton and the analyzer for visible signs of damage. If the analyzer is damaged, immediately contact the carrier and Hologic Customer Service.

The carton should contain the following parts/accessories:

- TLiQ Analyzer
- Power Adapter
- User Manual
- TLiQ QCette®

NOTE: Retain the shipping carton for future use. If the analyzer needs to be shipped, use the original shipping carton.



Printer

Carefully remove the printer and accessories from the shipping carton. Inspect the carton and the printer for visible signs of damage. If the printer is damaged, immediately contact the carrier and Hologic Customer Service.

The printer carton should contain the following parts/accessories:

1. Printer (shown with cover open)
2. Printer Labels (1 roll)
3. Power Cord
4. Power supply with AC connector (wall connector)
5. Printer Cable

NOTE: Retain the shipping carton for future use.
If the printer needs to be shipped, use the original shipping carton.

Use only the printer labels available from Hologic. Printer errors may occur if the wrong labels are used.



SYSTEM SETUP

1. The Analyzer and Printer should be placed on a flat, level surface.
2. Connect the 9-pin connector of the printer cable to the analyzer and the modular jack to the printer.



System



Printer



Analyzer

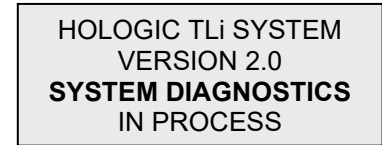
3. Connect the small connector of the analyzer power adapter to the analyzer and the larger power connector to a grounded AC electrical outlet. **Caution:** Only power connectors provided with the TLi_Q analyzer and printer may be used. Any substitutions can result in damage to the TLi_Q analyzer and printer.
4. Connect the small connector from the printer power supply to the printer. Connect the printer power cord to the printer power supply. Plug the printer power supply into a grounded AC electrical outlet. The light on the printer power supply will illuminate.

GETTING STARTED

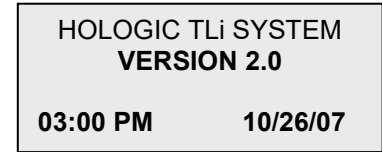
Turn the analyzer power switch to the ON position. The power switch is located on the left side of the instrument. (If the analyzer does not turn on, see Section 6, Troubleshooting.)

The analyzer will perform **SYSTEM DIAGNOSTICS** (a self-test of the analyzer components).

If there is a problem after the self-test, a beep will sound to indicate an error and an error code will be displayed. If an error code is displayed, refer to the troubleshooting section of the manual.



HOLOGIC TLi SYSTEM
VERSION 2.0
SYSTEM DIAGNOSTICS
IN PROCESS

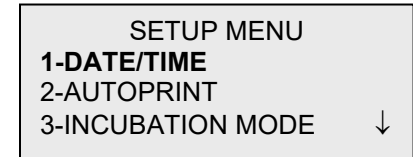
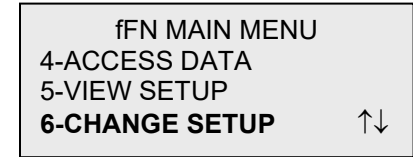


HOLOGIC TLi SYSTEM
VERSION 2.0
03:00 PM **10/26/07**

Once **SYSTEM DIAGNOSTICS** is complete, the display will change to the software **VERSION**, **DATE**, and **TIME** for five seconds, and then to the fFN Main Menu. The date and time may need to be reset for your time zone.

SETTING THE DATE AND TIME

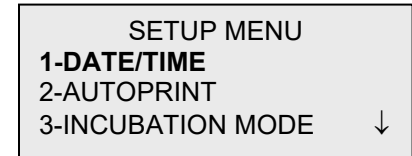
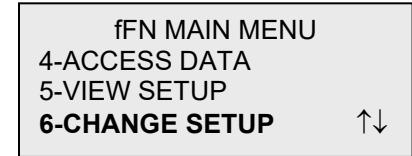
1. From the Main Menu, select CHANGE SETUP by pressing the ↓ to get to the second page of the Main Menu. Press 6 for CHANGE SETUP. This will display the SETUP MENU.
2. From the SETUP MENU, press 1 to display DATE/TIME and follow the prompts.



For more details about setting the date and time, see Section 4, Software Functions – Detailed Descriptions.

TLiQ QCette® SETUP

1. From the Main Menu, select CHANGE SETUP by pressing the ↓ to get to the second page of the Main Menu. Press 6 for CHANGE SETUP. This will display the SETUP MENU.
2. From the SETUP MENU, press the ↓ or 4 to display QCette SETUP and follow the prompts.



For more details about setting up the TLiQ QCette, see Section 4, Software Functions – Detailed Descriptions.

FACTORY DEFAULT SETTINGS

The TLiQ System uses the following default settings. To customize the unit to your laboratory requirements, refer to Section 4, Software Functions – Detailed Descriptions.

The Default Settings are as follows:

AUTOPRINT

Factory setting is Autoprint ON. After every result, the printer will generate a printed result.

INCUBATION MODE

Factory setting is INTERNAL Mode. The incubation mode refers to the timing of the incubation process and the initiation of the cassette analysis.

In the INTERNAL mode, the analyzer will time the incubation and automatically start the analysis when the incubation is complete.

In the EXTERNAL mode, the user will be responsible for timing the incubation and for starting the analysis.

NOTE: The INTERNAL mode is recommended by the manufacturer to ensure proper timing of the assay.

SECTION 3 – GENERAL OPERATING / TESTING INSTRUCTIONS

After instrument installation, the TLIQ analyzer can be operated on a day-to-day basis by using the following procedures. Read Section 4 for detailed descriptions of displays, prompts and operating sequences.


STARTING THE SYSTEM

1. Turn on the analyzer using the on/off switch located on the left side of the analyzer.

The screen will display SYSTEM DIAGNOSTICS. If the analyzer fails the self-test, two beeps will sound; otherwise the analyzer will go to the next screen.

Once SYSTEM DIAGNOSTICS is complete, the display will change to the software VERSION and the DATE and TIME for five seconds and then to the Main Menu. Verify the date and time are correct.

See Section 4 for setting Date/Time.

2. Turn on the printer by pressing the power  button on the top of the printer. Ensure labels are in the printer. The status light on the printer will change from solid red to solid green. See Section 6 for loading printer labels.

HOLOGIC TLI SYSTEM
VERSION 2.0
SYSTEM DIAGNOSTICS
IN PROCESS

HOLOGIC TLI SYSTEM
VERSION 2.0
03:00 PM **10/26/07**

SET CALIBRATION

NOTE: Calibration must be set when changing cassette lots.

1. From the Main Menu, press 2 to select SET CALIBRATION.
2. Enter USER ID and press ENTER.
3. Enter the CASSETTE LOT# (on cassette pouch) and press ENTER.
The lot number must be entered to proceed to the next step.

```
ffN MAIN MENU
1-TEST PATIENT
2-SET CALIBRATION
3-DAILY QC      ↓
```

```
SET CALIBRATION
  USER ID
>JOHN SMITH
  ENTER-CONFIRM
```

```
SET CALIBRATION
  CASSETTE LOT#
>L1002
  ENTER-ACCEPT
```

4. Enter the CALIBRATION CODE# (on cassette box label) and press ENTER. The code number must be entered to proceed to the next step.

NOTE: The calibration code is established by Hologic for each lot of Rapid fFN Cassettes.

