HOLOGIC®

TLi$_{IQ}$® Installation Training

RapidfFN

Protocol

- The installation protocol is designed to establish and verify the performance of the TLi$_{IQ}$® system.

- Please read through the installation protocol before beginning analyzer setup and verification, running the daily QC, liquid controls and the 20 correlation samples.

Materials (1/2)

Provided by Hologic:

- Rapid fFN® Cassettes
- Rapid fFN® Control Kit
- TLi_{IQ}® QCette® QC Device
- Clinical Correlation Kit
  - The samples in this kit **MUST BE REFRIGERATED** upon receipt. **DO NOT FREEZE**.
  - These are pooled samples that have been previously tested for fFN (fetal fibronectin).
  - **USE WITHIN 7 DAYS OF RECEIPT.**

Materials (2/2)

Provided by the laboratory:

- Pipette capable of delivering **200 µL**
- Disposable pipette tips
- Laboratory wipes
- Gloves
- Tube racks to hold 20 specimen tubes
- Timer
- Permanent marker

Setting up the Analyzer

Following the directions in the TLi$_{IQ}$® System User Manual, unpack the TLi$_{IQ}$® analyzer and printer — see Sections 2-1 – 2-5 in the TLi$_{IQ}$® Operator's Manual.

- Carefully remove the analyzer and accessories from the shipping carton.
- Inspect the carton for damage.
- The carton should contain:
  1. TLi$_{IQ}$® System
  2. Power Adapter
  3. User Manual
  4. TLi$_{IQ}$® QCette® QC Device

NOTE: Retain the carton in case the analyzer needs to be returned.

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Setting up the Printer

- Carefully remove the printer and accessories from the shipping carton.
- Inspect the carton for damage.
- The printer should contain the following:
  1. Printer (shown with cover open)
  2. Printer labels (one roll)
  3. Power cord
  4. Power supply with AC connector
  5. Printer cable

NOTE: Retain the carton in case the printer needs to be returned.

Connecting the Analyzer to the Printer

- Connect the 9-pin connector of the printer cable to the analyzer and the modular jack to the printer.
- Connect the small connector of the analyzer power adapter to the analyzer and the larger power connector to a grounded AC electrical outlet.
- Connect the small connector from the printer power supply to the printer. Plug the printer power supply into a grounded AC electrical outlet.

System

Printer

Analyzer

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Stepwise Procedure: Analyzer Setup & Verification

- Turn on the analyzer using the on/off switch located on the left side of the analyzer.
- The screen will display SYSTEM DIAGNOSTICS – IN PROCESS.
- If the analyzer fails the self-test, a beep will sound, otherwise the analyzer will go to the next screen.
- If an error code is displayed, refer to the User Manual, Section 7: Troubleshooting.
- Once SYSTEM DIAGNOSTICS have been completed, the display will show the software VERSION and the DATE and TIME for five seconds and then the fFN main menu.
- The date and time will need to be reset for your time zone. Refer to the User Manual, Section 2-6 for setting the date and time. **(6 – Change Setup, 1 – Date time)**
- Turn on the printer by pressing the power button. ⏻
- Ensure labels are in the printer. Status light on the printer will change from red to green. See Section 6 in the User Manual for loading printer labels.

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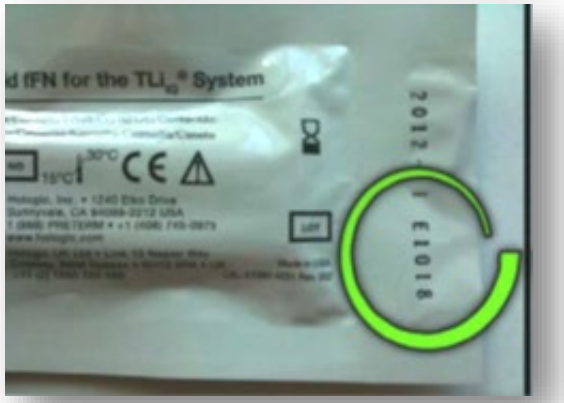
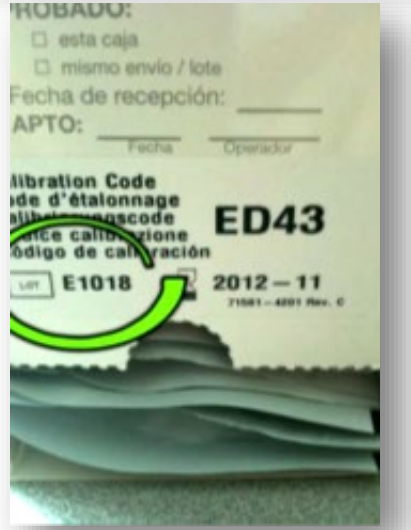
To Set the Autoprint Feature

