

Evaluation of a quantitative fetal fibronectin test for spontaneous preterm birth in symptomatic women

Danielle S. Abbott, MBBS; Samara K. Radford, B Med Sci; Paul T. Seed, MSc; Rachel M. Tribe, PhD; Andrew H. Shennan, MD. *American Journal of Obstetrics and Gynecology*, February 2013.

Objective:

To determine whether quantification of cervicovaginal fluid fetal fibronectin (fFN) improves diagnostic accuracy of spontaneous preterm birth in symptomatic women.

Key Findings:

Added value.

Spontaneous preterm birth risk ranged from 20 – 75% depending on the threshold used, allowing for greater risk stratification that may alter patient management.

Proven correlation.

The relative risk of a spontaneous preterm birth within 14 days of the test increased as fFN concentration increased.

Overview:

Evaluation of a quantitative fetal fibronectin test for spontaneous preterm birth in symptomatic women

Spontaneous preterm birth rate within fetal fibronectin categories¹

Fetal fibronectin category, ng/mL	n (%)	Spontaneous preterm birth at ≤7 days gestation, %	Spontaneous preterm birth at ≤14 days gestation, %	Spontaneous preterm birth at ≤34 weeks gestation, %
0-9	170 (57)	1	1.8	1.5
10-49	62 (21)	0	1.6	8.2
50-199	41 (14)	0	7.7	11.5
200-499	14 (5)	14	29	33
≥500	13 (4)	38	46	75



Study Methods and Populations:

- ▶ A prospective observational, blinded study that took place over an 18 month period between October 2010 and April 2012 at five hospitals in the UK
- ▶ 300 patients with signs and symptoms of preterm labour were enrolled between 22-35 weeks gestation
- ▶ The study examined thresholds of 10, 50, 200, and 500 ng/mL of fFN, which were predefined before analysis

Inclusion criteria:

- Patients with signs and symptoms of preterm labour
- Singleton pregnancies
- Gestational age between 22+0 and 35+6

Exclusion criteria:

- Previous vaginal examination
- Intercourse within the preceding 24 hours
- Frank bleeding
- Rupture of membranes on speculum examination
- Blood-stained swabs
- Cervical dilation of >3cm

Discussion:

The study determined that the quantitative fFN test:

- Could lead to more directed management decisions: appropriate use of steroids, in-utero transfer or discharging patients at a low threshold.
- Delivered results in a clinically relevant timeframe (within ten minutes).
- Required minimal personnel training to collect specimen and run the sample in the analyser.

Reference: 1. Abbott DS, Radford SK, Seed PT, et al. Table 4. Evaluation of a quantitative fetal fibronectin test for spontaneous preterm birth in symptomatic women. *Am J Obstet Gynecol.* 2013;208(2):122.31-6.

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PeriLynx System

Rapid fFN Test for Symptomatic Patients

What your patient's results mean

Once the analyser has determined the patient's fFN concentration, use the chart below to help evaluate her risk level. These risk levels are for patients experiencing signs and symptoms of preterm labour.

Concentration	Risk of Delivery \leq 14 Days	Risk of Delivery \leq 34 weeks
<10 ng/mL	98% chance delivery will NOT occur <14 days	99% chance delivery will NOT occur <34 weeks
10-49 ng/mL	98% chance delivery will NOT occur <14 days	92% chance delivery will NOT occur <34 weeks
50-199 ng/mL	8% chance delivery WILL occur <14 days	12% chance delivery WILL occur <34 weeks
200-499 ng/mL	29% chance delivery WILL occur <14 days	33% chance delivery WILL occur <34 weeks
\geq 500 ng/mL	46% chance delivery WILL occur <14 days	75% chance delivery WILL occur <34 weeks

Reference: Rapid fFN 10Q Cassette Kit [package insert]. AW-09189-001, Rev. 003. Sunnyvale, CA: Hologic, Inc.; 2015.