5. When calibration is complete, the system will automatically display and print the result if AUTOPRINT is set to ON, or it may be printed/reprinted by pressing the PRINT/ENTER key.
6. Press ESC to return to the Main Menu.

```
SET CALIBRATION  
CALIBRATION CODE#  
>FG56  
ENTER-ACCEPT
```

```
FETAL FIBRONECTIN  
03:00 PM 10/26/07  
SYSTEM CALIBRATED  
USER:JOHN SMITH →
```

TEST PATIENT (Internal Incubation Mode)

1. From the Main Menu, press 1 to select TEST PATIENT.
2. Enter USER ID and press ENTER.
3. Enter the **last two digits** of the CASSETTE LOT# (on cassette pouch) and press ENTER. The lot number must be entered to proceed to the next step.

NOTE: The analyzer will automatically compare the CASSETTE LOT# used to set calibration with the cassette lot number used for patient testing. If the lot numbers do not match, the analyzer will request the user to recalibrate the system. The cassette lot number used for calibration will be displayed on the third line.

```
fFN MAIN MENU
1-TEST PATIENT
2-SET CALIBRATION
3-DAILY QC      ↓
```

```
TEST PATIENT
USER ID
>JOHN SMITH
ENTER-CONFIRM
```

```
TEST PATIENT
CASSETTE LOT#
>L1002
ENTER-ACCEPT
```

4. Enter up to 16 alphanumeric characters for a PATIENT ID and press ENTER.

PATIENT ID
>JANE DOE 123

ENTER-ACCEPT

5. Insert cassette and press ENTER.

INTERNAL INCUBATION
INSERT CASSETTE
PRESS ENTER
TO CONTINUE

6. Add sample and **immediately** press ENTER.

ADD SAMPLE
AND IMMEDIATELY
PRESS ENTER

7. The analyzer will begin a 20-minute incubation countdown.

TEST IN PROCESS
DO NOT REMOVE
CASSETTE
19 MIN 56 SEC

8. Following incubation, the analyzer will begin analysis of the cassette.

TEST IN PROCESS
ANALYZING
DO NOT REMOVE
CASSETTE

9. When testing is complete, the system will automatically display and print the result if AUTOPRINT is set to ON, or it may be printed/reprinted by pressing the PRINT/ENTER key.

FETAL FIBRONECTIN
03:00 PM 10/26/07
PT:JANE DOE 123
RESULT:POSITIVE →

10. Press ESC to return to the Main Menu.

DAILY QC

NOTE: TLi_Q QCette SETUP must be performed PRIOR to running the QCette as a quality control device. See Section 4 for TLi_Q QCette SETUP.

1. From the Main Menu, press 3 to select DAILY QC.
2. Enter USER ID and press ENTER.
3. Enter the QCette SN (on QCette plastic housing) and press ENTER. The serial number must be entered to proceed to the next step. The correct format is 6 numbers (e.g., 001004). Enter all leading zeros.

NOTE: The serial number entered at daily QC must be identical to the serial number entered at TLi_Q QCette setup.

```
fFN MAIN MENU
1-TEST PATIENT
2-SET CALIBRATION
3-DAILY QC ↓
```

```
QCette
USER ID
>JOHN SMITH
ENTER-CONFIRM
```

```
QCette
ENTER QCette SN
>001004
ENTER-ACCEPT
```

4. Insert the QCette and press ENTER. The analyzer will begin the analysis of the QCette.

INSERT QCette
ENTER-CONTINUE

5. When testing is complete, the system will automatically display and print the result if AUTOPRINT is set to ON, or it may be printed/reprinted by pressing the PRINT/ENTER key.
6. Press ESC to return to the Main Menu.

TEST IN PROCESS
ANALYZING
DO NOT REMOVE
CASSETTE

QCette
03:00 PM 10/26/07
SYSTEM: PASS
USER:JOHN SMITH →

LIQUID CONTROLS (Internal Incubation Mode)

1. From the Main Menu, press 8 to select LIQUID CONTROLS.
2. Enter USER ID and press ENTER.
3. Enter the CASSETTE LOT# (on cassette pouch) and press ENTER.
The lot number must be entered to proceed to the next step.

```
fFN MAIN MENU
7-TEST COUNTS
8-LIQUID CONTROLS
↓
```

```
RUN CONTROL
USER ID
>JOHN SMITH
ENTER-CONFIRM
```

```
RUN CONTROL
CASSETTE LOT#
>L1002
ENTER-ACCEPT
```

4. Select Negative or Positive Control.

CONTROL TEST MENU
1-NEGATIVE CONTROL
2-POSITIVE CONTROL

5. Enter the CONTROL LOT# (on bottle label) and press ENTER.

NEGATIVE CTL LOT#
>M1023

ENTER-CONFIRM

6. Insert cassette and press ENTER.

INTERNAL INCUBATION
INSERT CASSETTE
PRESS ENTER
TO CONTINUE

7. Add sample and **immediately** press ENTER.
8. The analyzer will begin a 20-minute incubation countdown.
9. Following incubation, the analyzer will begin analysis of the cassette.
10. When testing is complete, the system will automatically display and print the result if AUTOPRINT is set to ON, or it may be printed/reprinted by pressing the PRINT/ENTER key.
11. Press ESC to return to the Main Menu.

ADD SAMPLE
AND IMMEDIATELY
PRESS ENTER

TEST IN PROCESS
DO NOT REMOVE
CASSETTE
19 MIN 56 SEC

TEST IN PROCESS
ANALYZING
DO NOT REMOVE
CASSETTE

FETAL FIBRONECTIN
03:00 PM 10/26/07
NEG CTL:M1023
RESULT:PASS →

VIEWING RESULTS ON SCREEN

Upon completion of every test, the analyzer will automatically display the results on up to three screens. Each screen can be accessed by using the ← and → keys. To print the result record, press the ENTER/PRINT key from any screen.

NOTE: Internal controls are performed automatically during each Rapid fFN test. These internal controls check for (1) a threshold level of signal at the procedural control line, (2) proper sample flow across the Rapid fFN Cassette, (3) absence of conjugate aggregation, and (4) proper functioning of the TLiQ analyzer hardware.

```
FETAL FIBRONECTIN
03:00 PM          10/26/07
PT:JANE DOE 123
RESULT:POSITIVE  →
```

```
INTERNAL CONTROLS
USER:JOHN SMITH
ANALYZER: PASS
CASSETTE: PASS  ← →
```

```
CAL CODE:FG56
CASSETTE LN:L1002
ANALYZER ID:00426
ESC-MAIN MENU  ←
```

INCUBATION MODE

The incubation mode may be Internal (incubation timed by analyzer) or External (incubation timed by user). The user prompts are the same for both modes until the analyzer reaches the “INSERT CASSETTE” screen.

NOTE: The INTERNAL mode is recommended by the manufacturer to ensure proper timing of the assay.

INTERNAL MODE – In this mode, pressing ENTER will prompt the user to add the sample and the analyzer will automatically complete the test. If the sample is not added within 2 minutes, the test is invalidated.



INTERNAL INCUBATION
INSERT CASSETTE
PRESS ENTER
TO CONTINUE

ADD SAMPLE
AND IMMEDIATELY
PRESS ENTER

TEST IN PROCESS
DO NOT REMOVE
CASSETTE
19 MIN 56 SEC

EXTERNAL MODE – In this mode, the user is responsible for timing the incubation and starting the analysis. Upon completion of 20 minute incubation, insert cassette and press ENTER. The analyzer will automatically complete the test. If additional cassettes are run, wait at least 5 minutes before adding sample to the next cassette.