1. Go to fFN main menu (press ESC to go to this screen)
2. Use ↓ to go to the next page
3. Press 6 CHANGE SETUP
4. Press 2 AUTOPRINT
5. Press 1 to turn ON, Press 2 to turn OFF
6. Press ENTER to accept this choice
7. Press ESC to return to fFN main menu

Setting Calibration (1/2)

- From main menu, press 2 to select SET CALIBRATION.
- Enter USER ID (Refer to the User Manual section on keypad functions (Section 1) to enter the desired alpha or numeric characters needed) and press ENTER.
- Enter the **CASSETTE LOT #** found on the cassette pouch (green circle) or on the side of the cassette box, and press ENTER. The lot number must be entered to proceed to the next step. The software requires that the lot number is entered in the correct format: one alpha character followed by 4 numeric characters (e.g, E1018).





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Setting Calibration (2/2)

- Enter the **CALIBRATION CODE #** (on cassette box label) and press ENTER. The code number must be entered to proceed to the next step.
- ***NOTE: Specific calibration codes are established during manufacturing for each lot of Rapid fFN® cassettes.***
- 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.
- Attach the calibration result label to the TLi_{IQ}® System Verification Results, Appendix I.

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TLi$_{IQ}$® QCette® Setup

Prior to running the TLi$_{IQ}$® QCette® QC Device for the first time, QCette setup must be performed:

- Select option 6, Change Setup on the main menu and then press option 4, 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 alphanumeric characters. To leave this field blank, delete the information using the ← key.
- QCette QC Device serial number (SN) must be entered to proceed to the next step. The serial number is printed on the QCette® plastic housing (green circle).
- The software requires that the serial number is entered in the correct format: six numeric characters (e.g., 011120). Make sure to enter all leading zeros.
- After you enter the serial number, the analyzer will prompt you to insert the Qcette QC Device – this cycle will take about 7-10 minutes.
- Note: No label will print for this action.

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QCette® QC Device Daily QC

After the Qcette QC Device has been set up, you need to complete daily calibration

- Select option 3 from main menu to run the daily QCette® calibration.
- The analyzer will then prompt the user to insert the Qcette QC Device and press ENTER. A two-minute timer starts during which time the display flashes and the analyzer beeps.
- Insert the Qcette QC Device and press ENTER.
- Do not disturb the analyzer until the results are displayed. Analysis takes 2-3 minutes.
- After QCette® analysis, the results will be displayed across 2 screens. Each screen can be accessed 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® results are SYSTEM PASS, SYSTEM FAIL or INVALID.
- Attach the Qcette® result label to the TLi_{IQ}® System Verification Results, Appendix I.
- Return the Qcette QC Device to its box and Press ESC to return to the main menu.

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Liquid Controls (1/2)

To run Liquid Controls, you must set internal incubation and ensure they are at room temperature.

- Remove the box of Rapid fFN® controls from the refrigerator.
- Roll the Rapid fFN controls gently between the palms to mix.
- To set to internal incubation:
  1. Go to fFN main menu (press ESC to go to this screen)
  2. Use ↓ to go to the next page
  3. Press 6 CHANGE SETUP
  4. Press 3 INCUBATION MODE
  5. Press 2 to set as INTERNAL INCUBATION
  6. Press ENTER to accept this choice
  7. Press ESC to return to fFN main menu

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Liquid Controls (2/2)

- From main menu screen press ↓ twice to go to next page, then 8 to run the LIQUID CONTROLS.
- Most recent USER ID is always displayed. Press ENTER to accept the ID or enter a new User ID. This field will accept 15 alphanumeric 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 can only 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: 1 alpha character followed by 4 numeric characters (e.g., L1002).

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Liquid Controls – Negative (1/2)

- From the CONTROL TEST MENU select 1-NEGATIVE CONTROL. The most recent CONTROL LOT# for the liquid control is always displayed.
- Press **ENTER** to accept the lot number or enter the new control lot number **(this alphanumeric ID is printed on the individual bottles – NOT on the box).**

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Liquid Controls – Negative (2/2)

- Open a cassette package and label it "negative control". Add 200 µL of control sample into the round well of the cassette, insert it into the analyzer & press ENTER.
  - Discard the used pipette tip.
  - Set on internal incubation, the timer will begin the 20-minute incubation countdown.
- Upon completion of the 20-minute incubation, the analyzer will begin analysis of the cassette. Do not disturb until the results are displayed. The analysis will take approximately 2-3 minutes.
- After analysis, the complete record will be printed automatically if AUTOPRINT is ON.
  - Control results are PASS, FAIL or INVALID.
  - Attach the control result label to the TLi_{IQ}® System Verification Results, Appendix I.

