PROCEDURE

Title: Fetal Fibronectin Testing

Procedure #: 2015BLOODBANK57

Institution: Highlands Regional Medical Center

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Accepted by: _____ Date: 6-5-15

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Review of procedure every two years

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PROCEDURE GUIDELINE

Procedure: Fetal Fibronectin Determination using the Hologic Rapid fFN™ for the TLi$_{IQ}$® System

Purpose

This procedure provides instructions for the testing of cervicovaginal samples for the presence of fetal fibronectin using the Rapid fFN for TLi$_{IQ}$ System

Sample

Cervicovaginal, collected using the Hologic Specimen Collection Kit. This kit is the only specimen collection system that can be used to collect samples for the Hologic Rapid fFN test

Materials

Reagents	Supplies	Equipment
• Rapid fFN™ Cassette Kit • Rapid fFN™ Control Kit	• 200 µL pipette • Pipette tips • Test tube rack • Specimen Collection Kit	• TLi$_{IQ}$ System (Analyzer, Printer and TLi$_{IQ}$® QCette®)

- The TLi$_{IQ}$ Analyzer and Printer should be operated at room temperature (18° to 30°C / 64° to 86°F).
- Rapid fFN Cassettes should be stored at room temperature (15° to 30°C / 59° to 86°F).
- The shelf life of Rapid fFN Cassettes is 18 months from the date of manufacture. Unopened cassettes may be used until the expiration date printed on the foil pouch and the box containing the pouched cassettes. Once the foil pouch is opened, the Rapid fFN Cassette should be used immediately.

QC

The system must be evaluated each day of use with the appropriate controls. ***Verify that QC has been performed before testing patient samples.*** If QC has not been performed, refer to the QC procedure, XXX "Quality Control for the Rapid fFN for the TLi$_{IQ}$ System".

Procedure

Step	Action
Sample Collection	
1	Obtain the specimen using the Hologic Specimen Collection Kit. The sample should be obtained from the posterior fornix of the vagina during a speculum examination. The polyester-tipped applicator provided in the Specimen Collection Kit should be inserted into the vagina and lightly rotated across the posterior fornix for approximately 10 seconds to absorb the cervicovaginal secretions.
2	Once the sample is obtained, carefully remove the applicator from the vagina and immerse the tip in the tube of buffer provided with the Specimen Collection Kit.
3	Break the shaft (at the score) even with the top of the tube. Align the shaft with the hole inside the tube cap and push down tightly over the shaft, sealing the tube.
4	Label the tube with the patient's name and any other identifying information required on the tube label.

Sample Storage & Transport	
1	Samples that are not tested within eight (8) hours of collection must be stored refrigerated at 2° to 8°C and assayed within three (3) days of collection, or frozen and assayed within three (3) months. Store appropriately and avoid extreme temperatures.
2	Transport samples at 2° to 25°C, or frozen.
3	Discard or samples after testing according to laboratory procedures.

NOTE: The following are considered unacceptable samples-

- Samples collected in or by any sample device other than the Hologic Specimen Collection Kit.
- Samples with insufficient volume for testing.
- Samples received unlabeled.
- Samples which were not frozen and received > 3 days after the sampling date.
- Samples not tested within 8 hours of collection if maintained at room temperature.
- Samples not tested within 3 days of collection if maintained at 2° to 8°C.
- Frozen samples older than 3 months from the sampling date.
- Samples received at temperatures >25°C.
- Samples subjected to more than one freeze-thaw cycle.

Procedure (Continued)

Sample Preparation	
1	Allow all specimen transport tubes to come to room temperature before testing.
2	Gently mix the sample transport tube prior to removing the applicator.
3	Open the specimen transport tube cap and applicator assembly. The applicator shaft should be seated in the cap. Express as much liquid as possible from the applicator by rolling the tip against the inside of the tube. Dispose of the used applicator in a manner consistent with handling of biohazardous materials.
4	Test patient samples on the TLi_{IQ} Analyzer using internal or external incubation mode.

NOTE:

- The TLi_{IQ} Analyzer has two incubation modes for testing samples: INTERNAL and EXTERNAL. The incubation mode refers to the timing of the incubation process and the initiation of the cassette analysis. In the internal mode, the analyzer times the incubation and starts the analysis. In the external mode, the user will be responsible for timing the incubation and for starting the analysis.

