HOLOGIC®

Using Rapid fFN® Controls for Verification of the Rapid fFN® for the TLi_{IQ}® System

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Purpose

The protocol is designed to establish and verify the performance of the TLi$_{IQ}$® System using Rapid fFN® Controls upon initial installation of the system.

The Rapid fFN for the TLi$_{IQ}$® System is an *in vitro* diagnostic device for the detection of fetal fibronectin in cervicovaginal secretions.

Summary and Explanation

The Rapid fFN® Controls are Quality Control samples of known values and provide a means of meeting the requirements of:

1. The Clinical Laboratory Improvement Amendments (CLIA)
2. Laboratory regulatory agencies for instrument performance verification.

Warnings

- Please read through this protocol before beginning analyzer setup and verification. Running the daily QC, liquid controls, twenty samples (using the staggered timing guide) takes a minimum of three hours.
- Follow universal precautions and institutional guidelines for the handling of potentially infectious materials, including the use of protective gloves.

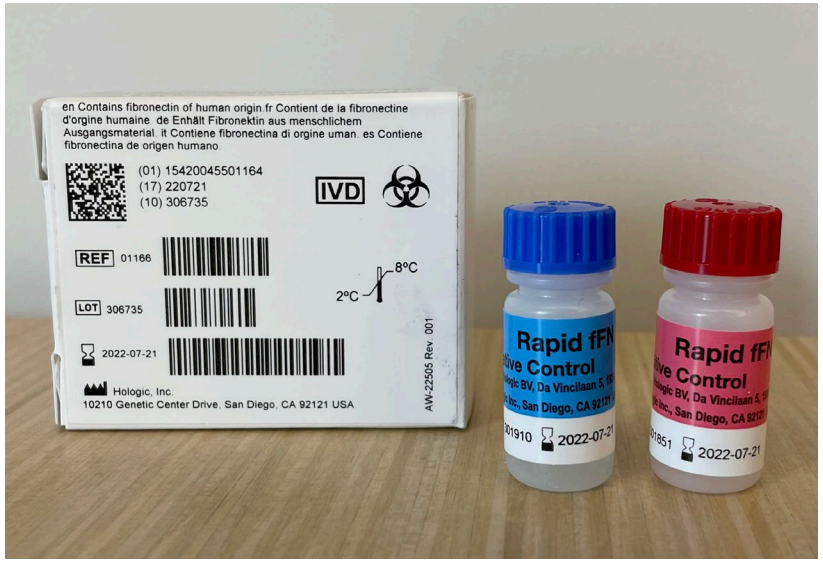
❖ ***NOTE: follow the warnings indicated in the Rapid fFN® Controls package insert.***

Storage Conditions

- Store Rapid fFN® Controls samples between 2°C – 8°C.

Materials Needed

1. Rapid fFN Cassettes
2. Rapid fFN Control Kit (x2)
3. TLi_{IQ} QCette®
4. Pipette capable of delivering 200 µL (microliters)
5. Disposable pipette tips
6. Laboratory wipes
7. Gloves
8. Timer
9. Permanent marker



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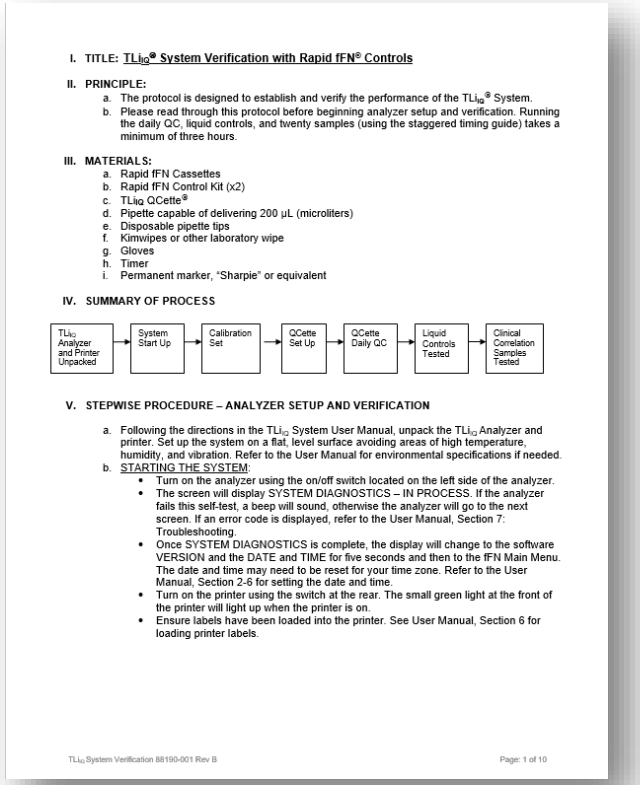
Reference Documents