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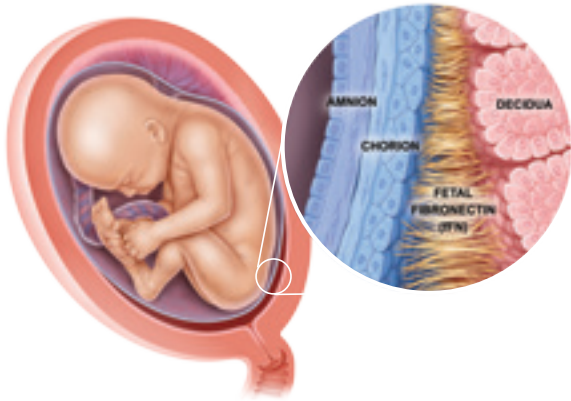


Sometimes the
symptoms are real
but the risk isn't.

A clinically proven, powerful indicator
for planning and peace of mind.

*Rapid*FN[®]Test

Important facts about the risk of preterm birth



Why fetal fibronectin matters.

Fetal fibronectin (fFN) is a “glue-like” protein that bonds the membranes around the baby to the uterus. It is detectable in vaginal secretions at the very beginning of pregnancy, when this bond is first forming and then again at the end of your pregnancy.

From weeks 22 to 35, this “glue” should be almost undetectable. If it is detectable during this time frame, it could indicate your body is getting ready to deliver early. The quantitative fFN test not only detects if fFN is present, but how much is present to help your doctor determine your best management pathway.⁴

Your doctor will advise if the Rapid fFN Test is suitable for you.

References: **1.** Queensland Maternity and Neonatal Clinical Guideline, Assessment and Management of Preterm Labour, Queensland Government **2.** Rapid fFN 10Q Cassette Package Insert, AW-09189-001-002-02, Hologic Inc. 2015. **3.** Dekker GA et al. (2012) Risk Factors for Preterm Birth in an International Prospective Cohort of Nulliparous Women. *PLoS ONE* 7(7): e39154. **4.** Abbott DS et al. Evaluation of a quantitative fetal fibronectin test for spontaneous preterm birth in symptomatic women. *Am J Obstet Gynecol* 2013; 208(2). **5.** Abbott DS et al. Quantitative Fetal Fibronectin to Predict Preterm Birth in Asymptomatic Women at High Risk. *Obstetrics & Gynecology* 2015;125:1168-1176.

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*Rapid*fFN®
10Q System

Who is at risk of preterm birth?

Understanding your risks can help your doctor and you work out a suitable management plan. Any of following factors may mean you are at risk of preterm birth.²

- You have experienced a previous preterm birth (< 37 weeks)
- You are carrying twins or triplets
- You have had cervical surgery or uterine abnormalities
- You have had previous miscarriage/s during second trimester
- Your cervical length is 25mm or less during pregnancy
- You have undergone *in vitro* fertilisation (IVF)³

What are the signs and symptoms of preterm labour?

Even if you do not have any known risks, you should contact your doctor or midwife if you have any symptoms of preterm labour, which can include:¹

- Regular painful contractions that don't stop
- Period type cramps that come and go, or are constant
- Changes in the amount, colour, consistency and smell of vaginal discharge
- Constant, dull back pain, loin pain or urinary cramps
- Pelvic pressure, as though the baby is pushing downward

What are some of the issues related to preterm birth?

Your baby's organs finish developing near the end of your pregnancy. If your baby is born early, these organs may not have enough time to grow. While many health problems related to preterm birth can be treated, some children born preterm may have difficulties throughout their lives, such as developmental problems and learning disabilities. If your doctor has determined you are at risk for preterm birth, he or she will provide you with additional information to help you understand the specific issues you may face.

What is a quantitative fFN test?

If you are experiencing symptoms of preterm labour - or if you are at risk of preterm birth - your doctor may perform a quantitative fFN test. This test quantifies the amount of fetal fibronectin (fFN) in your vaginal secretions, which provides an indication of your risk of preterm birth.

If you have symptoms, this test helps your doctor decide whether you should be admitted for treatment, observed for further diagnosis, transferred to a specialist hospital or discharged.^{4,5}

If you do not have symptoms but remain at risk, the test result can assist your doctor to determine the best plan for your pregnancy.



PeriLynX[®] System



More information and less guesswork, to better predict the likelihood of preterm birth.