Sample Analysis – Internal Incubation Mode	
1	Turn on the TLi_{IQ} Analyzer and the attached printer. Select option 6 from the Main Menu for CHANGE SETUP by pressing the down arrow once and then entering the number 6.
2	Select option 3 from the Setup Menu for INCUBATION MODE. Then select option 1 for INTERNAL. Press ESC to return to Main Menu.
3	Select the appropriate option (TEST PATIENT) from the Main Menu of the TLi_{IQ} Analyzer.
4	Enter User ID and press ENTER
5	Enter the cassette lot number (printed on the foil pouch of the cassettes). The first three characters of the lot number will be displayed because the calibration has been set for a specific cassette lot number. Enter the remaining numbers of the lot number and press ENTER.

Procedure (Continued)

6	Remove one Rapid fFN Cassette from the foil pouch being careful not to touch the sample well or the reaction area. When prompted, insert the cassette into the analyzer. Push it in until it clicks and press ENTER.
7	Invert the patient sample to mix before testing. Using a calibrated pipette, add 200 µL of patient sample to the sample well and **immediately** press ENTER.
8	The analyzer times the 20-minute incubation of the cassette and starts the analysis. When the analysis is complete, the result will be displayed on the analyzer screen and the printed label. Press ESC to return to the Main Menu.
9	Remove the cassette from the analyzer.

Sample Analysis – External Incubation Mode	
1	Turn on the TLi_{IQ} Analyzer and the attached printer. Select option 6 from the Main Menu for CHANGE SETUP by pressing the down arrow once and then entering the number 6.
2	Select option 3 from the Setup Menu for INCUBATION MODE. Then select option 2 for EXTERNAL. Press ESC to return to Main Menu.
3	Select the appropriate option (TEST PATIENT) from the Main Menu of the TLi_{IQ} Analyzer.
4	Enter User ID and press ENTER
5	Enter the cassette lot number (printed on the foil pouch of the cassettes). The first three characters of the lot number will be displayed because the calibration has been set for a specific cassette lot number. Enter the remaining numbers of the lot number and press ENTER.
6	Remove the desired number of Rapid fFN Cassettes from the foil pouches being careful not to touch the sample well or the reaction area. Label each cassette appropriately.
7	Using a calibrated pipette, add 200 µL of sample #1 to the sample well on the appropriately labeled cassette and set a timer for 20 minutes.
8	If additional cassettes are run, wait at least five minutes before adding sample to the next cassette, then set a timer for 20 minutes for sample #2.

Procedure (Continued)

9	When sample #1's cassette has completed the 20-minute incubation period, insert the cassette into the analyzer. Push it in until it clicks and **immediately** press ENTER.
10	When the analysis is complete, the result will be displayed on the analyzer screen and the printed label. Press ESC to return to the Main Menu.
11	Remove the cassette from the analyzer.
12	Repeat steps 9-11 for sample #2

Interpretation

Result	Interpretation
POSITIVE	fFN concentration in the sample is ≥ 50 ng/mL
NEGATIVE	fFN concentration in the sample is < 50 ng/mL
INVALID "Analyzer Pass" "Cassette Fail"	The test does not meet internal quality control requirements. Potential causes include sample viscosity, inaccurate sample volume dispensed, or incorrect incubation time (if using external mode)
INVALID "Analyzer Fail" "Cassette Pass"	The test does not meet internal quality control requirements. Troubleshoot based on error code

If the test result is Invalid, retest with 200 µL of additional sample, if available, on a new Rapid fFN Cassette. If the repeated test is Invalid, contact Hologic, Inc. for technical assistance.

Result Reporting Enter results per laboratory procedure

Precautions and Warnings

- **Do not use glass tubes or glass pipettes, as fetal fibronectin binds to glass. Tubes and pipettes of polypropylene or polyethylene are acceptable.**
- Test results may not be interpreted visually and must be based on the use of the TLi_{IQ} Analyzer.
- Do not mix materials from different kit lots.
- Do not use cassettes past their expiration dates.
- Handle cassettes with care: do not touch, scratch or compress membrane materials in the Rapid fFN Cassette.
- Labels (e.g., barcode labels) can be placed on the thumb grip area of the cassette. Do not place labels on an area of the cassette that will be inserted into the TLI_{IQ} Analyzer.

