PoCT PROCEDURE

## Point of Care Testing for Foetal Fibronectin on Hologic 10Q

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| LOCATION OF COPIES | 1. PA2  
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1 SCOPE AND PURPOSE
This document details the procedure for performing a Point of Care foetal fibronectin assay on the Hologic Rapid fFN10Q system.

2 RESPONSIBILITY
It is the responsibility of the local management team to ensure that the content of this document is applied to the performance of this test in order to ensure best practice, quality of results and health and safety.

All suitably trained staff are responsible for complying with the guidance set out in this document.

3 REFERENCES
1. 10Q System Manual.
4 DEFINITIONS
Rapid fFN Cassette The plastic pallet containing the reactive ingredients which is
inserted into the reader.
Foetal Fibronectin An isoform of fibronectin protein found between the decidua
and chorion.

5 RELATED DOCUMENTS
Trust Medical Devices Policy – Accessed via Trust Intranet
Infection Control Policy – Accessed via Trust Intranet
Pathology Sample Acceptance Policy Q-PULSE TRUST-POLICY 1 and Trust
Intranet
Rapid fFN 10Q system operators manual POC-EXT-25
Rapid fFN 10Q system pack inserts POC-EXT-24
Cytyc Safety Data sheets POC-EXT-26

6 INDICATIONS FOR ASSAY
The Rapid fFN 10Q Cassette for use in the Rapid fFN 10Q 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
asymptomatic women ≤ 34 weeks, 6 days when a cervicovaginal sample is
obtained during a routine prenatal visit between 22 weeks, 0 days and
30 weeks, 6 days of gestation in women with a singleton pregnancy.

7 PRINCIPLES OF ASSAY
Detection of fFN in cervicovaginal secretions is associated with preterm delivery
in symptomatic pregnant women between 24 weeks and 34 weeks, 6 days
gestation, and in asymptomatic pregnant women between 22 weeks and 30
weeks, 6 days gestation. The Rapid fFN® 10Q System is an in vitro diagnostic
device for the detection of fetal fibronectin and consists of the Rapid fFN® 10Q
Cassette used in the Rapid fFN® 10Q Analyzer. The Rapid fFN® 10Q Cassette is
a lateral flow, solid-phase immunochromatographic assay. The cervicovaginal
specimen is extracted into a buffer and a 200-µL sample is dispensed onto the
sample application well of the Rapid fFN 10Q Cassette. The sample flows from
an absorbent pad across a nitrocellulose membrane via capillary action through
a reaction zone containing murine monoclonal anti-fFN antibody conjugated to
blue microspheres (conjugate); the monoclonal antibody is FDC-6, specific for
fFN. 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 7 minutes of reaction time, the intensities of the test line and control line are interpreted with the Rapid fFN 10Q Analyzer.

7.1 Personnel permitted to perform assay
All suitably trained staff who have undergone the necessary training and competency assessment.

8 PRECAUTIONS AND WARNINGS
Do not use glass tubes or glass pipettes, as fetal fibronectin binds to glass. Tubes and pipettes of polypropylene or polyethylene are acceptable. Test results may not be interpreted visually and must be based on the use of the Rapid fFN 10Q Analyzer. 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. Handle cassettes with care: do not touch, scratch, or compress membrane materials in the Rapid fFN 10Q Cassette. Avoid cross-contamination of reagents. Recap controls tightly with the correct colour-coded caps. Source material used to prepare the controls is of human origin. The donors were tested and found to be negative for HIV1, HIV2, 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 Rapid fFN 10Q Analyzer.

9 SPECIMEN REQUIREMENTS

9.1 Collection
Obtain the specimen using the Cytyc Specimen Collection Kit, do not use any other swabs.

1. The polyester-tipped applicator provided in the Specimen Collection Kit should be inserted into the vagina during a speculum examination and lightly rotated across the posterior fornix for approximately 10 seconds to absorb the cervicovaginal secretions.
2. Once the specimen is obtained, carefully remove the applicator from the vagina and immerse the tip in the tube of buffer provided with the Specimen Collection Kit.
3. Break the shaft (at the score) even with the top of the tube.
4. Align the shaft with the hole inside the tube cap and push down tightly over the shaft, sealing the tube.
5. Label the tube with the patient's name and any other identifying information required on the tube label.
9.2 Specimen Storage and Transport
1. Specimens that are not tested within eight hours of collection must be stored refrigerated at 2° to 8°C and assayed within three days of collection, or frozen and assayed within three months.
2. Transport specimens at 2° to 25°C, or frozen.
3. Discard specimens after testing according to infection control policy.

9.3 Unacceptable Specimens
Specimens should not be tested if any of the following apply.

1. Specimens collected in or by any sample device other than the Rapid fFN Specimen Collection Kit.
2. Specimens with insufficient volume for testing.
3. Specimens received unlabelled.
4. Specimens not tested within 8 hours of collection if maintained at room temperature.
5. Specimens not tested within 3 days of collection if maintained at 2° to 8°C.
6. Frozen specimens older than 3 months from the sampling date.
7. Specimens received at temperatures >25°C.
8. Specimens subjected to more than one freeze-thaw cycle.

