Clinical Correlation Kit for Use in the Verification of Performance of the Rapid fFN® for the TLiIQ® System
Purpose

The Clinical Correlation Kit, containing 20 simulated clinical samples, is intended to be used to verify the performance of the Rapid fFN® for the TLi IQ® System 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.
The Clinical Correlation Kit samples are simulated patient samples 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

- The Clinical Correlation Kit is formulated and supplied by Hologic, Inc. specifically for use in the verification of the TLi\textsubscript{IQ}® System performance. The samples in the kit cannot be considered a substitute material for the Rapid fFN® Positive and Negative Controls.

- The simulated samples in the Clinical Correlation Kit contain human-sourced material. Follow universal precautions and institutional guidelines for the handling of potentially infectious materials, including the use of protective gloves.

- Samples in this kit contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides.
Storage Conditions

- Store Clinical Correlation Kit samples between 2°C – 8°C.
- The samples may be used for up to 7 days post receipt in your laboratory when refrigerated at 2°C – 8°C.
1. Twenty simulated cervicovaginal samples in a stable protein matrix with sodium azide as a preservative. Store at 2°C – 8°C. Use at room temperature.

2. A Clinical Correlation Kit Expected Results Table, Document #MAN-01822-001, Attachment 1. This document contains a table with the expected result for each sample in the kit. Results for each numbered tube may vary with lot number.

3. The performance verification procedure, TLIQ® System Verification with Clinical Correlation Samples, Document #MAN-01822-001

4. MSDS-Clinical Correlation Samples for Verification of the TLIQ® System, Document #88210-001
Reference Documents

- TLIQ® System Verification with Clinical Correlation Samples
- TLIQ® System Verification Results
- Clinical Correlation Kit Expected Results Table

I. TITLE: TLIQ® System Verification with Clinical Correlation Samples

II. PRINCIPLE:
- a. The protocol is designed to establish and verify the performance of the TLIQ® System.
- b. The protocol is executed in a controlled laboratory environment following the manufacturer's instructions.
- c. Samples in this kit MUST BE REFRIGERATED upon receipt. DO NOT FREEZE.

III. REFERENCE DOCUMENTS:
- a. TLiIQ® System Verification with Clinical Correlation Samples
- b. TLiIQ® System Verification Results
- c. Clinical Correlation Kit Expected Results Table

IV. MATERIALS:
- a. Rapid 96-Cassette
- b. Rapid 96-Cassette Kit
- c. Clinical Correlation Kit
- d. Clinical Correlation Kit

V. SUMMARY OF PROCESS FLOW:
- a. Follow the directions in the TLIQ® System User Manual to unpack the TLIQ® Assay pack and printer.
- b. Set up the system as a Rapid 96-Cassette containing samples.
- c. Add reagents to the plate, using the reagent wells located on the left side of the analyzer.
- d. Connect the analyzer to the computer using the USB cable.
- e. The analyzer will display "SYSTEM DIAGNOSTICS... IN PROCESS." The printer will begin printing the results.
- f. The final result will be displayed on the computer monitor.

VI. STEPS FOR PROCEDURE - ANALYZER SET UP AND VERIFICATION:
- a. Following the directions in the TLIQ® System User Manual to unpack the TLIQ® Assay pack and printer.
- b. Set up the system as a Rapid 96-Cassette containing samples.
- c. Add reagents to the plate, using the reagent wells located on the left side of the analyzer.
- d. Connect the analyzer to the computer using the USB cable.
- e. The analyzer will display "SYSTEM DIAGNOSTICS... IN PROCESS." The printer will begin printing the results.
- f. The final result will be displayed on the computer monitor.
Clinical Correlation Kit
The Clinical Correlation Kit includes 20 tubes that contain simulated fetal fibronectin (fFN) samples (positives, negatives and one "invalid" sample containing 500 μL samples each) and the documents needed to complete correlation testing of these samples.

**NOTE:** These are simulated samples, but they do contain human-sourced material. Follow universal precautions and institutional guidelines for the handling of potentially infectious materials, including the use of protective gloves.
Clinical Correlation Sample Testing

- Place all tubes into a test tube rack and allow to sit upright for 3-5 minutes.
  - Before testing, shake down each tube with the flick of the wrist.
  - Cover the cap with a laboratory wipe or gauze and then slowly open the cap by rocking the cap back and forth. This prevents aerosol exposure and allows excess fluid caught in the inner cap to drain back into the tube.

