

# FETAL FIBRONECTIN/100 FETAL FIBRONECTIN

Copy of version 1.0 (past periodic review date (3/4/2024))

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## Comments for version 1.0

Initial version Header of SOP updated Edited Reference

## Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	3/4/2022	1.0	Ali Mousa Ramadan MD	
Approval	Laboratory Operations Manager	3/2/2022	1.0	Wendell McMillan (108860)	
Approval	Quality Coordinator	2/12/2022	1.0	Lorraine Foster	

## Version History

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1.0	Past Periodic Review Date (3/4/2024)	Initial version	4/14/2021	3/4/2022	Indefinite

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**HOWARD UNIVERSITY HOSPITAL  
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE  
STANDARD OPERATING POLICY AND PROCEDURE MANUAL**

**Fetal Fibronectin/100**

**FETAL FIBRONECTIN**

**PRINCIPLE:**

The Rapid fFN Cassette is a lateral flow, solid-phase immuno-chromatographic assay. The cervicovaginal specimen is extracted into a buffer and a 200 µL sample is dispensed into the sample application well of the Rapid fFN Cassette. The sample flows from an absorbent pad across a nitrocellulose membrane via capillary action through a reaction zone containing murine monoclonal anti-fetal fibronectin antibody conjugated to blue microspheres (conjugate). The conjugate, embedded in the membrane, is mobilized by the flow of the sample. The sample then flows through a zone containing goat polyclonal anti-human fibronectin antibody which captures the fibronectin-conjugate complexes. The remaining sample flows through a zone containing goat polyclonal anti-mouse IgG antibody which captures unbound conjugate, resulting in a control line. After 20 minutes of reaction time, the intensities of the test line and control line are interpreted with the TLiQ R Analyzer.

The Fetal Fibronectin Enzyme Immunoassay and Rapid fFN should be used in conjunction with other clinical tests and information to assess overall risk of preterm delivery and assure appropriate patient management.

**INTENDED USE:**

- The Rapid fFN Cassette for use in the TLiQ System is an *in vitro* diagnostic device for the detection of fetal fibronectin in cervicovaginal secretions to be used as an aid to rapidly assess the risk of preterm delivery in 7 or 14 days from the time of cervicovaginal sample collection in pregnant women with signs and symptoms of early preterm labor, intact amniotic membranes and minimal cervical dilatation (< 3 cm), sampled between 24 weeks, 0 days and 34 weeks, 6 days of gestation.
- The Rapid fFN test is further indicated for use in conjunction with other clinical information as an aid to rapidly assess the risk of preterm delivery in 34 weeks, 6 days when a cervicovaginal sample is obtained during a routine prenatal visit between 22 weeks, 0 days

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**HOWARD UNIVERSITY HOSPITAL  
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE  
STANDARD OPERATING POLICY AND PROCEDURE MANUAL**

**Fetal Fibronectin/100**

**FETAL FIBRONECTIN**

and 30 weeks, 6 days of gestation in women with a singleton pregnancy.

**SPECIMEN COLLECTION**

The Hologic Specimen Collection Kit for fetal fibronectin testing is the only acceptable specimen collection system that can be used to collect specimens for this assay. See the Specimen Collection Kit directional insert for complete instructions.

**SPECIMEN PREPARATION**

**Note: Handle the Specimen Transport Tube and all Patient Specimens as if potentially infectious.**

1. Allow all Specimen Transport Tubes to come to room temperature before testing.
2. Gently mix the Specimen Transport Tube prior to removing the swab.
3. Open the Specimen Transport Tube cap and swab assembly. The swab shaft should be seated in the cap. Express as much liquid as possible from the swab by rolling the tip against the inside of the tube. Dispose of the used swab in a manner consistent with handling biohazardous materials.

**SPECIMEN STORAGE and TRANSPORT**

- Transport specimens at 2° to 25°C, or frozen.
- Specimens are stable for up to eight (8) hours at room temperature.
- Specimens not tested within eight 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 to avoid degradation of the analyte.
- Specimens arriving frozen may be tested as described below (subject to a single freeze-thaw cycle only).

