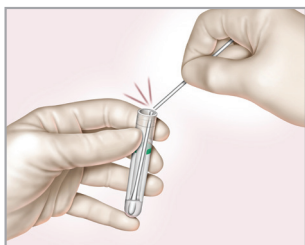


Transportation of Collected Sample*

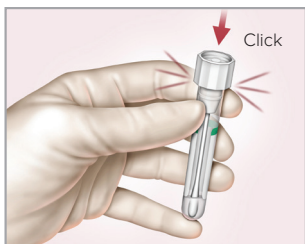
After collecting the specimen with the polyester swab proceed with the following steps to prepare the sample for transportation.

- 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 ffntest@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 / 200µl) is being pipetted into the Rapid fFN 10Q Cassette well
- **DO** refrigerate Liquid Controls and discard after 6 months from opening
- **DO** bring Liquid Controls to room temperature prior to testing
- **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 more than once

If you have any questions please contact your local representative.



Rapid fFN® PeriLynx System Quick Reference Guide

PeriLynx[®] System

The Quick Reference Guide is designed to be used in conjunction with, not replace, the respective instruction manuals for the Rapid fFN® PeriLynx System and ancillaries. Be familiar with the instruction manuals prior to performing the test review.



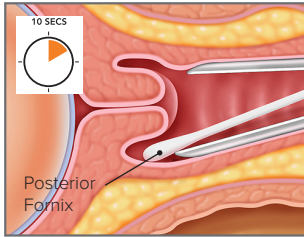
For more information on preterm birth and fetal fibronectin, visit:
www.ffntest.co.uk

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

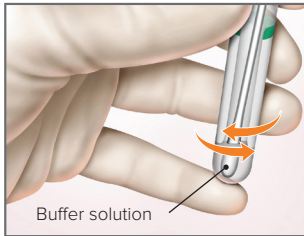


5 Easy Steps to Collect and Test for Fetal Fibronectin (fFN)



STEP 1

During speculum examination (warm water lubrication only), 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 for 10 seconds and remove if the analysis of your sample is to be performed immediately. Your sample can now be analysed.

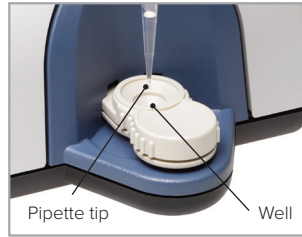
Note: Refer to transportation and storage notes overleaf if sample is to be analysed at a later time.



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
- Pipette **0.2ml (200µl)** from the sample collected in the buffer solution
- Press 'NEXT'

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



STEP 4

- Pipette the sample into the well of the Rapid fFN 10Q Cassette and press 'START TEST'
- Walk away



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
- Collection of ROM Test sample
- Vaginal probe ultrasound exams

Do not contaminate swab or specimen with:

- Lubricants
- Soaps
- Disinfectants
- Gels

* Moderate or gross bleeding is an independent risk factor for preterm delivery and may be associated with other severe obstetrical or medical problems.

‡ Presence of blood or semen in a Fetal Fibronectin sample can sometimes lead to a falsely elevated result, however results under the specified threshold for treatment at your facility can still be considered valid in either of these situations.

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.

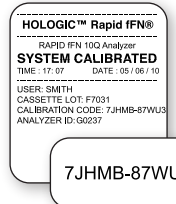


Rapid fFN PeriLynx QCette QC Device

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



Run Liquid Controls

- For Each New Cassette Lot

Allow Liquid Controls to reach room temperature before running a control test.

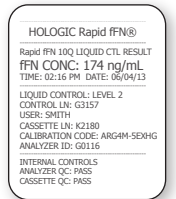
1. Select 'RUN LIQUID QC' on Main Menu
2. Enter User ID, Rapid fFN 10Q Cassette Lot, select either **Negative/Level 1** or **Positive/Level 2** Control and enter the Control Lot from the vial then press 'NEXT'
3. Pipette **0.2ml (200µl)** of Liquid Controls sample into well of Rapid fFN 10Q Cassette 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 Controls 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.

Please note that Liquid Controls must be kept in the fridge and expire 6 months after opening.



Liquid Controls



Rapid fFN 10Q Cassette