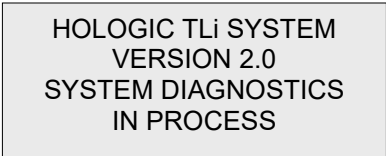
EXTERNAL INCUBATION
WHEN TIME COMPLETE
INSERT CASSETTE
AND PRESS ENTER

TEST IN PROCESS
ANALYZING
DO NOT REMOVE
CASSETTE

SECTION 4 – SOFTWARE FUNCTIONS - DETAILED DESCRIPTIONS

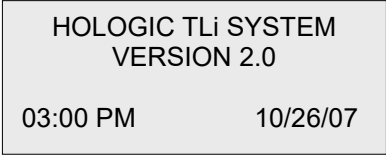
STARTUP SCREEN

When the analyzer is turned on, the screen will display HOLOGIC TLi SYSTEM and the software version, while performing an internal self-test (SYSTEM DIAGNOSTICS).



HOLOGIC TLi SYSTEM
VERSION 2.0
SYSTEM DIAGNOSTICS
IN PROCESS

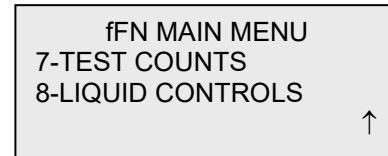
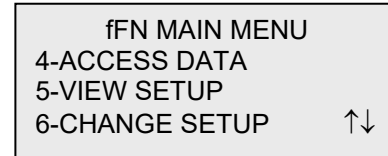
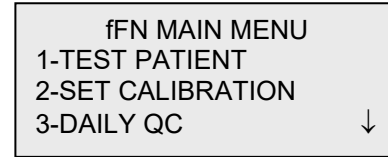
Following the self-test, the analyzer displays the software version and the current date and time for five seconds before displaying the Main Menu.



HOLOGIC TLi SYSTEM
VERSION 2.0
03:00 PM 10/26/07

MAIN MENU

The Main Menu, displayed over three screens, consists of Test Patient, Set Calibration, Daily QC, Access Data, View Setup, Change Setup, Test Counts, and Liquid Controls. Selecting the number in front of each option initiates that procedure or displays a submenu.

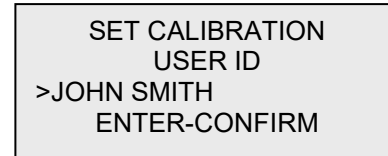
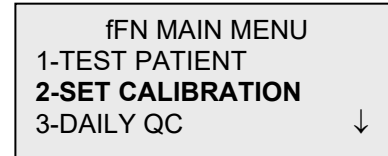


SET CALIBRATION

Option 2 on the Main Menu screen allows the user to set the calibration on the analyzer. Follow the analyzer prompts. Calibration must be set when changing cassette lots.

NOTE: If the calibration has not been set, menu option 2 will flash. Calibration must be set before the analyzer can be used for testing.

The most recent USER ID is always displayed. Press ENTER to accept the ID, or enter a new User ID. This field will accept 15 alpha or numeric characters. To leave this field blank, delete the information using the ← key.



The CASSETTE LOT# must be entered to proceed to the next step. The CASSETTE LOT# is located on the cassette pouch. The software requires that the lot number is entered in the correct format: one alpha character followed by four numeric characters (e.g., L1002).

The CALIBRATION CODE# must be entered to proceed to the next step. The CALIBRATION CODE# is located on the cassette box. The software requires that the code number is entered in the correct format: two alpha characters followed by two numeric characters (e.g., FG56).

NOTE: The calibration code is established by Hologic for each lot of Rapid fFN Cassettes.

Calibration Data Record - This record is displayed over two screens. Each screen can be accessed by using the → and ← keys. The complete record will be printed automatically if AUTOPRINT is set to ON, or it may be printed/reprinted by pressing the PRINT/ENTER key.

```
SET CALIBRATION
CASSETTE LOT#
>L1002
ENTER-ACCEPT
```

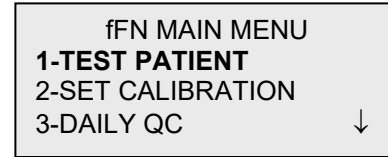
```
SET CALIBRATION
CALIBRATION CODE#
>FG56
ENTER-ACCEPT
```

```
FETAL FIBRONECTIN
03:00 PM          10/26/07
SYSTEM CALIBRATED
USER:JOHN SMITH →
```

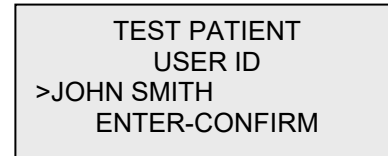
```
CAL CODE:FG56
CASSETTE LN:L1002
ANALYZER ID:00426
ESC-MAIN MENU ←
```

TEST PATIENT (Internal Incubation Mode)

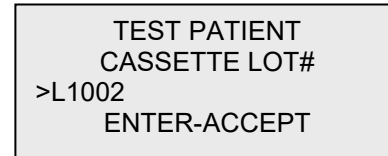
Option 1 on the Main Menu screen allows the user to test a patient sample. Follow the analyzer prompts.



The most recent USER ID is always displayed. Press ENTER to accept the ID, or enter a new User ID. This field will accept 15 alpha or numeric characters. To leave this field blank, delete the information using the ← key.



The CASSETTE LOT# must be entered to proceed to the next step. For convenience, the last 2 numbers only can be entered if the lot has not changed. The CASSETTE LOT# is located on the cassette pouch. The software requires that the lot number is entered in the correct format: one alpha character followed by four numeric characters (e.g., L1002).



The analyzer automatically compares the CASSETTE LOT# used to set calibration with the cassette lot number used for patient testing. If the lot numbers do not match, the test process cannot continue. When this occurs, the cassette lot number used for calibration will be displayed, and the user is prompted to recalibrate the system.

CASSETTE LOT CHANGED
CALIBRATE SYSTEM
L1002
ESC-MAIN MENU

Enter up to 16 alphanumeric characters for a PATIENT ID and press ENTER.

PATIENT ID
>JANE DOE 123

ENTER-ACCEPT

This message will be displayed if a cassette is present in the analyzer prior to reaching the next screen. Remove cassette and press ENTER.

REMOVE CASSETTE

PRESS ENTER
TO CONTINUE

The analyzer then prompts the user to insert cassette and press ENTER.

INTERNAL INCUBATION
INSERT CASSETTE
PRESS ENTER
TO CONTINUE

This message will be displayed if a cassette is not inserted. Press ENTER to return to the previous screen.

CASSETTE NOT
INSERTED

ENTER-CONTINUE

A two-minute timer starts during which time this message flashes and the analyzer beeps. Add patient sample and **immediately** press ENTER.

ADD SAMPLE
AND IMMEDIATELY
PRESS ENTER

If the patient sample is not added and ENTER not pressed within allotted time, the test process cannot continue. This message will be displayed. Press ESC to return to the Main Menu. No record of the test will be held in memory.

SAMPLE NOT ADDED
WITHIN ALLOTTED TIME

ESC-MAIN MENU

Once the sample is added, the analyzer will begin a 20-minute incubation countdown. To abort the test, press ESC. Pressing ESC will terminate the test and the data will be lost.