Your patient's pregnancy is high risk, and yet her chance of preterm birth might actually be quite low. Now there's a test that can help you quantify her risk of delivery before 34 weeks.

Admit, observe or discharge?

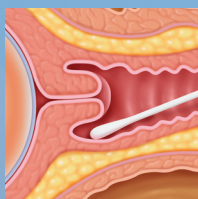
Quantitative fFN testing detects the concentration levels of fetal fibronectin (fFN) that are present, giving you the data you need to determine a woman's risk of preterm delivery.

If more than 500 ng/ml of fFN is present in a patient with symptoms of preterm labor, there is a **75%** chance that the patient will deliver before 34 weeks.¹

If less than 10 ng/ml of fFN is present in a patient with symptoms of preterm labor, you can be **99%** sure that the patient will not deliver before 34 weeks.¹

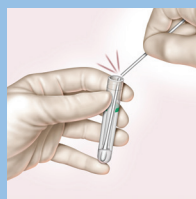
Clinician Collection Procedure*

STEP 1 & 2



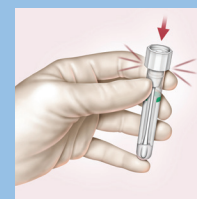
Collect specimen prior to digital examination or manipulation of the cervix to avoid sample contamination. During speculum examination, lightly rotate swab across posterior fornix of the vagina for 10 seconds to absorb cervicovaginal secretions.

STEP 3



Remove swab and immerse tip in buffer. Break the shaft at the score even with the top of the tube.

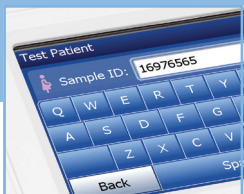
STEP 4



Insert the swab shaft into the hole inside the tube cap and push down tightly over the shaft, sealing the tube with a click. Ensure the shaft is inserted securely to avoid leakage.

Collect definitive data for a more complete answer in just 5 steps.

STEP 1



Enter User ID, Rapid fFN 10Q Cassette Lot and Sample ID/ Patient ID. When prompted, press ENTER.

STEP 2



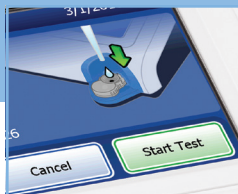
Insert Rapid fFN 10Q Cassette into the analyser.

STEP 3



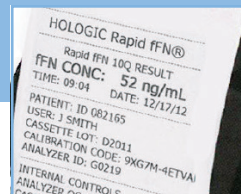
Dispense sample into the Rapid fFN 10Q Cassette well.

STEP 4



Press START TEST and walk away.

STEP 5



Results ready in 10 minutes.

Integrated quality control for reliable patient results.



Daily Quality Control

Analyser QC and system verification

PeriLynx QCette® QC Device

- Verification that the analyser performance is within specification
- Reusable (no expiration date) QC device with results in 3 minutes
- Pre-calibrated cassette for quick and easy use

Internal Quality Control

Automatic QC with every patient test

Rapid fFN 10Q Cassette

The existing Rapid fFN 10Q Cassettes are compatible with PeriLynx analyser.

Each cassette used for patient testing includes controls for proper function of the chemistry.

- Procedural control line verifies the threshold level of signal by instrument
- Sample flow detection ensures sample travels across Rapid fFN 10Q Cassette properly
- Confirms absence of conjugate aggregation to ensure correct operator and chemistry performance
- Shelf life 18 months from date of manufacture

Quality Control Testing Summary

	PERILYNX QCETTE	INTERNAL CONTROLS	LIQUID CONTROLS	CALIBRATION
Frequency	Daily	Automatic each test	Each shipment or lot	Each lot of cassettes used for testing
Function	Verifies analyser performs within specification	Verifies analyser and cassette performance during patient testing	Qualifies cassette lot or shipment	Lot-specific calibration

Order Information

CATALOG #	ITEM	DESCRIPTION
PRD-04001	PeriLynx System	Analyser, Printer and QCette
PRD-01018	Rapid fFN 10Q Cassette Kit	26 Cassettes Per Box
PRD-01019	Rapid fFN Control Kit	1 Positive and 1 Negative Control
PRD-01020	Specimen Collection Kit	25 Polyester Swabs and Vials of Buffer Solution
PRD-04007	PeriLynx QCette	1 QCette with Storage Case
52660-001	Printer Labels	1 Roll of 400 Labels
MEL-00970	Barcode Scanner (optional)	1 Barcode Scanner and Stand
52843-001	Mini Pipette	1 Pipette 200 µL
52844-001	Mini Pipette Tips	1 Bag of 100 Tips

Reference: 1. Rapid fFN 10Q Cassette Kit [package insert], AW-09189-001, Rev. 003. Sunnyvale, CA: Hologic, Inc.; 2015.