**HOWARD UNIVERSITY HOSPITAL  
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE  
STANDARD OPERATING POLICY AND PROCEDURE MANUAL**

**Fetal Fibronectin/100**

**FETAL FIBRONECTIN**

**PRECAUTIONS and WARNING**

- Carefully follow the instructions and procedures described in this insert.
- **Test results may not be interpreted visually and must be based on the use of the TLiIQ<sup>®</sup> System.**
- **Do not use glass tubes or glass pipettes, as fetal fibronectin binds to glass. Tubes and pipettes of polypropylene or polyethylene are acceptable.**
- Do not mix materials from different kit lots.
- Do not use cassettes or controls past their expiration dates.
- Do not use controls if they are cloudy or discolored. Avoid cross-contamination of reagents. Use a new pipette tip for each control or patient sample. Recap controls tightly with the correct color-coded caps.
- Handle cassettes with care; do not touch, scratch, or compress membrane materials in the Rapid fFN Cassette.
- Source material used to prepare the controls is of human origin. The donors were tested and found to be negative for HIV 1, HIV 2, and HCV antibody and hepatitis B surface antigen (HBsAg) using established methods. No known test method can offer total assurance that HIV, hepatitis C virus, hepatitis B virus, or other infectious agents are absent. **Handle the controls and all patient specimens as if potentially infectious.**
- Labels (e.g., bar code 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 TLiIQ Analyzer.

**REAGENT STORAGE:**

- The Rapid fFN Cassettes should be stored at room temperature (15° to 30°C / 59° to 86°F).

**REAGENT STABILITY**

- The shelf life of the Rapid fFN Cassette is 18 months from the date of manufacture.
- Unopened cassettes may be used until the expiration date printed on the foil pouch and the

**HOWARD UNIVERSITY HOSPITAL  
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE  
STANDARD OPERATING POLICY AND PROCEDURE MANUAL**

**Fetal Fibronectin/100**

**FETAL FIBRONECTIN**

box containing the pouched cassettes.

- Once the foil pouch is opened, the Rapid fFN Cassette should be used immediately.

**MATERIALS PROVIDED**

- Rapid fFN for the TLiIQ System, REF 01200 (includes Cassettes and Directional Insert).

**MATERIALS REQUIRED BUT NOT PROVIDED**

- TLiIQ System, REF 01202 (includes Analyzer, Printer, User Manual, and TLiIQ QCetteR)
- Rapid fFN Control Kit, REF 01166 (includes Positive Control, Negative Control, and Directional Insert)
- 200 µL pipette

**CALIBRATION**

Select SET CALIBRATION from the TLiIQ Analyzer Main Menu and enter the information requested (Cassette Lot# and Calibration Code #).

- The Cassette Lot # is located on the cassette pouch.
- The Calibration Code # is located on the cassette box. *See the TLi/Q System User Manual for details.*

**QUALITY CONTROL PROCEDURES**

**Use TLiIQ Q Cassette for daily QC**

- The TLiIQ QCette is a quality control device used to verify that the TLiIQ Analyzer performs within specification. The TLiIQ QCette is a Rapid fFN Cassette replica, containing a membrane with printed test and control lines, which is read by the TLiIQ Analyzer. Three different levels of response are measured with this QC device:
  1. **High Level:** The blue line at the procedural control position, which is in the high positive range, must be above a minimum threshold value for QC to pass.
  2. **Low Level:** The blue printed line at the test line position is in the cutoff range. This line

**HOWARD UNIVERSITY HOSPITAL  
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE  
STANDARD OPERATING POLICY AND PROCEDURE MANUAL**

**Fetal Fibronectin/100**

**FETAL FIBRONECTIN**

is measured and compared with a value established during instrument Setup and must be within 5% of that value for QC to pass.

3. **Negative:** The white space between the blue lines is measured and should always be in the negative range for QC to pass. Internal controls monitor all components of the TLiIQ 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).

**LIQUID CONTROL**

- The Rapid fFN Control Kit (REF 01166) contains two liquid controls: one Rapid fFN Positive Control and one Rapid fFN Negative Control. The controls are recommended for use in monitoring the performance of the Rapid fFN Cassette.

**Liquid control must be run:**

- Once a month of patient testing or/and each time a new lot or a new shipment of cassettes is received, or whenever there is uncertainty about Rapid fFN Cassettes.
- If the criteria for controls are not met, do not test patient samples until acceptable results are obtained.

**TESTING PROCEDURE:**

**SPECIMEN PREPARATION**

**Note: Handle the Specimen Transport Tube and all Patient Specimens as if potentially infectious.**

1. Allow all Specimen Transport Tubes to come to room temperature before testing.
2. Gently mix the Specimen Transport Tube prior to removing the swab.
3. Open the Specimen Transport Tube cap and swab assembly. The swab shaft should be seated in the cap. Express as much liquid as possible from the swab by rolling the tip against the

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**HOWARD UNIVERSITY HOSPITAL  
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE  
STANDARD OPERATING POLICY AND PROCEDURE MANUAL**

**Fetal Fibronectin/100**

**FETAL FIBRONECTIN**

inside of the tube. Dispose of the used swab in a manner consistent with handling biohazardous materials.

**TESTING PATIENT SAMPLES**

**Incubation Mode - Internal**

**Note:** The default setting for the TLiQ Analyzer is Internal Incubation Mode. In this mode, the analyzer will time the incubation and automatically initiate reading of the cassette when incubation is complete.