- Each sample takes 20 minutes to incubate, plus 2-3 minutes of analysis.
Clinical Correlation Sample Testing

Follow these steps to test the correlation samples

- Set TLiQ® to *internal* incubation. Confirm AUTOPRINT is on.

- Assemble materials for testing: correlation samples in a test tube rack, 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.
Clinical Correlation Sample Testing

Follow these steps to test the correlation samples

- Enter the clinical correlation sample ID#. Use the numbers 1-20 to designate each tube for testing. Start with tube 1. Enter 1 and press ENTER.

- Unwrap and then label the cassette with the sample ID.

- Insert cassette and press ENTER.

- The analyzer should display the following message:
  
  INTERNAL INCUBATION
  INSERT CASSETTE
  PRESS ENTER TO CONTINUE

- Tap down correlation sample tubes and aspirate 200 μL of sample 1 into the pipette tip. Add sample to the well of the cassette. Press ENTER.
Clinical Correlation Sample Testing

Follow these steps to test the correlation samples

- The analyzer will begin a 20-minute incubation countdown. The message on the analyzer will read:
  TEST IN PROCESS
  DO NOT REMOVE
  CASSETTE
  19 MIN 56 SEC

- 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.

- Repeat this process for all 20 samples until the Clinical Correlation Kit is complete.
**External Incubation – Alternative Method**

- This method allows the completion of all 20 samples in the Clinical Correlation Kit within approximately 3 hours.

- External incubation staggers testing by allowing one cassette to incubate on the benchtop while another is being read by the analyzer. Each sample takes 20 minutes to incubate plus 2-3 minutes of analysis.

- To simplify this method of staggered sample testing for all 20 samples, use the provided table as a timing guide.

- The guide will remind you when samples need to be pipetted into specific cassettes and when the cassettes are ready to be read.

- Cassettes must be read within 20 minutes of sample addition. Prolonged incubation may result in an erroneous result.
Clinical Correlation Using **External** Incubation

Follow these steps to test the correlation samples

- Place all tubes into a test tube rack and allow to sit upright for 3 – 5 minutes.
  - Before testing, shake down each tube with a flick of the wrist.
  - Cover the cap with a laboratory wipe or gauze and then slowly open the cap by rocking the cap back and forth. This prevents aerosol exposure and allows excess fluid caught in the inner cap to drain back into the tube.
Clinical Correlation Using External Incubation

Follow these steps to test the correlation samples

- Set the TLiQ® System to external incubation. Confirm AUTOPRINT is on.

- Assemble materials for testing: correlation samples in a test tube rack, 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.
Clinical Correlation Using **External** Incubation

Follow these steps to test the correlation samples

- Enter the clinical correlation sample ID#. Use the numbers 1-20 to designate each tube for testing. Start with tube 1. Enter 1 and press **ENTER**.

- The analyzer should be displaying the following message:
  
  EXTERNAL INCUBATION
  WHEN TIME COMPLETE
  INSERT CASSETTE

- Unwrap and then label the cassette with the sample ID.

- Tap down correlation sample tubes and aspirate 200 μL of sample 1. Add sample to the well of the cassette. **Do not** insert the cassette into the analyzer. Start timer and wait for sample testing to complete.
Clinical Correlation Using External Incubation:

Follow these steps to test the correlation samples

- Eject pipette tip and load clean tip onto pipette for the next sample
- When timer reads 6 minutes, aspirate 200 μL of sample. Immediately add sample to the well of the cassette. Leave cassette on benchtop.
- Continue labeling cassettes, pipetting new samples into cassettes, leaving them to incubate on the benchtop, & discarding used pipette tips every 6 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 6-minute separation between samples.
- As the cassettes are read by the TLiIQ® analyzer, the results will print out via the label printer. Affix the labels in consecutive order to the TLiIQ® System Verification document, Appendix I. Compare the results for each sample to those published on the results table provided with the Clinical Correlation Kit.
Critical: Change TLIQ® Back to **Internal** Incubation

1. Go to fFN main menu (press ESC to get to this screen)
2. Use ↓ to get to the next page
3. Press 6 CHANGE SET UP
4. Press 3 INCUBATION MODE
5. Press 1 to set as INTERNAL INCUBATION
6. Press ENTER to accept this choice
7. Press ESC to return to fFN main menu
The laboratory director or designee will determine if the verification process is acceptable. Retain all records of this verification.

If you have any questions regarding the Clinical Correlation samples, please contact our laboratory at (408) 745-5172.

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

Customer Support:
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