* Hologic provides this collection procedure guide as a general informational tool only; it is not an affirmative instruction or guarantee of performance. It is the sole responsibility of medical professionals to read and understand the appropriate package insert and comply with applicable local, state and federal rules and regulations.

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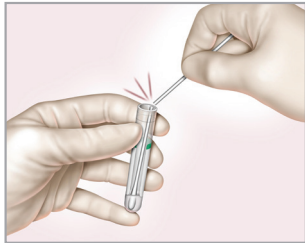
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PeriLynx System

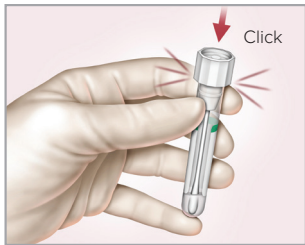
Transportation of Collected Sample*

After collecting the specimen with the polyester swab proceed with the following steps to prepare the sample for transportation.

- Transport samples at 2-25°C, or frozen
- Samples are stable for up to 8 hours at room temperature
- Samples not tested within 8 hours of collection must be stored refrigerated at 2-8°C and tested within 3 days of collection, or frozen and tested within 3 months to avoid degradation of the analyte



STEP 1
Break the shaft (at the score) even with the top of the tube



STEP 2
Align the shaft with the hole inside the tube cap and push down tightly over the shaft, sealing the tube for transfer
Warning: The shaft must be aligned to avoid leakage.

* In instances where a patient sample is not processed immediately but rather sent to an off site location for analysis.

STEP 3
Send fFN sample to a Rapid fFN PeriLynx Analyser near you

If you have any questions please contact your local representative or email euinfo@hologic.com.

The Quick Reference Guide is designed to be used in conjunction with, not to replace, the PeriLynx Operators Manual.

DO and DO NOT:

- **DO** Read test results generated by the PeriLynx System only (not visually from the cassette)
- **DO** Handle Rapid fFN 10Q Cassettes with care
- **DO** Ensure you are using the correct polyester swab from the Rapid fFN Test Specimen Collection Kit
- **DO** Handle liquid controls and all patient samples as if potentially infectious
- **DO** Ensure that the correct sample volume (0.2mL) is being pipetted into the Rapid fFN 10Q Cassette well
- **DO NOT** use glass tubes/pipettes
- **DO NOT** mix materials from different kit lots
- **DO NOT** use Rapid fFN 10Q Cassettes or liquid controls past their expiration dates
- **DO NOT** use liquid controls if they are discoloured or cloudy
- **DO NOT** cross contaminate reagents
- **DO NOT** use the same pipette tip for each control or patient sample

If you have any questions please contact your local representative.



Rapid fFN® PeriLynx System Quick Reference Guide

WOMEN AT GREATEST RISK OF PRETERM BIRTH

PeriLynx System



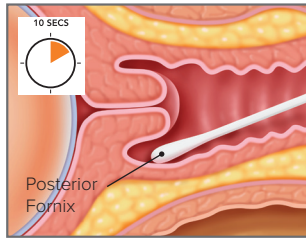
For more information on preterm birth and fetal fibronectin, visit: www.ffntest.com

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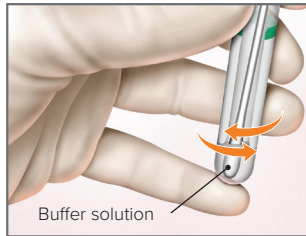


5 Easy Steps to Collect and Test for Fetal Fibronectin (fFN)



STEP 1

During speculum examination, lightly rotate the supplied swab across the posterior fornix of the vagina for 10 seconds to absorb cervicovaginal secretions



STEP 2

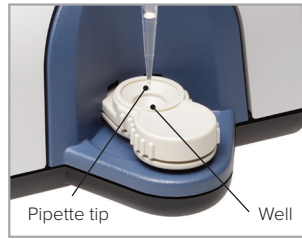
Remove swab and immerse tip in buffer. Gently mix the swab in the buffer solution and remove if the test is to be performed immediately

Note: Refer to transportation and storage notes overleaf if test is to be performed at a later time.



