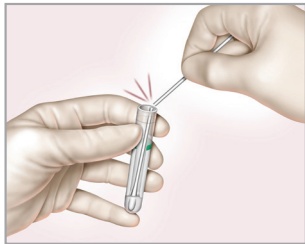


Transportation of Collected Sample*

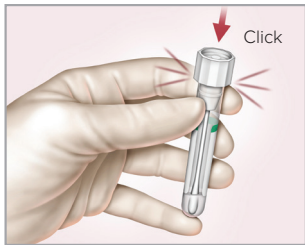
After collecting the specimen with the polyester swab proceed with the following steps to prepare the sample for transportation.

- 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

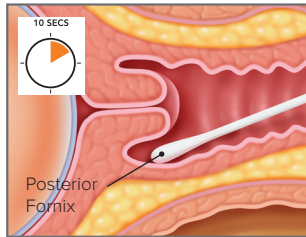
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The Rapid fFN® PeriLynx System and ancillaries are not for sale in the United States.

PRENATAL HEALTH

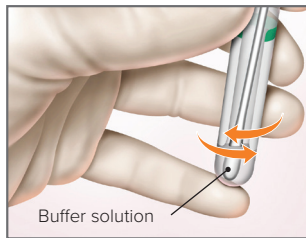


5 Easy Steps to Collect and Test for Fetal Fibronectin (fFN)



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

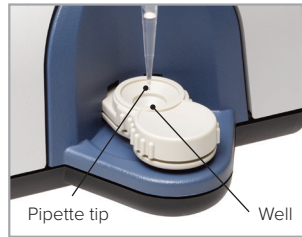
Remove swab and immerse tip in buffer. Gently mix the swab in the buffer solution and remove if the test is to be performed immediately

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



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Run Liquid Controls

- For Each New Cassette Lot

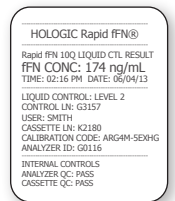
Allow liquid controls to reach room temperature before running a control test.

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

Note: Place a printed record on a log sheet for safe keeping.



Liquid Controls



Rapid fFN 10Q Cassette