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Liquid Controls – Positive

- From CONTROL TEST MENU select 2-POSITIVE CONTROL. The most recent CONTROL LOT# for the liquid control is always displayed.
- Press **ENTER** to accept the lot number or enter the new control lot number (this alphanumeric ID is printed on the individual bottles – NOT on the box).
- Repeat the process for the positive control by selecting 2-POSITIVE CONTROL on the instrument and using a new pipette tip to deliver 200 µL of positive control into the well of a new cassette labeled "positive control".

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Patient Testing (1/3)

Note: Handle the specimen transport tube and all patient samples as potentially infectious.

- From the main menu, press 1 to select TEST PATIENT.
- Enter USER ID and press ENTER.
- Enter the last 2 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.

Patient Testing (2/3)

- Enter up to 16 alphanumeric characters for a PATIENT ID and press ENTER.
- Insert cassette and press ENTER.
  - Gently mix the specimen transport tube prior to removing the swab.
  - Express as much liquid as possible from the swab by rolling the tip against the side of the tube. Dispose of the used swab in a manner consistent with handling biohazardous material.
- Add sample and **immediately** press ENTER.

Patient Testing (3/3)

- The analyzer will begin a 20-minute incubation countdown.
- Following incubation, the analyzer will begin analyzing the cassette.
- 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.
- Press ESC to return to the main menu.

Next Step: Run Clinical Correlation Kit Samples

If calibration and all QC pass, then Clinical Correlation Kit Samples may be run.

Please refer to the CCK PowerPoint presentation:

"Clinical Correlation Kit for Use in the Verification of Performance of the Rapid fFN® for the TLi$_{IQ}$® System"

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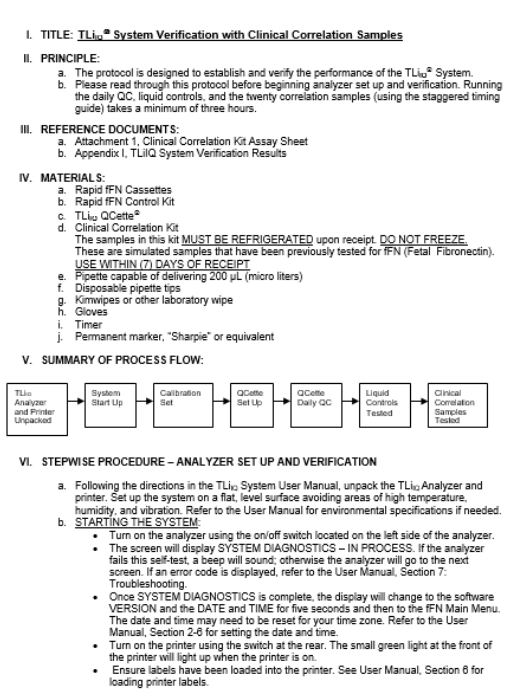
Reference Documents

- TLi_{IQ}® System Verification with Clinical Correlation Samples
- TLi_{IQ}® System Verification Results
- Clinical Correlation Kit Expected Results Table



I. **TITLE:** TLiIQ® System Verification with Clinical Correlation Samples

II. **PRINCIPLE:**
a. The protocol is designed to establish and verify the performance of the TLiIQ® System.
b. Please read through this protocol before beginning analyzer set up and verification. Running the daily QC, liquid controls, and the twenty correlation samples (using the staggered timing guide) takes a minimum of three hours.

III. **REFERENCE DOCUMENTS:**
a. Attachment 1, Clinical Correlation Kit Assay Sheet
b. Appendix I, TLiIQ System Verification Results

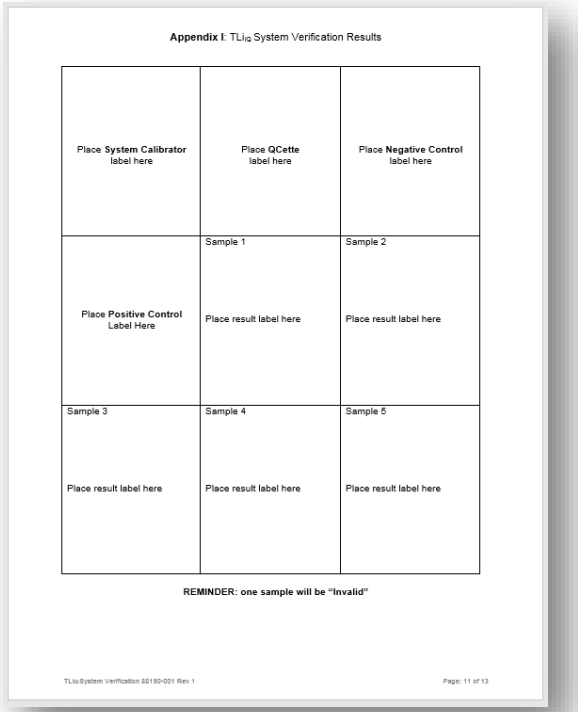
IV. **MATERIALS:**
a. Rapid fFN Cassettes
b. Rapid fFN Control Kit
c. TLiIQ QCette®
d. Clinical Correlation Kit
The samples in this kit MUST BE REFRIGERATED upon receipt. DO NOT FREEZE.
These are simulated samples that have been previously tested for fFN (Fetal Fibronectin).
USE WITHIN (7) DAYS OF RECEIPT
e. Pipette capable of delivering 200 µL (micro liters)
f. Disposable pipette tips
g. Kimwipes or other laboratory wipe
h. Gloves
i. Timer
j. Permanent marker, "Sharpie" or equivalent