STEP 3

- Enter User ID, Press 'NEXT'
- Enter Rapid fFN 10Q Cassette Lot number and press 'NEXT'
- Enter Patient ID and press 'NEXT'
- Insert the Rapid fFN 10Q Cassette and press 'NEXT'



STEP 4

- Pipette **0.2mL (200µl)** from the sample collected in the buffer solution into the well of a Rapid fFN 10Q Cassette and press 'START TEST'

- Walk away

Note: For more information regarding the pipette please refer to the micropipettor instructions.



STEP 5

- Internal Quality Control results can be found on the print out
- The fFN concentration will be displayed and printed in 10 minutes
- A permanent record is now available for patient notes

Note: Press Print to obtain a second copy of the printout.

Specimens should be collected prior to:

- Digital cervical exam
- Collection of culture specimens
- Vaginal probe ultrasound exams

Do not contaminate swab or specimen with:

- Lubricants
- Soaps
- Disinfectants
- Creams

Do not test if patients have: Symptomatic

- Advanced cervical dilation (3 centimetres or greater)
- Rupture of amniotic membranes
- Cervical cerclage
- Moderate or gross vaginal bleeding*
- Placenta previa
- Sexual intercourse in the last 24 hours*

*If the test is <10ng/ml it can be interpreted as a valid result.

Before Patient Testing

Quality Control (QC)

- Performed Once Daily

1. Select 'Run QCette QC' from the Main Menu
2. Enter User ID and Press 'NEXT'
3. Enter the Rapid fFN PeriLynx QCette® QC Device ID, or 'VERIFY' if it is already entered and press 'NEXT'
4. Insert the QCette and press 'NEXT'
5. Results are displayed and printed in 3 minutes

Note: Ensure the QCette has been set up with the PeriLynx Analyser before performing the daily QC.



Rapid fFN PeriLynx QCette® QC Device

Set Calibration

- For Each New Cassette Lot

1. Select 'ENTER NEW CALIBRATION CODE' from the Main Menu
2. Enter User ID, Rapid fFN 10Q Cassette Lot and Calibration Code when prompted



7JHMB-87WU3

Run Liquid Controls

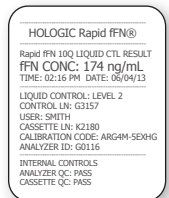
- For Each New Cassette Lot

Allow liquid controls to reach room temperature before running a control test.

1. Select 'RUN LIQUID QC' on Main Menu
2. Enter User ID, Rapid fFN 10Q Cassette Lot, select either Negative/Level 1 or Positive/Level 2 Control and enter the Control Lot from the vial then press 'NEXT'
3. Pipette **0.2ml (200µl)** of liquid control sample into well of Rapid fFN 10Q Cassette and press 'START TEST'
4. The fFN concentration result will be displayed and printed in 10 minutes and the Negative/Level 1 and the Positive/Level 2 Controls should fall within the expected values printed on the liquid control box
5. Test for both Negative/Level 1 and Positive/Level 2 liquid controls



