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Standard Operating Procedure

Fetal Fibronectin Testing by Assisted Birth Practitioner Midwives

Document History

Document Location

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Revision History

Date of this Revision: 20/01/20	Date of Next Revision: 20/01/22

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1	21/01/17	Initial Draft Document	MAD/NG
2	21/01/20	No changes required	Faye Rodger

Approvals

This document requires the following approvals:

Name	Title
Dr B Magowan Mrs N Berry N Gammie	Lead Obstetric Consultant Associate Nurse Director/Head of Midwifery Supervisor of Midwives

Distribution

This document is to be distributed to:

Name	Title
All All All	Midwives/Nurses Operational Managers Service Managers

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Guideline/Standard Operating Procedure for APB Midwives in Fetal Fibronectin Testing

1. Introduction

Fetal Fibronectin (fFN) testing is carried out on women who present with signs and symptoms of pre-term labour. Detection of fFN in cervico- vaginal secretions is associated with preterm delivery in symptomatic pregnant women between 24 and 32 weeks gestation. Rapid fFN 10Q System is a quantative test for the detection of fetal fibronectin and consists of the Rapid fFN Cassette used in the Rapid fFn 10Qanalyzer. Use of fFN has been shown to reduce in-utero transfers (Giles *et al 2000*).

2. Purpose

fFN testing is currently carried out by the Obstetric Consultants or Registrars in the unit and the purpose of this document is to give guidelines for Assisted Birth Practitioner Midwives carrying out this procedure.

3. Intended use and Indications

The Rapid fFN 10 Q System is to be used as an aid in assessing the risk of preterm delivery in pregnant women with signs and symptoms of early preterm labour.

Indications:

24+0-32+0
Intact amniotic membranes
Cervical dilatation (≤ = 3cm)
Light PV Bleeding
Uterine tightening

4. Contraindications

Staff collecting the sample should only proceed to take the sample if the patient is suitable and should be aware of the following contraindications:

Advanced Cervical Dilatation (> = 3cm)
Rupture of Amniotic Membranes
Cervical Cerclage
Placental abruption
Moderate or gross vaginal bleeding.
Multiple gestations-triplets or more
Placenta Praevia
Sexual Intercourse and vaginal examination in the last 24hours

5. Limitations

The specimen must be taken from the posterior fornix

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

Manipulation of the cervix may lead to false positive results. Specimens should be obtained prior to digital examination of the cervix

Care must be taken not to contaminate the applicator or cervicovaginal secretions with lubricants, soaps, disinfectants or creams. These substances may interfere with absorption of the specimen by the applicator or with antibody-antigen reaction of the Rapid fFN 10Q test.

False positives may occur as a result of blood or semen, therefore history of sexual intercourse in last 24hrs / vaginal bleeding should be obtained.

6. Before Patient Testing

Explain to the mother that testing is similar to the experience of having a smear test and obtain verbal consent.

Perform the daily Analyzer Quality Control by selecting Option 3 (Daily QC) from the main menu of the Rapid fFN 10Q analyzer. When analysis is complete the result will be displayed on the analyzer screen and printed label as SYSTEM PASS & Level 1 PASS (numeric value) : Level 2 PASS (numeric value). A FAIL or INVALID result should not be repeated. Place sticker with results in the log book and sign.

7. Procedure

Obtain the specimen using the Rapid fFN 10 Q System Specimen Kit.

- Insert a sterile speculum using warm water ONLY as a lubricant into the vagina. Once the posterior fornix of the vagina is identified the polyester-tipped applicator should be inserted into the vagina and lightly rotated across the posterior fornix for approximately 10 seconds to absorb the cervico-vaginal secretions.

- Once the specimen is obtained, carefully remove the applicator from the vagina and immerse the tip in the tube provided with the specimen collection kit.

- Break the shaft (at the score) even with the top of the tube. Align the shaft with the hole inside the tube cap and push down tightly over the shaft sealing the tube.

- Label the tube with the patients name and CHI number.

- Samples should be tested as soon as possible- preferably straight after collection.