TEST IN PROCESS
DO NOT REMOVE
CASSETTE
19 MIN 56 SEC

Upon completion of the incubation period, the analyzer will begin the analysis of the cassette. Do not disturb the analyzer until the results are displayed. The analysis will take approximately 2 - 3 minutes.

TEST IN PROCESS
ANALYZING
DO NOT REMOVE
CASSETTE

TEST WARNING: This message will be displayed if ESC was pressed during testing. Lines 1 and 2 will flash prompting the user to select ENTER to continue test, or ESC to end test. This message will hold for 5 seconds and then revert back to its respective screen. If the test is cancelled, a new cassette will be required to repeat the test.

**ARE YOU SURE YOU
WANT TO CANCEL TEST**
ENTER-CONTINUE
ESC-MAIN MENU

Patient Data Record – This record is displayed over three screens. Each screen can be accessed by using the ← and → keys. The complete record will be printed automatically if AUTOPRINT is set to ON, or it may be printed/reprinted by pressing the PRINT/ENTER key.

FETAL FIBRONECTIN
03:00 PM 10/26/07
PT:JANE DOE 123
RESULT:POSITIVE →

Patient results are POSITIVE, NEGATIVE, or INVALID.

An INVALID result should be repeated. (See Section 7, Item 13.)

INTERNAL CONTROLS
USER:JOHN SMITH
ANALYZER: PASS
CASSETTE: PASS ← →

Invalid results will not be stored in memory.

NOTE: Internal Controls are performed automatically during each Rapid fFN test. These internal controls check for (1) a threshold level of signal at the procedural control line, (2) proper sample flow across the Rapid fFN Cassette, (3) absence of conjugate aggregation, and (4) proper functioning of the TLiQ analyzer hardware.

CAL CODE:FG56
CASSETTE LN:L1002
ANALYZER ID:00426
ESC-MAIN MENU ←

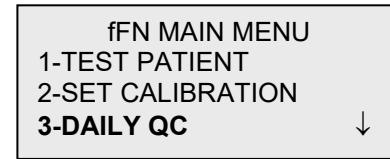
DAILY QC

Prior to running the TLiQ QCette® for the first time, QCette SETUP must be performed. See page 4-29. Refer to the TLiQ QCette directional insert for more information.


Option 3 on the Main Menu screen allows the user to run the QCette.

The most recent USER ID is always displayed. Press ENTER to accept the ID, or enter a new User ID. This field will accept 15 alpha or numeric characters. To leave this field blank, delete the information using the ← key.

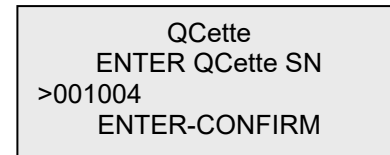
The QCette SN must be entered to proceed to the next step. The serial number is printed on the QCette plastic housing. The software requires that the serial number is entered in the correct format: six numeric characters (e.g., 001004). Enter all leading zeros.



```
fFN MAIN MENU
1-TEST PATIENT
2-SET CALIBRATION
3-DAILY QC
```



```
QCette
USER ID
>JOHN SMITH
ENTER-CONFIRM
```



```
QCette
ENTER QCette SN
>001004
ENTER-CONFIRM
```


This message will be displayed if the QCette serial number entered is not identical to the serial number entered at the time of QCette setup.

```
CASSETTE # CHANGED
NNNNNN
SETUP ANALYZER CTL
ESC-MAIN MENU
```

This message will be displayed if a cassette is present in the analyzer prior to reaching the next screen. Remove cassette and press ENTER.

```
REMOVE CASSETTE

PRESS ENTER
TO CONTINUE
```

The analyzer then prompts the user to insert the QCette and press ENTER.

```
INSERT QCette

ENTER-CONTINUE
```

This message will be displayed if the QCette is not inserted. Press ENTER to continue.

```
CASSETTE NOT
INSERTED

ENTER-CONTINUE
```

A two-minute timer starts during which time this message flashes and the analyzer beeps. Insert the QCette and press ENTER.

INSERT QCette
ENTER-CONTINUE

The analyzer will read the QCette. Do not disturb the analyzer until the results are displayed. The analysis will take approximately 2-3 minutes.

TEST IN PROCESS
ANALYZING
DO NOT REMOVE
CASSETTE

TEST WARNING: This message will be displayed if ESC was pressed during testing. Lines 1 and 2 will flash prompting the user to select ENTER to continue test, or ESC to end test. This message will hold for 5 seconds and then revert back to its respective screen.

```
ARE YOU SURE YOU
WANT TO CANCEL TEST
ENTER-CONTINUE
ESC-MAIN MENU
```

QCette Data Record – This record will be displayed on two screens. Each screen can be accessed by using the ← and → keys. The complete record will be printed automatically if AUTOPRINT is set to ON, or it may be printed/reprinted by pressing the PRINT/ENTER key.

```
QCette
03:00 PM 10/26/07
SYSTEM: PASS
USER:JOHN SMITH →
```

QCette results are SYSTEM PASS, SYSTEM FAIL, or INVALID.

A FAIL or INVALID result should be repeated. (See Section 7, Items 9 and 10.)

```
CAL CODE:FG56
QCette SN:00104
ANALYZER ID:00426
ESC-MAIN MENU ←
```

Invalid results will not be stored in memory.

LIQUID CONTROLS (Internal Incubation Mode)

Option 8 on the Main Menu screen allows the user to run the LIQUID CONTROLS.

The most recent USER ID is always displayed. Press ENTER to accept the ID, or enter a new User ID. This field will accept 15 alpha or numeric characters. To leave this field blank, delete the information using the ← key.

The CASSETTE LOT# must be entered to proceed to the next step. For convenience, the last 2 numbers only can be entered if the lot has not changed. The CASSETTE LOT# is located on the cassette pouch. The software requires that the lot number is entered in the correct format: one alpha character followed by four numeric characters (e.g., L1002).

```
fFN MAIN MENU
7-TEST COUNTS
8-LIQUID CONTROLS ↓
```

```
RUN CONTROL
USER ID
>JOHN SMITH
ENTER-CONFIRM
```

```
RUN CONTROL
CASSETTE LOT#
>L1002
ENTER - ACCEPT
```

The analyzer automatically compares the CASSETTE LOT# used to set calibration with the cassette lot number used for testing controls. If the lot numbers do not match, the test process cannot continue. When this occurs, the cassette lot number used for calibration will be displayed, and the user is prompted to recalibrate the system.

CASSETTE LOT CHANGED
CALIBRATE SYSTEM
L1002
ESC-MAIN MENU

From the CONTROL TEST MENU, select 1-NEGATIVE CONTROL or 2-POSITIVE CONTROL.

CONTROL TEST MENU
1-NEGATIVE CONTROL
2-POSITIVE CONTROL

The most recent CONTROL LOT# is always displayed. Press ENTER to accept the lot number, or enter a new control lot number. This field will accept up to 12 alphanumeric characters.

NEGATIVE CTL LOT#
>M1023

ENTER-CONFIRM

This message will be displayed if a cassette is present in the analyzer prior to reaching the next screen. Remove cassette and press ENTER.

REMOVE CASSETTE
PRESS ENTER
TO CONTINUE

The analyzer then prompts the user to insert the cassette and press ENTER.