Liquid Controls



Rapid fFN 10Q Cassette

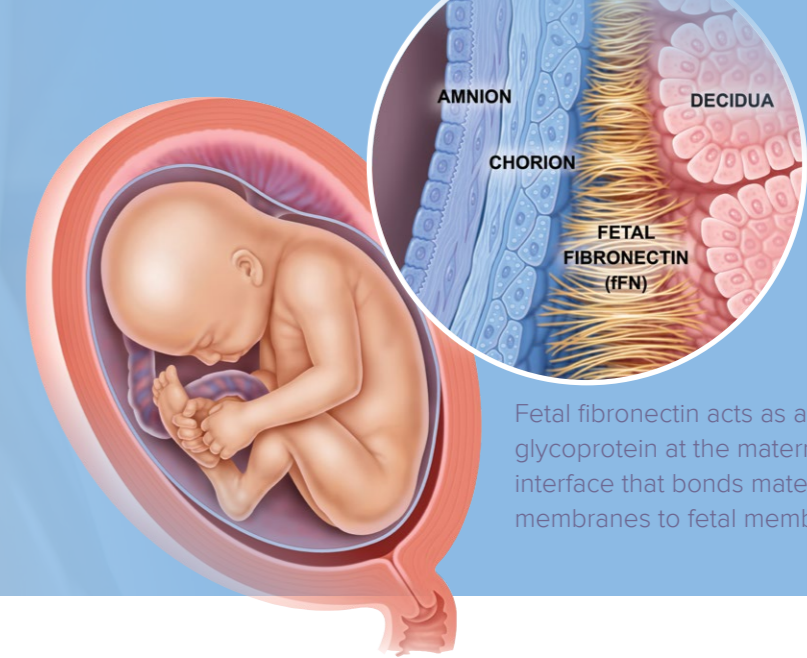
Quantitative Fetal Fibronectin

Let the numbers
tell her story.

Rapid fFN 10Q System
There's knowledge in the number.

Quantitative Fetal Fibronectin (fFN): Know the number to calculate a plan.

When a patient is experiencing symptoms of preterm labour, you need to determine if her risk of preterm birth is real or perhaps quite low. With Quantitative fFN testing, you can precisely measure the fetal fibronectin concentration to help quantify the risk of delivery before 34 weeks in both patients who have symptoms of preterm labour and high-risk patients. In a matter of minutes, understand the risk of preterm birth to help complete every patient's story.



Fetal fibronectin acts as an adhesive glycoprotein at the maternal-fetal interface that bonds maternal membranes to fetal membranes

Symptomatic Patients

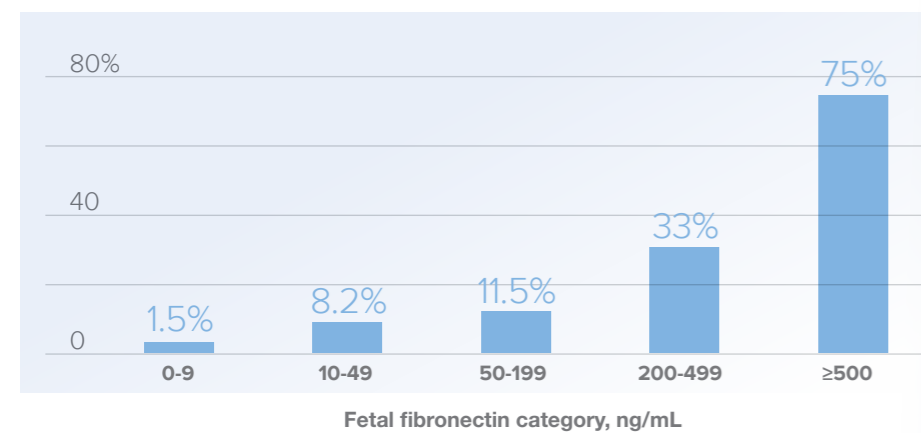
Approved for collection between 22-36 weeks' gestation

For patients who have symptoms of preterm labour, the detection of fetal fibronectin concentrations can help you quickly determine the risk of delivery within 2 weeks.

CONCENTRATION ¹	RISK OF DELIVERY
< 10 ng/mL	98% chance delivery will NOT occur < 14 days
10-49 ng/mL	98% chance delivery will NOT occur < 14 days
50-199 ng/mL	8% chance delivery WILL occur < 14 days
200-499 ng/mL	29% chance delivery WILL occur < 14 days
> 500 ng/mL	46% chance delivery WILL occur < 14 days

A clinical study evaluating fFN concentration showed that women with symptoms of preterm labor were 50 times more likely to deliver before 34 weeks with a test result of 500 ng/mL compared with < 10 ng/mL.²

