UPMC | HANOVER

Department of Pathology/Laboratory *Policy/Procedure*

Rapid Fetal Fibronectin fFN procedure ImmunologyManual]		
Doc#: MIC 202	**Section: IMMUNOLOGY**	**Effective Date: 1/21/2021**

SCOPE: This policy applies to UPMC Hanover.

KEYWORDS: Ffn, Fetal Fibronectin, Pre-term labor

PURPOSE: Detection of fetal fibronectin (hereafter "fFN") in cevicovaginal secretions is associated with preterm delivery in symptomatic pregnant women between 24 and 34 weeks, 6 days gestation, and in asymptomatic pregnant women between 22 weeks and 30 weeks, 6 days gestation.
The Rapid fFN Test is to be used to assess the risk of preterm delivery in less than or equal to 7 to 14 days from the time of sample collection in women with signs of early preterm labor, intact amniotic membranes and minimal cervical dilatation.

EQUIP0MENT: Specimen storage tubes for swabs after collection containing buffer. All other reagents are in the cassette.
• Rapid fFN Cassettes—store at room temperature
• TLiIQ Analyzer
• TLiIQ QCette
• Printer
•200 цL micropipettor, with disposable plastic tips
• **Do Not Use Glass tubes or pipettes, as fFN binds to glass**. Tubes/pipettes of polypropylene or polyethylene are acceptable.

QUALITY CONTROL:
• **TliIQ QCette**—for instrument calibration on a daily basis.
• **Internal control** are present in each cassette. 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).

External kit controls: To be run with each new lot or shipment of cassettes and every month. (Run as patient, using "8—Liquid Controls", adding cassette #, and control # for each at appropriate prompts.)
• Rapid fFN Positive Control: One 2.5 mL bottle containing human fetal fibronectin (>0.050µg/mL) in a stable protein matrix with sodium azide preservative. Store at 2-8°C. Use at room temperature.
• Rapid fFN Negative Control: One 2.5 mL bottle containing human fetal fibronectin (<0.050µg/mL) in a stable protein matrix with sodium azide preservative. Store at 2-8ºC. Use at room temperature.

Rapid Fetal Fibrinectin
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(Stability of QC kit is one year from manufacture date. Unopened controls may be used until the expiration date printed on bottle. Once opened, they should be used within 6 months. They are to be run as patient with 200 mL of specimen, but using #8—Liquid Controls.)

SPECIMEN:
See "Fetal Fibronecton Collection Procedure"
Transport specimen at 2° to 25°C, or frozen.
Specimens are stable up to 8 hours at room temperature.
If not tested within 8 hours of collection, store refrigerated at 2° to 8°C and assay within 3 days of collection, or freeze and assay within 3 months of collection to avoid degradation of the analyte.

PROCEDURE:

1	Specimen is collected and transported to laboratory. See detailed specimen collection under "Fetal Fibronectin Collection" Procedure
2	Perform Daily Analyzer Quality Control. See "Fetal Fibronectin TLIIQ QCette and Analyzer Verification"
3	Verify lot/shipment or monthly QC has been performed. If new lot of cassettes, please proceed to highlighted "Calibration of New Lot of Cassettes". If same lot number, proceed to 8 of white area
4	**Calibration of New Lot of Cassettes Select** "2—Set Calibration" from Main Menu. Enter the cassette lot number. All letters & numbers must be entered. Enter the number that corresponds to the correct letter and use the up & down arrows to scroll to the correct letter. Press "ENTER" when completed. Enter the Calibration Code provided on each box of cassettes. This code consists of two letters followed by two numbers. If the code is not entered correctly or does not match the cassette lot number that has been entered, the analyzer will request that the code be re-entered. This Calibration Code is used with all cassettes of that lot number. When calibration is complete, the result will be displayed on the analyzer screen and the printed label as SYTEM CALIBRATED. Press "ESC" to return to the Main menu.
5	Allow all Specimen Transport Tubes to come to room temperature before testing.(If running liquid controls, allow these to come to room temperature, inverting to mix prior to testing.)

6	Gently mix the Specimen Transport Tube prior to removing the swab. Open the cap of tube/swab assembly. The swab shaft should be seated in the cap. Express as much liquid as possible from swab by rolling the tip against the inside of tube. Dispose of used swab in biohazard container.
7	Print label for worksheet in LIS,
	Incubation Mode: Internal
8	Select VIEW SETUP from the TLiIQ Analyzer Main Menu to determine if the analyzer is set to Internal Incubation Mode. If Internal Mode is indicated, proceed to next step. If the analyzer is not set to Internal Mode, select CHANGE SETUP from the Main Menu and change to Internal Incubation mode.
9	Select TEST PATIENT from the TLiIQ Analyzer Main Menu and enter necessary information until the analyzer prompts for cassette insertion.
10	Insert cassette into analyzer and press ENTER.
11	When prompted by analyzer, pipette 200 µL of patient sample into the sample application well of the Rapid fFN Cassette. Immediately press ENTER to activate the analyzer. The analyzer will countdown for 20 minutes and analyze the Rapid fFN Cassette.
	Incubation Mode: External
12	In External mode: tech is responsible for timing incubation and starting the analysis. If more than one cassette is set up, allow 5 minutes before adding reagent to next cassette (to allow for the 3 minute reading and entering information into analyzer). Mix samples before testing.
13	Remove one Rapid fFN Cassette from foil pouch.
14	Select VIEW SETUP from the TLiIQ Analyzer Main Menu to determine if analyzer is set to Internal or External mode. If External is indicated, proceed to next step. If you need external but internal is indicated, select CHANGE SETUP from the Main Menu and change to External Incubation Mode.
15	Pipette 200 µL of patient sample into the sample application well of the Rapid fFN Cassette and allow to incubate at room temperature for 20 minutes.
16	Select TEST PATIENT from TLiIQ Analyzer Main Menu when previous patient is finished and add necessary information. When incubation time is complete, insert cassette into analyzer and press ENTER. The analyzer will complete the analysis of the Rapid fFN Cassette.

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INTERPRETATION/RESULTS:

1	Test results may not be interpreted visually and must be based on the use of the TLi_{IQ} System. The fFN result for the patient sample will be displayed on the TLi_{IQ} Analyzer display screen as POSITIVE, NEGATIVE, or INVALID.
2	If an INVALID result is obtained, retest with 200 µL of additional specimen, if available, on a new cassette.
3	The result is POSITIVE if the value 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 value derived from the patient sample is less than th reference calibration value specified by the calibration code. INVALID means the test does not meet internal quality control.

RESULT REPORTING:

1	POSITIVE result indicates that the level of fetal fibronectin is sufficient to indicate a possibility of preterm labor or of delivery within 7-14 days following collection.
2	NEGATIVE result indicates that the women is not probably going to deliver within the next 2 weeks.

METHOD LIMITATIONS:

• Specimens should be collected prior to digital exam or manipulation of the cervix. These may lead to false positive results.

• Patients with suspected or known placental abruption, placenta previa, or moderate or gross vaginal bleeding should not be tested.

REFERENCES:

Rapid fFN Cassette Kit, package insert. Hologic, Inc., 1240 Elko Dr. , Sunnyvale, California 94089-2212.AW-03520-002 Rev.003. www.hologic.com

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