- TLi$_{IQ}$® System Verification with Rapid fFN® Controls
- TLi$_{IQ}$® System Verification Results Table



I. TITLE: TLi$_{IQ}$® System Verification with Rapid fFN® Controls

II. PRINCIPLE:
a. The protocol is designed to establish and verify the performance of the TLi$_{IQ}$® System.
b. Please read through this protocol before beginning analyzer setup and verification. Running the daily QC, liquid controls, and twenty samples (using the staggered timing guide) takes a minimum of three hours.

III. MATERIALS:
a. Rapid fFN Cassettes
b. Rapid fFN Control Kit (x2)
c. TLi$_{IQ}$ QCette®
d. Pipette capable of delivering 200 µL (microliters)
e. Disposable pipette tips
f. Kimwipes or other laboratory wipe
g. Gloves
h. Timer
i. Permanent marker, "Sharpie" or equivalent

IV. SUMMARY OF PROCESS

TLi$_{IQ}$ Analyzer and Printer Unpacked → System Start Up → Calibration Set → QCette Set Up → QCette Daily QC → Liquid Controls Tested → Clinical Correlation Samples Tested

V. STEPWISE PROCEDURE – ANALYZER SETUP AND VERIFICATION

a. Following the directions in the TLi$_{IQ}$ System User Manual, unpack the TLi$_{IQ}$ 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.

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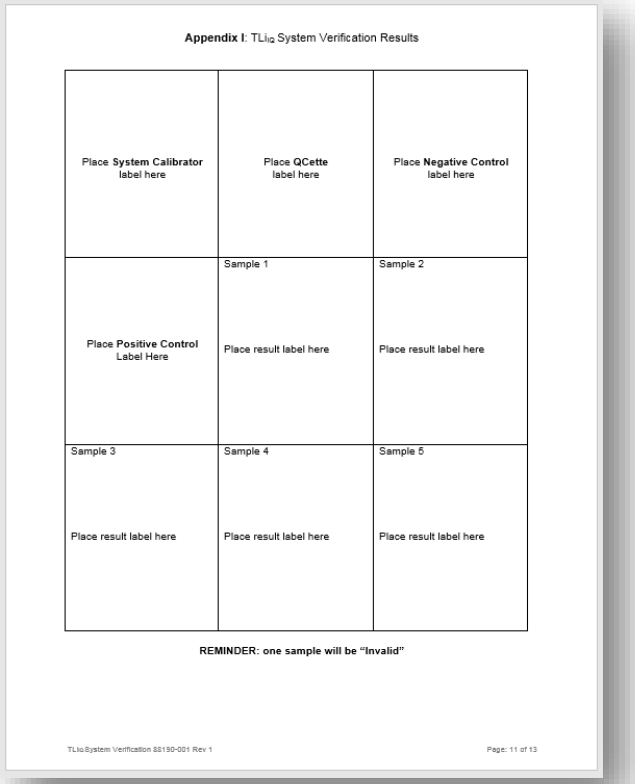

Appendix I: TLi$_{IQ}$ System Verification Results

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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Controls Sample Testing

Use a second box of Rapid fFN® Controls, separate from the box used to calibrate cassettes, and the documents provided to verify your TLi_{IQ}® System.

- ***NOTE: follow the warnings indicated in the Rapid fFN Controls package insert.***

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Controls Sample Testing

- Remove the box of Rapid fFN® Controls from the refrigerator.
- Roll the Rapid fFN Controls gently between the palms to mix.
- Each sample takes 20 minutes incubation plus 2-3 minutes of actual analysis
- It is most efficient to **set the system to external incubation**. This allows the operator to have time-staggered samples by incubating in cassettes on the lab benchtop while another cassette is being read by the analyzer.

Controls Sample Testing

- To set **external incubation**, perform the following steps:
    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 EXTERNAL INCUBATION
    6. Press ENTER to accept this choice
    7. Press ESC to return to fFN Main Menu

Controls Sample Testing

Follow these steps to test the controls

- Set TLi$_{IQ}$® to **external** incubation. Confirm AUTOPRINT is on.
- Assemble materials for testing: negative fFN control, positive fFN control, fFN cassettes, pipette and tips, laboratory wipes or gauze and gloves.
- Each sample will be tested using 1-TEST PATIENT from the fFN main menu. Press ESC to return to fFN main menu. Press 1 to select this mode. Enter USER ID and press ENTER.
- Enter the last 2 digits of the CASSETTE LOT# and press ENTER.