Risk of delivery < 34 weeks in women with symptoms of preterm labour



High-risk Patients

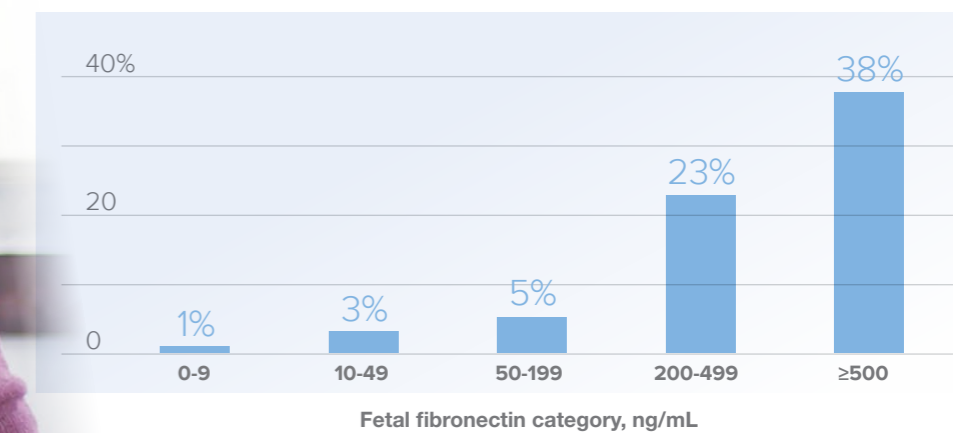
Approved for collection between 22-28 weeks' gestation

For high-risk asymptomatic patients, the detection of fetal fibronectin concentrations can help you construct an informed and timely management plan.

CONCENTRATION ¹	SPTB < 34 WEEKS
< 10 ng/mL	3%
10-49 ng/mL	11%
50-199 ng/mL	15%
200-499 ng/mL	34%
≥ 500 ng/mL	48%

A clinical study evaluating fFN concentration showed that high risk asymptomatic women were 38 times more likely to deliver before 30 weeks at 500 ng/mL compared with < 10 ng/mL.³

Risk of delivery < 30 weeks in high risk asymptomatic patients.



A more complete answer in just 5 steps.

With the new Rapid fFN 10Q System, it's easy to get a quantitative answer in a matter of minutes.

STEP 1



Enter user ID, Rapid fFN 10Q Cassette Lot and Patient ID. Press enter when prompted.

STEP 2



Insert Rapid fFN 10Q Cassette into the analyser.

STEP 3



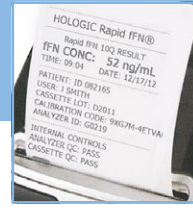
Dispense sample into the Rapid fFN 10Q Cassette well.

STEP 4



Press enter and walk away.

STEP 5



Results ready in 10 minutes.

Order Information

PART NUMBER	ITEM	DESCRIPTION
PRD-00930	Rapid fFN 10Q System	Analyser, Printer and QCette
PRD-01018	Rapid fFN 10Q Cassette Kit	26 Cassettes Per Box
PRD-01019	Rapid fFN Control Kit	Level 1 and Level 2 Controls
PRD-01020	Specimen Collection Kit	25 Polyester Swabs and Vials of Buffer Solution
PRD-01021	Rapid fFN 10Q QCette	1 QCette with Storage Case
52660-001	Printer Labels	1 Roll of 400 Labels
52843-001	Mini Pipette	1 Pipette 200 µL
52844-001	Mini Pipette Tips	1 Bag of 100 Tips

References: **1.** Rapid fFN 10Q Cassette Package Insert, AW-09189-001-002-02, Marlborough MA, Hologic Inc. 2015. **2.** Abbott DS, Radford SK, Seed PT, et al. Evaluation of a quantitative fetal fibronectin test for spontaneous preterm birth in symptomatic women. *Am J Obstet Gynecol* 2012;208. **3.** Abbott DS, Hezelgrave NL, Seed PT, et al. Quantitative Fetal Fibronectin to Predict Preterm Birth in Asymptomatic Women at High Risk. *Obstetrics & Gynecology* 2015;125:1168-1176.

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Rapid fFN 10Q System

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