1. Prepare Patient Samples according to the Specimen Preparation section. Mix patient samples before testing.
2. Remove one Rapid fFN Cassette from the foil pouch.
3. Select VIEW SETUP from the TLiQ Analyzer Main Menu to determine if the analyzer is set to Internal Incubation Mode. If Internal Mode is indicated, proceed to step 4. If the analyzer is not set to Internal Mode, select CHANGE SETUP from the Main Menu and change to Internal Incubation Mode. *See the TLiQ System User Manual/or details.*
4. Select TEST PATIENT from the TLiQ Analyzer Main Menu and enter the necessary information until the analyzer prompts for cassette insertion.
5. Insert the cassette into the analyzer and press ENTER.
6. When prompted by the analyzer, pipette 200  $\mu$ L of patient sample into the sample application well of the Rapid fFN Cassette. Immediately press ENTER to activate the analyzer.
7. The analyzer will count down for 20 minutes and analyze the Rapid fFN Cassette.
8. The fFN result for the patient sample will be displayed on the TLiQ Analyzer display screen as POSITIVE, NEGATIVE, or INVALID.
9. If an INVALID result is obtained, retest with 200  $\mu$ L of additional sample, if available, on a new cassette. If the problem is not corrected, see the TLiQ System User Manual for details, or contact Hologic for technical assistance.

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**HOWARD UNIVERSITY HOSPITAL  
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE  
STANDARD OPERATING POLICY AND PROCEDURE MANUAL**

**Fetal Fibronectin/100**

**FETAL FIBRONECTIN**

**Incubation Mode - External**

**Note:** In External Incubation Mode, the user is responsible for timing the incubation and starting the analysis. If additional cassettes are run, wait 5 minutes before adding sample to the next cassette to allow for the analysis of the previous cassette (approximately 3 minutes) and for entering menu information required by the analyzer for the next cassette.

1. Prepare Patient Samples according to the Specimen Preparation section. Mix patient samples before testing.
2. Remove one Rapid fFN Cassette from the foil pouch.
3. Select VIEW SETUP from the TLiQ Analyzer Main Menu to determine if the analyzer is set to External Incubation Mode. If External Mode is indicated, proceed to step 4. If the analyzer is not set to External Mode, select CHANGE SETUP from the Main Menu and change to External Incubation Mode. *See the TLiQ System User Manual for details.*
4. Select TEST PATIENT from the TLiQ Analyzer Main Menu and enter the necessary information until the analyzer prompts for cassette insertion.
5. Pipette 200  $\mu$ L of patient sample into the sample application well of the Rapid fFN Cassette and allow to incubate at room temperature for 20 minutes.
6. When the incubation time is complete, insert the cassette into the analyzer and press ENTER. The analyzer will complete the analysis of the Rapid fFN Cassette.
7. The fFN result for the patient sample will be displayed on the TLiQ Analyzer display screen as POSITIVE, NEGATIVE, or INVALID.
8. If an INVALID result is obtained, retest with 200  $\mu$ L of additional sample, if available, on a new cassette. If the problem is not corrected, see the TLiQ System User Manual for details, or contact Hologic for technical assistance.

**INTERPRETATION OF RESULTS**

- The fFN result for the patient sample will be displayed on the TLiQ Analyzer display screen as POSITIVE, NEGATIVE, or INVALID.



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**HOWARD UNIVERSITY HOSPITAL  
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE  
STANDARD OPERATING POLICY AND PROCEDURE MANUAL**

**Fetal Fibronectin/100**

**FETAL FIBRONECTIN**

- 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 the reference calibration value specified by the calibration code. The result is invalid if the test does not meet internal quality controls.

**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  $\leq 7$  days or  $\leq 14$  days from specimen collection in symptomatic women or delivery in  $\leq 34$  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.
- **Test results may not be interpreted visually and must be based on the use of the TLilQ System.**
- 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 or the ectocervical region of the external cervical. 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.

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**HOWARD UNIVERSITY HOSPITAL  
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE  
STANDARD OPERATING POLICY AND PROCEDURE MANUAL**

**Fetal Fibronectin/100**

**FETAL FIBRONECTIN**

- Assay interference from the following components has not been ruled out: douches, white blood cells, red blood cells, bacteria, and bilirubin.
- 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.
- Specimens should be obtained prior to digital examination or manipulation of the cervix. Manipulations of the cervix 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.

**EXPECTED VALUES**

Among symptomatic women, elevated levels ( $\geq 0.050 \mu\text{g/mL}$ ) of fFN between 24 weeks, 0 days and 34 weeks, 6 days indicate increased risk of delivery in  $\leq 7$  or  $\leq 14$  days from sample collection. Similarly, among asymptomatic women, elevated levels of fFN between 22 weeks, 0 days and 30 weeks, 6 days indicate increased risk of delivery in  $\leq 34$  weeks, 6 days of gestation. The cutoff of  $0.050 \mu\text{g/mL}$  fFN was established in a multicenter study conducted to evaluate the association between fetal fibronectin expression during pregnancy and preterm delivery (5).