Controls Sample Testing

Follow these steps to test the controls

- Enter the sample ID#. Use the numbers 1-20 to designate each tube for testing. Start with tube 1. Enter 1 and press **ENTER.**
- Test 5 negative controls, followed by 10 positive control samples, and then another 5 negative samples or use the order specified by the Lab Director
- The analyzer should display the following message:

  EXTERNAL INCUBATION
  WHEN TIME COMPLETE
  INSERT CASSETTE

- Unwrap and then label the cassette with the sample ID using a permanent marker. Prepare to pipette the sample; place a clean tip on the pipette.

Controls Sample Testing

Follow these steps to test the controls

- Pipette 200 µL of sample and add sample immediately to the well of the cassette. Do **NOT** insert the cassette into the analyzer.
- Start the timer by pressing the timer START/STOP button. The timer will not be touched again until the correlation sample testing is complete.
- Eject the pipette tip and load a clean tip onto the pipette in preparation for the next sample (#2)
- When the timer reaches almost six minutes, unwrap another cassette. Label as "2".

Controls Sample Testing

Follow these steps to test the controls

- When the timer reads **six minutes**, aspirate 200 µL of sample 2 into the pipette tip. Add sample immediately to the well of the cassette. Leave on the benchtop.

- Continue this process of labeling a cassette, pipetting a new sample into the cassette (and leaving it to incubate on the benchtop), and discarding the used pipette tip every six minutes.

- All 20 samples can be set up in this staggered manner or sets of 4 or 5 can be set up in a staggered manner with the same six-minute separation between samples.

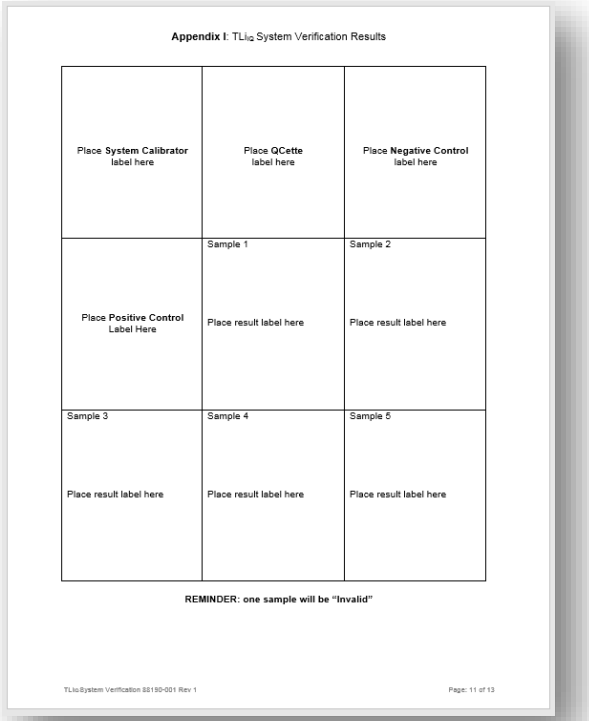
Controls Sample Testing

To simplify this method of staggered sample testing for all 20 samples, use the timing guide found in the documentation provided by Hologic. The guide will help remind you when samples need to be pipetted into specific cassettes and when the cassettes are ready to be read.

- ***NOTE: Cassettes must be read within twenty minutes of having samples pipetted into their wells. Prolonged incubation may result in an erroneous result.***

Controls Sample Testing

As the cassettes are read by the TLi_{IQ} Analyzer, the results will print out via the label printer. Affix the labels in consecutive order to the TLi_{IQ} System Verification Results document, in Appendix I.



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REMINDER: one sample will be "Invalid"

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Critical: Change TLi_{IQ}® Back to **Internal** Incubation

- To set **internal incubation** perform the following steps:
  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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Questions?

The laboratory director or designee will determine if the verification process is acceptable. Retain all records of this verification.

If you have questions regarding billing, invoices or shipment of product please contact Customer Support at 1(800)442-9892.

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Technical Support and Kit Information

Technical Support:

Hologic, Inc.
PHONE: 1-800-442-9892
EMAIL: TechSupport@hologic.com

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