INTERNAL INCUBATION
INSERT CASSETTE
PRESS ENTER
TO CONTINUE

This message will be displayed if a cassette is not inserted. Press ENTER to return to the previous screen.

CASSETTE NOT
INSERTED
ENTER-CONTINUE

A two-minute timer starts during which time this message flashes and the analyzer beeps. Add control sample and **immediately** press ENTER.

ADD SAMPLE
AND IMMEDIATELY
PRESS ENTER

If the sample is not added and ENTER not pressed within allotted time, the test process cannot continue. This message will be displayed. Press ESC to return to the Main Menu. No record of the test will be held in memory.

SAMPLE NOT ADDED
WITHIN ALLOTTED TIME

ESC-MAIN MENU

Once the sample is added, the analyzer will begin a 20-minute incubation countdown. To abort the test, press ESC. Pressing ESC will terminate the test and the data will be lost.

TEST IN PROCESS
DO NOT REMOVE
CASSETTE
19 MIN 56 SEC

Upon completion of the incubation period, the analyzer will begin the analysis of the cassette. Do not disturb the analyzer until the results are displayed. The analysis will take approximately 2-3 minutes.

TEST IN PROCESS
ANALYZING
DO NOT REMOVE
CASSETTE

TEST WARNING: This message will be displayed if ESC was pressed during testing. Lines 1 and 2 will flash prompting the user to select ENTER to continue test or ESC to end test. This message will hold for 5 seconds and then revert back to its respective screen. If the test is cancelled, a new cassette will be required to repeat the test.

Liquid Control Data Record - This record is displayed over three screens. Each screen can be accessed by using the ← and → keys. The complete record will be printed automatically if AUTOPRINT is set to ON, or it may be printed/reprinted by pressing the PRINT/ENTER key.

Control results are PASS, FAIL, or INVALID.

A FAIL or INVALID result should be repeated (See Section 7, Items 11 and 12.)

Invalid results will not be stored in memory.

```
ARE YOU SURE YOU
WANT TO CANCEL TEST
ENTER-CONTINUE
ESC-MAIN MENU
```

```
FETAL FIBRONECTIN
03:00 PM          10/26/07
NEG CTL:M1023
RESULT:PASS      →
```

```
INTERNAL CONTROLS
USER:JOHN SMITH
ANALYZER: PASS
CASSETTE: PASS   ← →
```

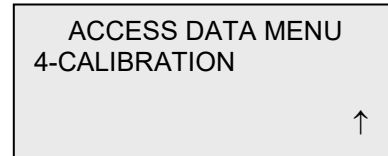
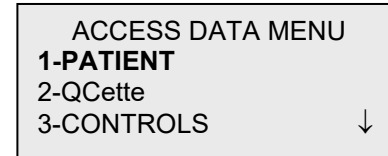
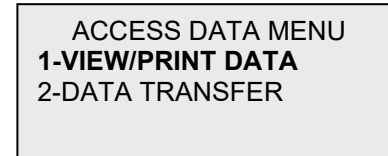
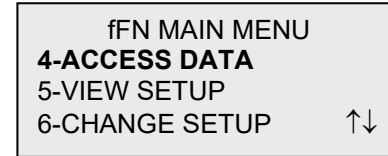
```
CAL CODE:FG56
CASSETTE LN:L1002
ANALYZER ID:00426
ESC-MAIN MENU   ←
```


ACCESS DATA - VIEW/PRINT DATA

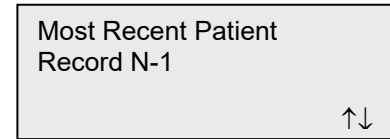
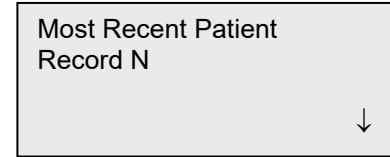
Option 4 on the Main Menu screen allows the user to ACCESS DATA stored in the analyzer.

Select option 1 on the ACCESS DATA MENU for VIEW/PRINT DATA.

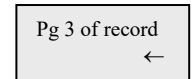
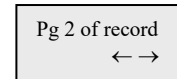
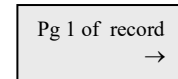
Select the category of data records to view/print. The categories are displayed over two screens. Each screen can be accessed by using ↓ and ↑ keys.



The most recent record for the category of data records selected will be displayed. PATIENT was chosen for this example. Use the ↑ and ↓ keys to view other records in the category.



Use the ← and → keys to view pages within a record.



Printing the record – The record displayed may be printed by pressing the ENTER/PRINT key while in any of the three pages of the record. The full record will be printed on a single label.

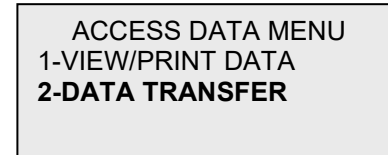
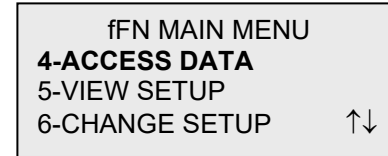
ACCESS DATA - DATA TRANSFER

Option 4 on the Main Menu screen allows the user to ACCESS DATA for data transfer to a computer via an RS232 port.

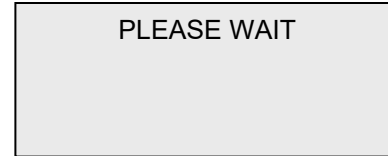
Select option 2 on the ACCESS DATA MENU for DATA TRANSFER.

Connect the appropriate end of the interface cable to the RS232 port (labeled DATA) of the analyzer. Connect the other end of the interface cable to the appropriate port of the laboratory computer.

NOTE: Data transferred to a computer is in ASCII format. Capture and organization of the transferred data is done at the discretion of the user. Hologic Inc. DOES NOT provide software or technical support relating to the manipulation of data once it has left the analyzer.

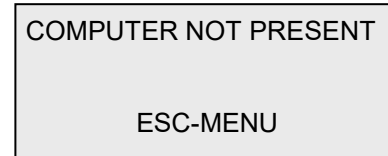


This message will be displayed while the data transfer is in process.

A rectangular box with a black border and a light gray background. The text "PLEASE WAIT" is centered in the box in a black, sans-serif font.

PLEASE WAIT

This message will be displayed if a computer is not attached. Press ESC to return to the ACCESS DATA MENU.

A rectangular box with a black border and a light gray background. The text "COMPUTER NOT PRESENT" is centered in the top half, and "ESC-MENU" is centered in the bottom half, both in a black, sans-serif font.

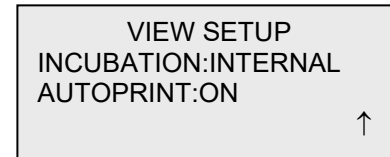
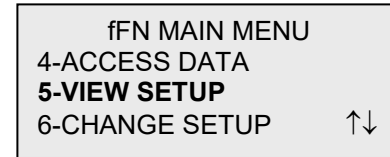
COMPUTER NOT PRESENT

ESC-MENU

VIEW SETUP

Option 5 on the Main Menu screen allows the user to view current settings without editing them.

VIEW SETUP is displayed over two screens. Each screen can be accessed by using ↓ and ↑ keys.