Only subjects with symptoms of preterm labor or preterm rupture of membranes were eligible for this study. Of the total study population, the association of vaginal fetal fibronectin expression to preterm delivery was evaluated for 117 symptomatic women with intact amniotic membranes. The strength of this association was determined at a variety of cutoffs using receiver operator characteristic (ROC) curves. These results show that the optimal sensitivity and specificity is provided at a cutoff of  $0.050 \mu\text{g/mL}$  fFN. Subsequent studies evaluating the fFN Enzyme Immunoassay test as a predictor of preterm delivery

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**HOWARD UNIVERSITY HOSPITAL  
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE  
STANDARD OPERATING POLICY AND PROCEDURE MANUAL**

**Fetal Fibronectin/100**

**FETAL FIBRONECTIN**

among symptomatic women and asymptomatic women with singleton pregnancies have confirmed that the optimal cutoff is 0.050 µg/mL fFN (5, 13, 15, 18). Laboratory studies have confirmed the optimal cutoff of 0.050 µg/mL fFN in the Rapid fFN. This analytical cutoff was used to show equivalency between the fFN Enzyme Immunoassay and the Rapid fFN.

**PERFORMANCE CHARACTERISTICS**

**Accuracy**

A comparison of the Fetal Fibronectin Enzyme Immunoassay to the Rapid fFN was assessed in 587 cervicovaginal samples. The two test formats were equivalent 94.9% of the time. The Kappa coefficient for inter-test agreement was 0.81 with 95% confidence interval of [0.75, 0.88].

**Within-Run Reproducibility**

Within-run reproducibility was determined using three lots of Rapid fFN Cassettes. Twenty replicates each of the Rapid fFN Negative Control (fFN concentration approximately 0.015 µg/mL) and of the Rapid fFN Positive Control (fFN concentration approximately 0.080 µg/mL) were tested on three lots of Rapid fFN Cassettes using three different TLilQ Analyzers. (One lot of cassettes was run on one analyzer on one day, on three different occasions.) The results from these studies show that the Rapid fFN correctly identified all specimens 100% of the time.

**Between-Run Reproducibility**

Between-run reproducibility was determined in 36 independent assays, using different lot combinations of Rapid fFN Cassettes (three lots) and TLilQ Analyzers (six each). Each assay consisted of the Rapid fFN Negative Control and assay of the Rapid fFN Positive Control. The Rapid fFN correctly identified all samples 100% of the time.

**Interfering Substances**

Care must be taken not to contaminate the swab or cervicovaginal secretions with

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**HOWARD UNIVERSITY HOSPITAL  
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE  
STANDARD OPERATING POLICY AND PROCEDURE MANUAL**

**Fetal Fibronectin/100**

**FETAL FIBRONECTIN**

lubricants, soaps, disinfectants, or creams (e.g., K-YR Jelly lubricant, BetadineR disinfectant, MonistatR cream). Lubricants or creams may physically interfere with absorption of the specimen onto the swab. Soaps or disinfectants may interfere with the antibody-antigen reaction.

Various concentrations of pharmacologic agents were added to specimens containing approximately 0.015 µg/mL to 0.080 µg/mL fFN and assayed in triplicate. The drugs added were: prostaglandin E2 (up to 250 µg/mL), ampicillin (up to 100 µg/mL), cephalixin (up to 18 µg/mL), erythromycin (up to 10 µg/mL), gentamycin (up to 4 µg/mL), dexamethasone (up to 200 µg/mL), magnesium sulfate (up to 50 µg/mL). Oxytocin (up to 100 µg/mL), terbutaline (up to 100 µg/mL), and ritodrine (up to 10 µg/mL). These drugs did not interfere with the assay at the concentration limits cited above.

**For detailed description and instructions refer to the ADEZA TLIQ systems user manual**

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**HOWARD UNIVERSITY HOSPITAL  
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE  
STANDARD OPERATING POLICY AND PROCEDURE MANUAL**

**Fetal Fibronectin/100**

**FETAL FIBRONECTIN**

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**HOWARD UNIVERSITY HOSPITAL  
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE  
STANDARD OPERATING POLICY AND PROCEDURE MANUAL**

**Fetal Fibronectin/100**

**FETAL FIBRONECTIN**

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HOWARD UNIVERSITY HOSPITAL  
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE  
STANDARD OPERATING POLICY AND PROCEDURE MANUAL

**Fetal Fibronectin/100**

**FETAL FIBRONECTIN**

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