10 PERFORMING ASSAY
1. Select the appropriate option (Test Patient or Liquid Controls) from the Main Menu of the Rapid fFN 10Q Analyzer.
2. Enter User ID and press ENTER.
3. Enter the cassette lot number (printed on the foil pouch of the cassettes). The first three characters of the lot number will be displayed because the calibration has been set for a specific cassette lot number. Enter the remaining numbers of the lot number and press ENTER.
4. Enter control lot numbers in the same manner.
5. Remove one Rapid fFN Cassette from the foil pouch being careful not to touch the sample well or the reaction area. When prompted, insert the cassette into the analyzer. Push it in until it clicks and press ENTER.
6. Invert patient sample (or liquid control) to mix before testing. Using a calibrated pipette, add 200 µL of patient sample (or liquid control) to sample well and immediately press ENTER.
7. The analyzer times the 10 minute incubation of the cassette and starts the analysis. When the analysis is complete, the result will be displayed on the analyzer screen and the printed label. Press ESC to return to the Main Menu.
8. Remove the cassette from the analyzer.
9. A FAIL or INVALID control result must be repeated before any further patient testing can be done.
10. Attach the label to the record sheet and fill in the information, as the labels are printed on a thermal printer they will fade with time so results must be recorded in ink.
11 QUALITY CONTROL

11.1 Performing Daily Analyser Quality Control
Note: The 10Q QCette Setup must be performed PRIOR to running the QCette as a daily quality control device. Setup is performed once for the QCette received with the 10Q System. (See the 10Q QCette directional insert for details or the manual).

1. Select Option 3 (DAILY QC) from the Main Menu of the analyzer.
2. Enter the User ID and press ENTER.
3. Enter the QCette Serial Number and press ENTER.
4. Insert the QCette and press ENTER.
5. When analysis is complete, the result will be displayed on the analyzer screen and the printed label as SYSTEM PASS, FAIL or INVALID. No patient testing should be performed unless the QC has passed.
6. Attach the label to the record sheet and fill in the information, as the labels are printed on a thermal printer they will fade with time so results must be recorded in ink.
7. If the system repeatedly fails QC checking contact the PoCT team.

11.2 Performing Liquid Quality Control
The QCette only checks the detection system in the analyser so it is essential to run positive and negative liquid Quality Controls to check the whole system, particularly when each box of test cassettes is first opened.

1. Select option 8 Liquid Controls.
2. Input user ID then press enter.
3. Input the cassette lot (on cassette foil pouch) and press enter.
4. Select Negative or Positive control.
5. Input Control lot (on bottle label) and press enter.
6. Insert the cassette into the analyser and press enter.
7. The analyser will beep repeatedly then, as prompted, add the 200ul of sample and immediately press enter.
8. After approximately 7 minutes the result will be shown on the display and printed.
9. Repeat with the other liquid QC.

11.3 External Quality Control
All PoCT users must be signed up to an approved external quality assurance scheme (EQA) which will send samples periodically for testing on each analyser this is supplied by WEQAS. This EQA testing is processed by PoCT who will raise any problems identified with the local managers.

12 CALIBRATION
1. Select Option 2 (SET CALIBRATION) from the Main Menu of the analyzer.
2. Enter the User ID and press ENTER.
3. Enter the cassette lot number. All letters and numbers must be entered. Enter the number that corresponds to the correct letter and use the up and down arrows to scroll to the correct letter. Press ENTER when completed.

4. Enter the Calibration Code provided on each box of cassettes. The calibration 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 will be used for all cassettes of that lot number.

5. When calibration is complete, the result will be displayed on the analyzer screen and the printed label as SYSTEM CALIBRATED.

6. Press ESC to return to the Main Menu.

13 LIMITATIONS OF ASSAY

1. A false 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.

2. Modification of the assay protocol described herein may yield erroneous results.

3. The assay has been optimized with specimens taken from the posterior fornix of the vagina. Samples obtained from other locations should not be used.

4. The safety and effectiveness of using a cut-off other than that provided by the Rapid fFN Cassette Calibration Code has not been established.

5. Assay interference from the following components has not been ruled out: douches, white blood cells, red blood cells, bacteria and bilirubin.

6. The presence of infections has not been ruled out as a confounding factor to risk of preterm delivery.

7. Assay interference from semen has not been ruled out. Specimens should not be collected less than 24 hours after intercourse (see below).

8. Care must be taken not to contaminate the applicator or cervicovaginal secretions with lubricants, soaps, disinfectants, or creams (e.g., K-Y® Jelly lubricant, Betadine® disinfectant, Monistat® cream, hexachlorophene). These substances may interfere with absorption of the specimen by the applicator or with the antibody-antigen reaction of the Rapid fFN test.

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

14 REFERENCE RANGES

The cut-off used is 0.05ug/mL (50ng/mL).
15 **INTERPRETATION OF RESULTS**

- The limitations above must be taken into account when results are interpreted and the system must not be used if valid QC and calibration have not been achieved.
- 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 less than or equal to 7 or 14 days from specimen collection.
- 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.
- A negative foetal fibronectin test result is valid where the patient falls into one of the categories described in 13.1 above e.g. reports having had intercourse in the previous 24 hours.

16 **COSHH**

Follow Universal Precautions when handling patient specimens as detailed by the Infection Control Manual. Handle all components and all patient samples as recommended for any potentially infectious human serum or blood specimen in the HHS Publication No. (CDC) 93-8395, Biosafety in Microbiological and Biomedical Laboratories, U.S. Government Printing Office; Washington, DC. Use supplied personal protective equipment. Wipe up spills promptly and decontaminate affected surfaces. Avoid generation of aerosols. Follow appropriate waste handling regulations applicable to your area.

See pack inserts and Material Safety Data Sheets on Pathology Q-Pulse system.

17 **INFORMATION**

Point of Care Ext: 3114

- fFN Specimen collection kit code PRD-01020
- Rapid fFN 10Q Cassettes code PRD-01018
- Rapid fFN 10Q QCette (daily check) code PRD-01021
- Rapid fFN 10Q Controls (liquid control) code PRD-01019