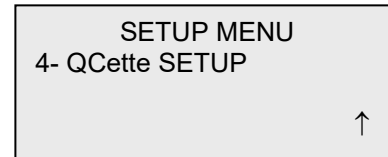
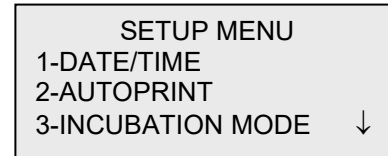
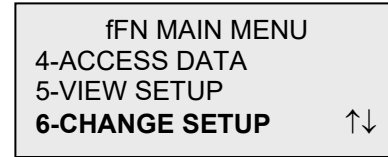


CHANGE SETUP – DATE/TIME

Option 6 on the Main Menu screen allows the user to change the DATE/TIME, Autoprint, or Incubation Mode, or to perform QCette Setup from the SETUP MENU.

The SETUP MENU is displayed over two screens. Each screen can be accessed by using ↓ and ↑ keys.

Select option 1 on the SETUP MENU to change the DATE/TIME.



Enter the date at the cursor position on the SET DATE display.

```
SET DATE
MM/DD/YY
> / /
ENTER-ACCEPT
```

Single digit months and days must be preceded by a zero (e.g., September 9, 2007 will be entered as 09/09/07). Use the ← key to delete incorrect entries. Press ENTER to accept.

```
SET DATE
MM/DD/YY
>09/09/07
ENTER-ACCEPT
```

Select **1** for 12 HOUR (AM/PM) format or **2** for 24 HOUR (Military Time) format on the SET TIME display.

```
SET TIME
1-12 HOUR
2-24 HOUR
```

12 Hour (AM/PM) Format

Enter the time at the cursor position on the TIME display.

Single digit hours or minutes must be preceded by a zero (e.g., 9:09am must be entered as 09:09AM). Use the ← key to delete incorrect entries. Use the ↑↓ keys to choose AM/PM. Press ENTER to accept and return to the SETUP MENU.

24 Hour (Military Time) Format

Enter the time at the cursor position on the TIME display.

Single digit hours or minutes must be preceded by a zero (e.g., 9:09am must be entered as 09:09). Use the ← key to delete incorrect entries. Press ENTER to accept and return to the SETUP MENU.

```
TIME
  : AM
  ↑↓ AM/PM
ENTER-ACCEPT
```

```
TIME
09:09AM
  ↑↓ AM/PM
ENTER-ACCEPT
```

```
TIME
HH:MM
  > :
ENTER-ACCEPT
```

```
TIME
HH:MM
>09:09
ENTER-ACCEPT
```

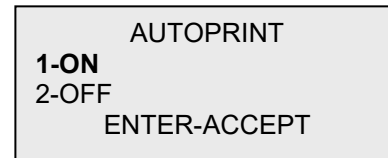
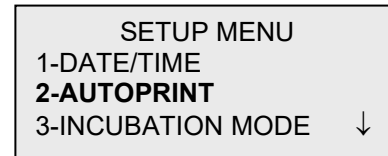
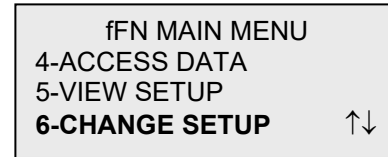

CHANGE SETUP – AUTOPRINT

Option 6 on the Main Menu screen allows the user to change the Date/Time, AUTOPRINT, or Incubation Mode, or to perform QCette Setup from the SETUP MENU.

Select option 2 on the SETUP MENU to change AUTOPRINT.

Autoprint automatically prints test results when set in the ON position. When set in the OFF position, printouts may be obtained by pressing the PRINT/ENTER key.

The current setting will be flashing. Select 1-ON or 2-OFF. Press ENTER to accept and return to the SETUP MENU.



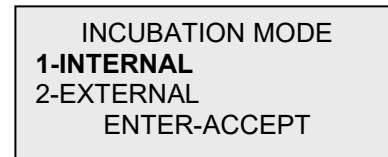
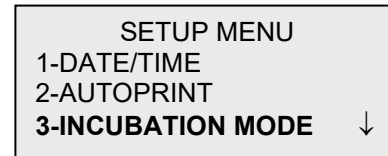
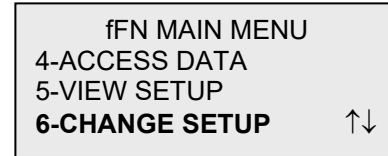
CHANGE SETUP – INCUBATION MODE

Option 6 on the Main Menu screen allows the user to change the Date/Time, Autoprint, or INCUBATION MODE, or to perform QCette Setup from the SETUP MENU.

Select option 3 on the SETUP MENU to change INCUBATION MODE.

In the Internal Mode, the analyzer times the incubation and starts the analysis. External Mode requires the user to manually time the incubation and start the analysis.

The current setting will be flashing. Select 1-INTERNAL or 2-EXTERNAL. Press ENTER to accept and return to the SETUP MENU.



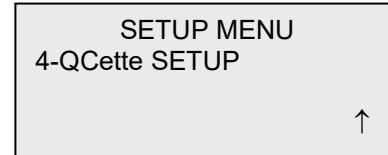
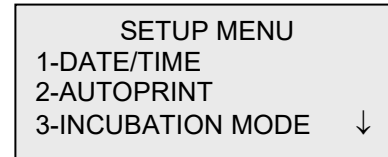
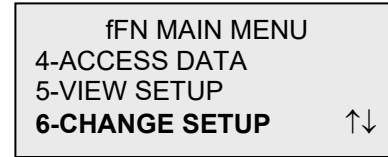
CHANGE SETUP – TLi_Q QCette® SETUP

Option 6 on the Main Menu screen allows the user to change the Date/Time, Autoprint, or Incubation Mode, or to perform QCette SETUP from the SETUP MENU.

The SETUP MENU is displayed over two screens. Each screen can be accessed by using ↓ and ↑ keys.

The QCette SETUP initializes the QCette for use in evaluating the performance of the analyzer. During the initialization process, the performance criteria of the analyzer are established. QCette SETUP must be performed PRIOR to running the QCette as a quality control device.

Select option 4 on the SETUP MENU to begin QCette SETUP.



The most recent USER ID is always displayed. Press ENTER to accept the ID, or enter a new User ID. This field will accept 15 alpha or numeric characters. To leave this field blank, delete the information using the ← key.

```
QCette SETUP
  USER ID
>JOHN SMITH
  ENTER-CONFIRM
```

The QCette SN must be entered to proceed to the next step. The serial number is printed on the QCette plastic housing. The software requires that the serial number is entered in the correct format: six numeric characters (e.g., 001004). Enter all leading zeros.

```
QCette SETUP
  ENTER QCette SN
>001004
  ENTER-CONFIRM
```

This message will be displayed if a cassette is present in the analyzer prior to reaching the next screen. Remove cassette and press ENTER.

```
REMOVE CASSETTE

  PRESS ENTER
  TO CONTINUE
```

The analyzer then prompts the user to insert the QCette and press ENTER. A two-minute timer starts during which time this message flashes and the analyzer beeps. Insert the QCette and press ENTER.

INSERT QCette
ENTER-CONTINUE

This message will be displayed if the QCette is not inserted. Press ENTER to continue. Then insert the QCette and press ENTER.

CASSETTE NOT
INSERTED
ENTER-CONTINUE

The analyzer will begin initializing the QCette. Do not disturb the analyzer until the results are displayed. The initialization process will take approximately 12-15 minutes. Initialization can be terminated by pressing ESC.