Specimens that are not tested within eight hours of collection must be stored refrigerated at 2 º to 8º C and assessed within three days of collection

See appendix 1 for information on reagent stability and storage

8. Patient Test

- From the main menu of the analyzer select “1 TEST PATIENT”.
- Enter User ID and press ENTER. Your User ID is your initial.
- 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.
- Enter the patients CHI and press ENTER.
- Remove the Rapid fFN 10Q 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 and push until it clicks and press ENTER, the cassette is checked.
- Using a calibrated pipette or 1ml syringe add PRECISELY 200ul /0.2 ml of patient sample to the well and press ENTER immediately. Dispose of the pipette/syringe as per clinical waste policy.
- The analyzer times the 7 minute incubation of the cassette and then 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. Remove the printed label and file in the case notes and in the log book and record the clinician who took the sample that was tested.
- The results are reported as fFN level in ng/m.l
- Remove the cassette from the analyzer – discard safely as clinical waste.

9. Interpretation of results

The fFN result for the patient sample will be displayed on the Rapid fFN 10Q Analyzer display screen as a quantitative value in ng/ml.

The result will be reported as INVALID if the test does not meet internal quality controls.

If the assay is reported as INVALID then retest with 200ul/0.2ml of additional sample on a new cassette.

The document NPT/287-Protocols and Action Guidance relating to Quantitative fetal Fibronectin determination contains guidance on the reference limits and action

protocols relating to results from this analyzer. This document can be found in the fFN folder.

The interpretation of the result MUST be done in conjunction with the clinical presentation of the woman, all other available test information and by reference to NPT/287-Protocols and Action Guidance relating to Quantitative fetal fibronectin determination.

10. Documentation

The following should be clearly documented in the hand held notes;

- Rationale for fFN testing
- Record of discussion with patient
- Consent to procedure
- Result sticker from fFN test
- Plan of action following result
- Consultant or registrar referral

11. Training for APB Midwives in fFN testing

1. Completion of Hologic CD Rom
2. Attendance at Rapid fFN10Q training by Hologic representative
3. 1-1 Practical Training Session with Obstetric Consultant or Registrar
4. Supervision of 2 procedures by Obstetric Consultant or Registrar
5. Record of Competence to be filed in personal training log (see appendix 2.)
6. Retain evidence in log book to demonstrate ongoing competence

12. References

Peaceman A, Andrews W, Thorp W (1997) Fetal Fibronectin as a predictor of preterm birth in patients with symptoms: a multicenter trial, AJOB Gyn 177 (1) pp 13-18

Gile W, Bistis A, Knox M (2000) The effect of Fetal Fibronectin Testing on admission to a tertiary maternal fetal medicine unit and cost savings, AAJOG, 182 pp 439-442

13. Appendices

Appendix 1.

Reagent Stability and Storage

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The shelf life of the Rapid fFN Cassette is 18 months from date of manufacture and unopened cassettes may be used until the expiration date printed on the foil pouch. Once the foil pouch is opened the cassette must be used immediately

The Rapid fFN 10Q Cassette should be stored at room temperature (15º to 30º C / 59º to 86º F)

The shelf life of the Rapid fFN Control Kit is one year from the date of manufacture. Unopened controls may be used until the expiration date printed on the bottle. **Once**

opened, they should be used within 6 months. Upon opening a bottle of control, label it up with the new expiry date (i.e. 6 months time). Controls should not be used if they are cloudy or discoloured.

Calibration and liquid Quality Control **MUST** be performed each time a new lot number or a new delivery of Rapid Ffn 10Q Cassettes is received.

The Rapid Ffn 10Q liquid control Kit should be stored refrigerated (2º to 8º C). Once opened expiry is 6 months from date of opening.

The Rapid fFN 10Q Analyzer and Printer should be operated at room temperature (15º to 30º C / 59º to 86º F)

The Rapid fFN 10Q QCette should be stored at room temperature (15º to 30º C / 59º to 86º F)

The Rapid fFN Test Specimen Collection Kit should be stored at 2º to 25ºC

Precautions

- 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 discoloured.
- 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.
- Handle the controls and all patient specimens as if potentially infectious.
- Ensure all waste is disposed of in an appropriate manner using NHS Borders Standard Precautions policy as Clinical waste.

Appendix 2

Fetal Fibronectin Testing Record of Competence

Training	Date	Name/designation
Completion of Hologic CD Rom		
Attendance at theory training session with Hologic representative		
1-1 Theory /practical training session with obstetric consultant registrar		
Direct Observation of Procedural Skills (1)		
Direct Observation of Procedural Skills(2)		
Record of competence filed in personal training log.		
Retain evidence in log book to demonstrate ongoing competence		

Name	Signature	Date
Lead consultant		
Assisted Birth Practitioner Midwife		
Supervisor of Midwives		