Limitations

- The Rapid fFN result should not be interpreted as absolute evidence for the presence or absence of a process that will result in delivery in less than or equal to 7 or 14 days from specimen collection in symptomatic women or delivery in less than or equal to 34 weeks, 6 days in asymptomatic women evaluated between 22 weeks, 0 days and 30 weeks, 6 days of gestation. A positive fFN result may be observed for patients who have experienced cervical disruption caused by, but not limited to, events such as sexual intercourse, digital cervical examination or vaginal probe ultrasound. The Rapid fFN result should always be used in conjunction with information available from the clinical evaluation of the patient and other diagnostic procedures such as cervical examination, cervical microbiological culture, assessment of uterine activity and evaluation of other risk factors.
- Modification of the assay protocol described herein may yield erroneous results.
- The assay has been optimized with specimens taken from the posterior fornix of the vagina. Samples obtained from other locations should not be used.
- The safety and effectiveness of using a cutoff other than that provided by the Rapid fFN Cassette calibration code has not been established.
- Assay interference from the following components has not been ruled out: douches, white blood cells, red blood cells, bacteria and bilirubin.

Limitations (Continued)

- The presence of infections has not been ruled out as a confounding factor to risk of preterm delivery.
- Assay interference from semen has not been ruled out. Specimens should not be collected less than 24 hours after intercourse. However, even when a patient reports having had intercourse in the previous 24 hours, a negative fetal fibronectin test result is valid.
- Care must be taken not to contaminate the applicator or cervicovaginal secretions with lubricants, soaps, disinfectants or creams (e.g., K-Y® Jelly lubricant, Betadine® disinfectant, Monistat® cream, hexachlorophene). These substances may interfere with absorption of the specimen by the applicator or with the antibody-antigen reaction of the Rapid fFN test.
- Patients with suspected or known placental abruption, placenta previa or moderate or gross vaginal bleeding should not be tested for fFN.

References

1.Rapid fFN for the TLi$_{IQ}$ System User Manual, 71795-001
2. Specimen Collection Kit directional insert, MAN-01484-4201
3. Information for Healthcare Providers, directional insert, MAN-01669-001
4. Rapid fFN Cassette Kit directional insert, MAN-01489-4201
5. Rapid fFN Control Kit direction insert, MAN-01482-4201
6. TLi$_{IQ}$ QCette directional insert, MAN-01486-4201

Related Documents

Procedure XXX: Quality Control for the Rapid fFN for the TLi$_{IQ}$ System
Procedure XXX: Result Entry Into LIS

HOLOGIC®

PROCEDURE GUIDELINE

Procedure: Quality Control for the Rapid fFN™ for the TLi$_{IQ}$® System

Purpose

This procedure provides instructions for the performance of quality control on the Rapid fFN for TLi$_{IQ}$ System. The TLi$_{IQ}$® QCette® and the Rapid fFN™ Control Kit monitor analyzer and cassette performance. The system must be evaluated each day of use with the appropriate controls. ***Verify that QC has been performed and has passed before testing patient samples.***

NOTE: This QC procedure as well as proficiency testing and training support the laboratory's overall quality plan for the use of the Rapid fFN for the TLi$_{IQ}$ System. Refer to the laboratory's Rapid fFN for the TLi$_{IQ}$ System quality plan for additional information on quality requirements for this test.

Materials

Reagents	Supplies	Equipment
• Rapid fFN™ Cassette Kit • Rapid fFN™ Control Kit (Positive and Negative control)	• 200 µL pipette • Pipette tips • Test tube rack • Specimen Collection Kit	• TLi$_{IQ}$ System (Analyzer, Printer and TLi$_{IQ}$® QCette®)

- The TLi$_{IQ}$ Analyzer and Printer should be operated at room temperature (18° to 30°C / 64° to 86°F).
- Rapid fFN Cassettes should be stored at room temperature (15° to 30°C / 59° to 86°F).
- The shelf life of Rapid fFN Cassettes is 18 months from the date of manufacture. Unopened cassettes may be used until the expiration date printed on the foil pouch and the box containing the pouched cassettes. Once the foil pouch is opened, the Rapid fFN Cassette should be used immediately.
- Unopened Rapid fFN controls may be used until the expiration date printed on the bottle. Once opened, they should be used within six months.
- Rapid fFN controls should be run once each time a new lot or new shipment of Rapid fFN Cassettes is received
- The TLi$_{IQ}$ QCette is run daily, before testing patient samples

Procedure

QCette:

Step	*Action*
QCette	
1	Prior to running the TLi_{IQ} QCette for the first time, QCette SETUP must be performed. Refer to the TLi_{IQ} QCette directional insert for more information
2	From the Main Menu, select DAILY QC
3	Enter the information requested until the analyzer prompts you to insert the QCette. Insert the QCette and press ENTER Analysis of the QCette will take approximately 2-3 minutes
4	The result for the QCette will be displayed on the analyzer display screen and automatically printed as SYSTEM PASS, SYSTEM FAIL, OR INVALID

Positive and Negative Liquid Controls:

Step	*Action*
Positive and Negative Liquid Controls	
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
4	Select Negative or Positive Control
5	Enter the CONTROL LOT# (on bottle label) and press ENTER
6	Remove one Rapid fFN Cassette from the foil pouch Insert cassette into the analyzer and press ENTER
7	Add 200 µL of Positive or Negative Control to the sample application well, and immediately press ENTER The analyzer will begin a 20 minute incubation countdown
8	Following incubation, the analyzer will begin analysis of the 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 by pressing the PRINT/ENTER key
10	Press ESC to return to the main menu
11	Repeat process for the remaining control

Interpretation QCette:

Result	Interpretation
PASS	• Verifies analyzer performance is within specification • Indicates that the daily QCette value is within the specification determined at setup • Patient samples may be tested
FAIL	• Indicates that the daily QCette value is outside the specification determined at setup • Patient samples may **not** be tested • Ensure that the QCette is clean and free of lint or moisture and repeat the test. A "canned air" product may be used to clean the QCette. If the problem persists, see the TLi_{IQ} System User Manual for further information or contact Hologic for technical assistance • Turn analyzer off and back on to reinitialize the system. Rerun the TLi_{IQ} QCette. If the QCette fails a second time, call Hologic technical service
INVALID	• Patient samples may **not** be tested • Ensure that the QCette is not damaged, is clean and free of lint or moisture. Repeat the test. A "canned air" product may be used to clean the QCette. If the problem persists, see the TLi_{IQ} System User Manual for further information or contact Hologic for technical assistance • Turn analyzer off and back on to reinitialize the system. Rerun the TLi_{IQ} QCette. If the QCette fails a second time, call Hologic technical service

Interpretation

Positive and Negative Liquid Controls:

Result	Interpretation
PASS	• Verifies cassette lot/shipment is acceptable to use. • Patient samples may be tested
FAIL	• Indicates cassette lot/shipment may be damaged. • Do **not** test patient samples until acceptable results are obtained with both liquid controls • Verify that the control has not expired and is neither cloudy or discolored • Review the control procedure and repeat the test • If the control fails a second time, call Hologic technical service
INVALID	• Indicates the control run did not meet internal quality control requirements. • Do **not** test patient samples until acceptable results are obtained with both liquid controls • Refer to the Error/Invalid Code table in the Rapid fFN for the TLi_{IQ} System User Manual • If the control result is invalid for a second time, call Hologic technical service

Result Reporting

Enter QC results per laboratory procedure

NOTE: Internal controls monitor all components of the TLi_{IQ} System and are performed automatically with every test. These internal controls check for (1) a threshold level of signal at the procedural control position, (2) proper sample flow across the Rapid fFN Cassette, (3) absence of conjugate aggregation (Cassette: Pass/Fail) and (4) proper function of analyzer hardware (Analyzer: Pass/Fail).

Precautions and Warnings

- **Do not use glass tubes or glass pipettes, as fetal fibronectin binds to glass. Tubes and pipettes of polypropylene or polyethylene are acceptable.**
- Test results may not be interpreted visually and must be based on the use of the TLi_{IQ} Analyzer.
- Do not use cassettes past their expiration dates.

- Handle cassettes with care: do not touch, scratch or compress membrane materials in the Rapid fFN Cassette.
- Labels (e.g., barcode labels) can be placed on the thumb grip area of the cassette. Do not place labels on an area of the cassette that will be inserted into the TLI_{IQ} Analyzer.

References

1.Rapid fFN for the TLi_{IQ} System User Manual, 71795-001
7. Rapid fFN Cassette Kit directional insert, MAN-01489-4201
8. Rapid fFN Control Kit direction insert, MAN-01482-4201
9. TLi_{IQ} QCette directional insert, MAN-01486-4201

Related Documents

Procedure XXX: Fetal Fibronectin Determination using the Hologic Rapid fFN for the TLiIQ System

Procedure XXX: Result Entry into LIS