INITIALIZING QCette
DO NOT REMOVE
CASSETTE

TEST WARNING: This message will appear if ESC was pressed during testing. Lines 1 and 2 will flash prompting the user to select ENTER to continue test, or ESC to end test. This message will hold for 5 seconds and then revert back to its respective screen.

**ARE YOU SURE YOU
WANT TO CANCEL TEST**
ENTER-CONTINUE
ESC-MAIN MENU

Upon completion of the QCette Setup, this message will be displayed. SETUP COMPLETE indicates that the performance criteria of the analyzer have been established.

QCette
SETUP COMPLETE
ESC-MAIN MENU

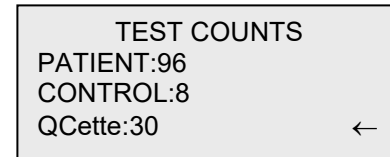
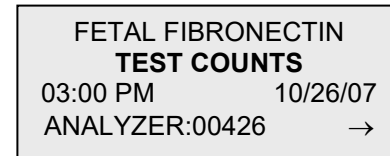
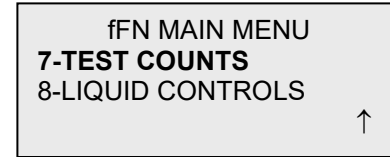
This message will be displayed if the QCette Setup is not completed. SETUP ERROR indicates that the performance criteria of the analyzer have not been established. Please refer to Section 7, Troubleshooting.

QCette
SETUP ERROR
NNNN
ESC-MAIN MENU

TEST COUNTS

Option 7 on the Main Menu screen allows the user to view the number of tests by category that were performed on the analyzer and automatically print a Test Counts Report (TCR).

TEST COUNTS are displayed over two screens. Each screen can be accessed by using the ← and → keys.



SECTION 5 – CARE OF THE ANALYZER

GENERAL CLEANING

Keep the analyzer free of dust. If needed, clean the exterior with a damp cloth and mild detergent.



WARNING: Liquids **MUST NOT** be allowed to seep into the analyzer. Keep the analyzer dry at all times. Liquids leaking into the analyzer may cause damage to the electrical components or possibly electrical shock to the user.

CAUTION: DO NOT use solvents of any type on any part of the analyzer. Solvents can damage the display and keypad.

CLEANING OF CASSETTE INSERTION SITE

The cassette insertion site can come into contact with biological fluids and should be cleaned regularly.

CAUTION: Use appropriate laboratory procedures for handling biohazardous materials.

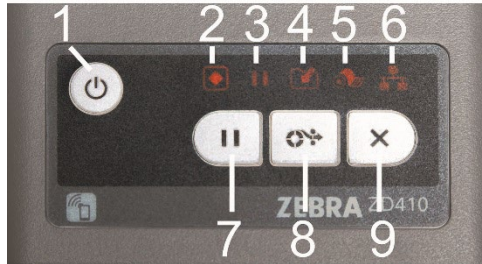
CLEANING AGENTS APPROVED FOR USE

Reagents not listed below may cause discoloration to the analyzer case and membrane keypad.

The following cleaning agents may be applied with a cloth or lab wiper only. NEVER apply agents by spray.

- 10% Bleach
- 75% Isopropyl Alcohol
- BacDown® (disinfectant)

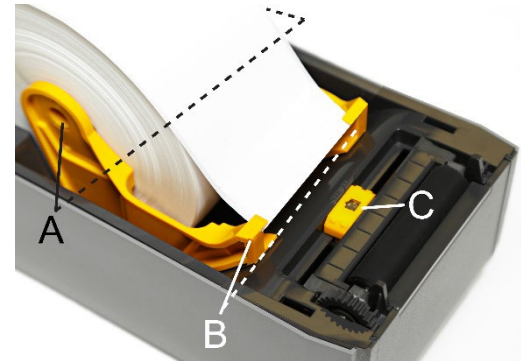
SECTION 6 – PRINTER



1. Printer power button
2. Printer status light
3. Printer pause light
4. Printer data light
5. Printer paper out light
6. Printer network light
7. Printer pause button
8. Printer paper feed button
9. Printer cancel button

LOADING PRINTER LABELS

1. Slide the yellow release latch levers on the sides of the printer cover forward to open the printer cover for access to the interior of the printer. Remove any packing material from the printer and label roll.
2. Pull the yellow holder open (A). Place the roll of labels on the yellow holder with the labels unrolling from the top of the roll. The labels face up.
Use only the printer labels available from Hologic. Printer errors may occur if the wrong labels are used.



3. Confirm that the roll spins easily on the holder. The roll must not touch the bottom of the label roll compartment.
4. Pull the paper beyond the front of the printer and push the paper underneath the guides on the left and right (B). If the yellow sensor is not centered between the arrows on the printer, slide the sensor so that it aligns with the center of the paper (C).
5. Close the printer. Press down in the middle of the cover until it snaps closed.
6. If the printer is turned off, ensure the power cord is connected, and turn on the printer. The printer power button is located on the top left of the printer. The lights will illuminate red. With the new roll of labels installed, the status light and the pause light on the printer will be red. Press the Pause button on the printer to advance the paper. If the status light remains red, press the paper feed button to advance the paper. The printer is ready when the status light is solid green.



REMOVING AN EMPTY LABEL ROLL

When the printer is out of labels, the status light and the paper out light will be solid red.

1. Slide the yellow release latch levers on the sides of the printer cover forward to open the printer cover.
2. Lift the old roll up and out of the holder to remove it. Discard the old roll.
3. Load a new roll of labels (see Loading Printer Labels for instructions), and press the Pause button if it is illuminated.

GENERAL PRINTER CARE AND MAINTENANCE

To turn the printer off, press and hold the printer power button.

The exterior of the printer may be wiped down with a dry cloth.

On the interior of the printer, the area under the paper roll, the roll holder, and the roll guides may be wiped down with a cloth or swab moistened with 99% solution medical-grade alcohol. Debris that is hard to remove may need to be wiped more than once. Wait one minute before closing the printer. Discard the swab or cloth after use.

The groove around the movable sensor may be wiped down with a cloth or swab moistened with 99% solution medical-grade alcohol, but do not wipe the sensor itself. Move the sensor to thoroughly clean the groove.

Remove dust from the interior of the printer cover with a dry cloth. The movable sensor may also be cleaned with a dry cloth.

Do not clean the cutter blade mechanism with any solvent.

SECTION 7 – TROUBLESHOOTING

GENERAL INFORMATION

The TLiQ analyzer software is designed for easy troubleshooting. Always heed the beep tones and follow the display screen prompts to obtain the best performance from your System. The following table lists potential problems, sources of trouble, and recommended solutions. Call Hologic Inc. Technical Service for any questions related to the performance of your TLiQ System.

ITEM	PROBLEM	SOURCE	SOLUTION
1	Analyzer display screen is blank.	Analyzer Power Cord and Adapter ON/OFF Switch	Ensure analyzer power cord is firmly connected to analyzer. Ensure analyzer power adapter is plugged into a grounded AC electrical outlet. Ensure analyzer ON/OFF switch is in ON position.
2	Error Code is displayed when analyzer is first turned on.	Analyzer	Turn analyzer off and back on to reinitialize the system. If the Error Code persists, refer to Error/Invalid Code table.