V. **SUMMARY OF PROCESS FLOW:**

TLiIQ Analyzer and Printer Unpacked → System Start Up → Calibration Set → QCette Set Up → QCette Daily QC → Liquid Controls Tested → Clinical Correlation Samples Tested

VI. **STEPWISE PROCEDURE – ANALYZER SET UP AND VERIFICATION**

a. Following the directions in the TLiIQ System User Manual, unpack the TLiIQ Analyzer and printer. Set up the system on a flat, level surface avoiding areas of high temperature, humidity, and vibration. Refer to the User Manual for environmental specifications if needed.
b. STARTING THE SYSTEM:
- Turn on the analyzer using the on/off switch located on the left side of the analyzer.
- The screen will display SYSTEM DIAGNOSTICS – IN PROCESS. If the analyzer fails this self-test, a beep will sound; otherwise the analyzer will go to the next screen. If an error code is displayed, refer to the User Manual, Section 7: Troubleshooting.
- 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 fFN Main Menu. The date and time may need to be reset for your time zone. Refer to the User Manual, Section 2-6 for setting the date and time.
- Turn on the printer using the switch at the rear. The small green light at the front of the printer will light up when the printer is on.
- Ensure labels have been loaded into the printer. See User Manual, Section 6 for loading printer labels.



Appendix I: TLiIQ System Verification Results

Place **System Calibrator** label here	Place **QCette** label here	Place **Negative Control** label here
Place **Positive Control** Label Here	Sample 1 Place result label here	Sample 2 Place result label here
Sample 3 Place result label here	Sample 4 Place result label here	Sample 5 Place result label here

REMINDER: one sample will be "Invalid"

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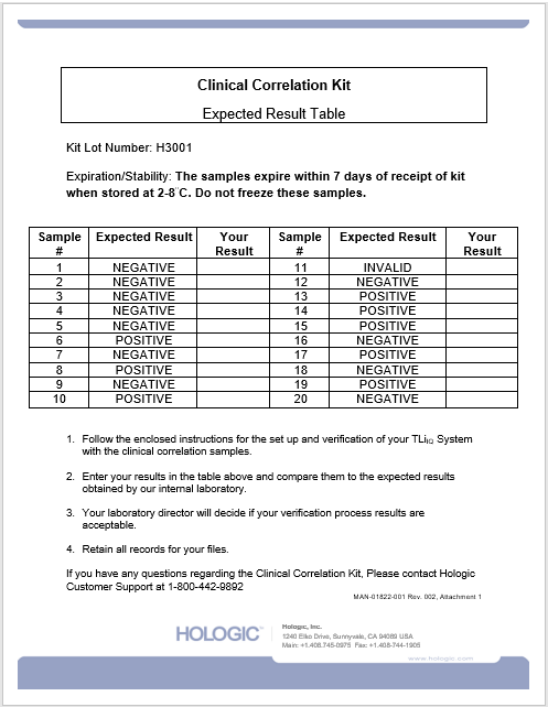

Clinical Correlation Kit
Expected Result Table

Kit Lot Number: H3001

Expiration/Stability: **The samples expire within 7 days of receipt of kit when stored at 2-8˚C. Do not freeze these samples.**

Sample #	Expected Result	Your Result	Sample #	Expected Result	Your Result
1	NEGATIVE		11	INVALID	
2	NEGATIVE		12	NEGATIVE	
3	NEGATIVE		13	POSITIVE	
4	NEGATIVE		14	POSITIVE	
5	NEGATIVE		15	POSITIVE	
6	POSITIVE		16	NEGATIVE	
7	NEGATIVE		17	POSITIVE	
8	POSITIVE		18	NEGATIVE	
9	NEGATIVE		19	POSITIVE	
10	POSITIVE		20	NEGATIVE	

1. Follow the enclosed instructions for the set up and verification of your TLiIQ System with the clinical correlation samples.
2. Enter your results in the table above and compare them to the expected results obtained by our internal laboratory.
3. Your laboratory director will decide if your verification process results are acceptable.
4. Retain all records for your files.

If you have any questions regarding the Clinical Correlation Kit, Please contact Hologic Customer Support at 1-800-442-9892

MAN-01822-001 Rev. 002, Attachment 1

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