ITEM	PROBLEM	SOURCE	SOLUTION
3	Analysis process is interrupted and/or unusual characters appear on display screen, and the analyzer does not respond to keypad inputs.	Electrostatic Discharge	Turn analyzer off and back on to reinitialize the system. Proceed with testing.
4	Printer fails to print.	<p>Printer Power Cord</p> <p>ON/OFF Button</p> <p>Printer Cable</p> <p>Printer Labels</p>	<p>Ensure printer power cord is firmly connected to printer.</p> <p>Ensure printer power cord is plugged into a grounded AC electrical outlet.</p> <p>Ensure green status light is lit. This indicates printer is ready.</p> <p>Ensure printer cable is connected to the printer and the analyzer.</p> <p>Ensure printer is not out of printer labels. Ensure that the labels in the printer are the labels provided by Hologic. Ensure that the labels are loaded properly. To order printer labels, contact Hologic Inc.</p>

ITEM	PROBLEM	SOURCE	SOLUTION
5	Printer not on when test was run.	Printer	Turn printer on. Recall the test result on the analyzer display screen. Press PRINT/ENTER on the analyzer to print the result.
6	Printer output in unusual font.	Printer	Turn analyzer and printer off and back on.
7	Analyzer turned off after calibration, or power failure occurred after calibration.	Power	The calibration remains in memory. Reset calibration only if prompted by analyzer.
8	Cassette cannot be removed.	Analyzer	Turn analyzer off and back on to reinitialize the system.

ITEM	PROBLEM	SOURCE	SOLUTION
9	TLi _Q QCette failed to complete setup.	TLi _Q QCette Analyzer	Ensure QCette is clean and not damaged. Repeat TLi _Q QCette setup as described in Section 4. If the QCette setup fails a second time, call technical service. Turn analyzer off and back on to reinitialize the system. Repeat TLi _Q QCette setup as described in Section 4. If the QCette setup fails a second time, call technical service.
10	TLi _Q QCette failed during daily quality control.	TLi _Q QCette Analyzer	Ensure QCette is clean and not damaged. Repeat TLi _Q QCette daily quality control as described in Section 4. If the QCette testing fails a second time, call technical service. Turn analyzer off and back on to reinitialize the system. Repeat TLi _Q QCette daily quality control as described in Section 4. If the QCette testing fails a second time, call technical service.

ITEM	PROBLEM	SOURCE	SOLUTION
11	Liquid control failed.	Liquid Control	<p>Review the control procedures and repeat the test.</p> <p>Verify the control has not expired, and is neither cloudy nor discolored.</p> <p>If the control fails a second time, call technical service.</p>
12	Invalid liquid control test result.	<p>Analyzer Internal Controls: Analyzer Fail/Cassette Pass</p> <p>Analyzer Internal Controls: Analyzer Pass/Cassette Fail</p>	<p>Refer to Error/Invalid Code table.</p> <p>Run TLI_Q QCette to verify analyzer is functioning properly.</p> <p>Do not bump or jar analyzer during the test.</p> <p>Review the Rapid fFN Cassette Kit directional insert to ensure the correct procedure was followed.</p> <p>Examine the cassette. Cassette imperfection may cause an invalid test result. Rerun control on a fresh cassette.</p>

ITEM	PROBLEM	SOURCE	SOLUTION
13	Invalid patient test result.	<p>Analyzer Internal Controls: Analyzer Fail/Cassette Pass</p> <p>Analyzer Internal Controls: Analyzer Pass/Cassette Fail</p>	<p>Refer to Error/Invalid Code table.</p> <p>Run TLI_Q QCette to verify analyzer is functioning.</p> <p>Do not bump or jar analyzer during the test.</p> <p>Review the Rapid fFN Cassette Kit directional insert to ensure the correct procedure was followed.</p> <p>Examine the cassette. Viscous patient samples that flow slowly may require testing by an alternate format such as the fFN Enzyme Immunoassay.</p> <p>Examine the cassette. Cassette imperfection may cause an invalid test result. Rerun patient sample on a fresh cassette.</p>
14	Computer not present message appears.	Data Transfer	Refer to Section 4, pp. 21, 22.

ERROR/INVALID CODES

ERROR CODE	DEFINITION	TROUBLE SHOOTING PROCEDURE
720, 721	Possible Motor Problem	Turn analyzer off and back on to reinitialize the system. If error code persists, call technical service.
621, 622	Possible Optics Problem	Turn analyzer off and back on to reinitialize the system. If error code persists, call technical service.
Other Codes		Call technical service

SECTION 8 – SERVICE AND WARRANTY

TECHNICAL SERVICE

Analyzer

The TLI_Q analyzer is a self-contained instrument. There are no user-serviceable parts. With proper care and use, the analyzer should operate reliably with minimal attention. If a problem should occur, refer to Section 7, Troubleshooting. For analyzer service, call Hologic Technical Service.

Printer

The printer is a self-contained instrument. If a problem should occur, refer to Section 7, Troubleshooting. For printer service, call Hologic Technical Service.

CONTACT INFORMATION

Hologic Inc.
10210 Genetic Center Drive
San Diego, CA 92121 USA
www.Hologic.com

TECHNICAL SERVICE (USA/Canada)

Tel: 1-800-442-9892
+1 (508) 263-2900
Fax: 1-508-263-2967
E-mail: TechSupport@Hologic.com

Replacement Parts

Item	Catalog Number
Printer	ASY-16893
Printer Labels	LBL-05818
TLiQ QCette®	01175
User Manual	MAN-07697-001

Contact fFN Customer Service to order replacement parts.

CONTACT INFORMATION

fFN CUSTOMER SERVICE (USA/Canada)

Tel: 1-800-442-9892
+1 (508) 263-2900
Fax: 1-508-229-2860

TLiQ® System

Analyzer Serial Number _____

Printer Serial Number _____

Shipment Date _____

MANUFACTURER'S WARRANTY

Hologic Inc. warrants to the original purchaser that this system will be free from defects in materials and workmanship for a period of one (1) year from shipment date (except as noted below). During the stated one-year period, Hologic Inc. shall, at its option, replace with a new unit, reconditioned unit, or repair at no charge a unit that is found to be defective.

This warranty is subject to the following exceptions and limitations:

1. This warranty is limited to repair or replacement due to defects in parts or workmanship. Hologic Inc. shall not be required to make any repairs or replacements which are necessitated by abuse, accidents, alterations, misuse, neglect, maintenance by other than Hologic Inc., or failure to operate the system in accordance with manufacturer's instructions. Further, Hologic Inc. assumes no liability for malfunction or damage to the system caused by the use of reagents other than reagents manufactured or recommended by Hologic Inc.

2. Hologic Inc. reserves the right to make changes in the design of this system without obligation to incorporate such changes into previously manufactured systems.

Disclaimer of Warranties

THIS WARRANTY IS EXPRESSLY MADE IN LIEU OF ANY AND ALL OTHER WARRANTIES EXPRESS OR IMPLIED (EITHER IN FACT OR BY OPERATION OF LAW) INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR USE WHICH ARE EXPRESSLY EXCLUDED, AND IS THE ONLY WARRANTY GIVEN BY HOLOGIC INC.

Limitations of Liability

IN NO EVENT SHALL HOLOGIC INC. BE LIABLE FOR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF HOLOGIC INC. HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

For warranty service and extended warranty service, purchaser must contact the Technical Service Department of Hologic Inc. by calling 1-800-442-9892 for assistance and/or instructions for obtaining repair of the system.