Draft Fetal Fibronectin (fFN) Testing Policy and Procedure

POLICY STATEMENT:

Acknowledgments:
Original Guideline produced by a sub-committee of the Canadian Perinatal Partnerships Coalition, October 15, 2007 with adaptations from the Child Health Network for the Greater Toronto Area (CHN) and the British Columbia Reproductive Care Program (BCRCP).
Guideline for Use in the Management of Preterm Labour Practice Guideline, Adapted with Revisions Approved by Ontario's Provincial Maternal-Newborn Advisory Committee (December**, 2008)**
Perinatal Partnership Program of Eastern and Southeastern
The Ottawa Hospital Fetal Fibronectin (fFN) testing policy.

When considering admission for symptoms of preterm labour (PTL) **between 24-34 weeks** a fFN swab will be obtained. **fFN testing can be ordered by the staff physician, resident, and midwife.**

DEFINITIONS:

Fetal Fibronectin (fFN) is a glycoprotein produced by the chorionic membranes and is localized to the deciduas basalis adjacent to the intervillous space. Its primary purpose appears to be that of an adhesion molecule (tissue glue) which helps bind the chorionic membranes to the underlying maternal decidua.
It is normally found in cervico-vaginal secretions until 22 weeks gestation but is virtually never found between 24 and 34 weeks gestation unless the cervix has undergone premature effacement and dilatation, usually in association with symptomatic uterine contractions. It can also be released in response to inflammation or separation of amniotic membranes from the deciduas. There is a strong association between the presence of Fetal Fibronectin in cervico-vaginal secretions and preterm labour after 24 weeks gestation.

ALERTS:

SWAB: **INCLUSION CRITERIA**

Intended admission/transfer of women between 24 and 34 completed weeks of gestation
24– 34 weeks gestation presenting with S&S of threatened preterm labour

- Regular uterine contractions > 6 per hour and /or pelvic pressure
- Lower abdominal pain, pressure, fullness
- Back pain
- Pelvic pain, pressure, fullness
- Vaginal bleeding (light)
- Abnormal discharge

Cervical dilatation < 3 cm
Intact membranes
Established fetal wellbeing
Intended administration of antenatal corticosteroids

NO SWAB: **EXCLUSION CRITERIA**

Estimated gestational age (EGA) < 24 weeks or > 34 completed weeks
Cervical dilatation $\geq$ 3 cm
Preterm rupture of membranes (PROM)
History of sexual intercourse, vaginal probe or lubricant use within 24 hours
Vaginal bleeding (moderate/heavy)
Ruptured membranes
Cervical cerclage

Swab is stable for 8 hours at room temperature. If not processed within 8 hours, refrigerate. Swab must be processed within 3 days of collection.

EQUIPMENT:
Sterile speculum
Sterile gloves
Light source
Hologic LP Fetal Fibronectin Kit: swab, collection tube, tube cap,
Laboratory requirements: test cartridge and instrument system

PROCEDURE:

1. Position for speculum examination
2. Physician/midwife/nurse performs speculum exam (no lubricant except water). Swab taken from the posterior vaginal fornix by rotating the swab for 10 seconds.
3. Remove swab and immerse Dacron® tip in buffer in fFN tube. Break the shaft even with the top of the tube (at the score). Align the shaft with the hole inside the tube cap and push down tightly over the shaft to seal the tube.
4. Physician/midwife/nurse follows with vaginal exam
   i) **Discard swab if cervix:**
   Closed and contractions settle with observation ➔ Discharge
   OR
   ≥ 3cm dilated or < 1 cm long (80-100% effaced), diagnosis of preterm labour ➔ Admit or Transfer
   ii) **Send swab if cervix:**
   < 3 cm dilated or > 1 cm long (<80% effaced)
   Ongoing uterine activity
   Clinical suspicion of preterm

   Inappropriate Use of the Test: fFN testing is not to be used in the absence of symptoms of PTL or for reassurance that PTL will NOT occur.
5. When sending swab to lab prepare as follows:
   i) Label
   ii) Complete stat Biochemistry lab requisition (pink)
   iii) Write "Fibronectin" under "Other tests" section
   iv) Complete fFN Datasheet - original to lab with requisition
   - photocopy remains on OAU chart
   v) Call the Biochemistry lab to confirm processing time (expected turnaround time ≈ 1 hr.)
6. Results - reported as **POSITIVE or NEGATIVE**
   - recorded on datasheet (photocopy) then placed in designated fFN binder

POSITIVE fFN (likelihood of Preterm Birth within 7 days - 11 to 39%, Vendor quotes 16-17%)

- **Positive ≥ 50 ng/ml**

If contractions are reported and/or noted on EFM initiate appropriate treatment consider admission or transfer of the woman to an appropriate facility for treatment of preterm labour.

<32 weeks – Tertiary centre
≥32 weeks – Level 2 or Level 2+ centre

i) **Cervical change**
- Initiate preterm labour therapy
  - Tocolytics
  - Corticosteroids
  - Antibiotics

ii) **No cervical change**
- Admit for observation for 12-24 hrs.
- Consider assessing cervical length via ultrasound
- Following observation period and no change in status consider discharge with standard preterm labour precautions
- Follow-up with physician within 1-2 weeks

NEGATIVE fFN (indicates that delivery is not likely to take place within 7-14 days > 95% accuracy)
Re-examine in 2-3 hrs

- **Negative < 50 ng/ml**

i.) **Cervical change**

- Initiate preterm labour therapy

ii) **No cervical change**

- Discharge patient from hospital with instructions to return if symptoms worsen. She should limit activities that aggravate her symptoms. Ultimately, patient disposition may be dependent on geographical, weather and/or other medical circumstances.
- Recommend follow-up with physician within 1-2 weeks
- Symptoms abate ➔ resume normal family and work activities
- Reassure mother
- Follow up care may include a vaginal ultrasound to assess cervical length if available (If cervical length is >2.5 cm it provides further reassurance that delivery will not occur preterm) +/- a swab for bacterial vaginosis.
- Consider repeat test in 7-14 days, if symptomatic. *An exception to the time for reassessment may be made if the woman lives in a remote community and fly out transportation must be arranged. In such a case the clinician may repeat the swab testing if the woman is symptomatic. Decisions regarding her disposition ultimately should be discussed with the mother, the remote health care providers and the consulting obstetrical service providers.*

DOCUMENTATION:
Order Sheet
Fetal fibronectin Datasheet (see sample)
Outpatient Assessment Record
Integrated progress notes
Audit tool: to be submitted with requests for test kit reimbursement to the Ministry of Health for reimbursement and will include

1. The number of fFN tests performed
2. The number of negative/positive tests recorded
3. Patient disposition (home, admitted, transferred by air, ground or combination to another centre)

PATIENT TEACHING:
Fibronectin testing and meaning of results
Explanation of test procedure
Signs and symptoms of PTL

REFERENCES

Abenhaim HA, Morin L, Benjamin A. Does availability of fetal fibronectin testing in the management of threatened preterm labour affect the utilization of hospital resources? J Obstet Gynaecology Can 2005; 27:689-94.

Giles W, Bisits A, Knox M, Madsen G, Smith R. The effect of fetal fibronectin testing on admissions to a tertiary maternal-fetal medicine unit and cost savings. Am J Obstet Gynecol 2000; 182:439-42.

Iams J, Casal D, McGregor JA, Goodwin TM, Kreaden US, Lowensohn R, Lockitch G. Fetal Fibronectin Improves the Accuracy of Diagnosis of Preterm Labour. Am. J. Obstet Gynecol 1995; 173: 141-5.

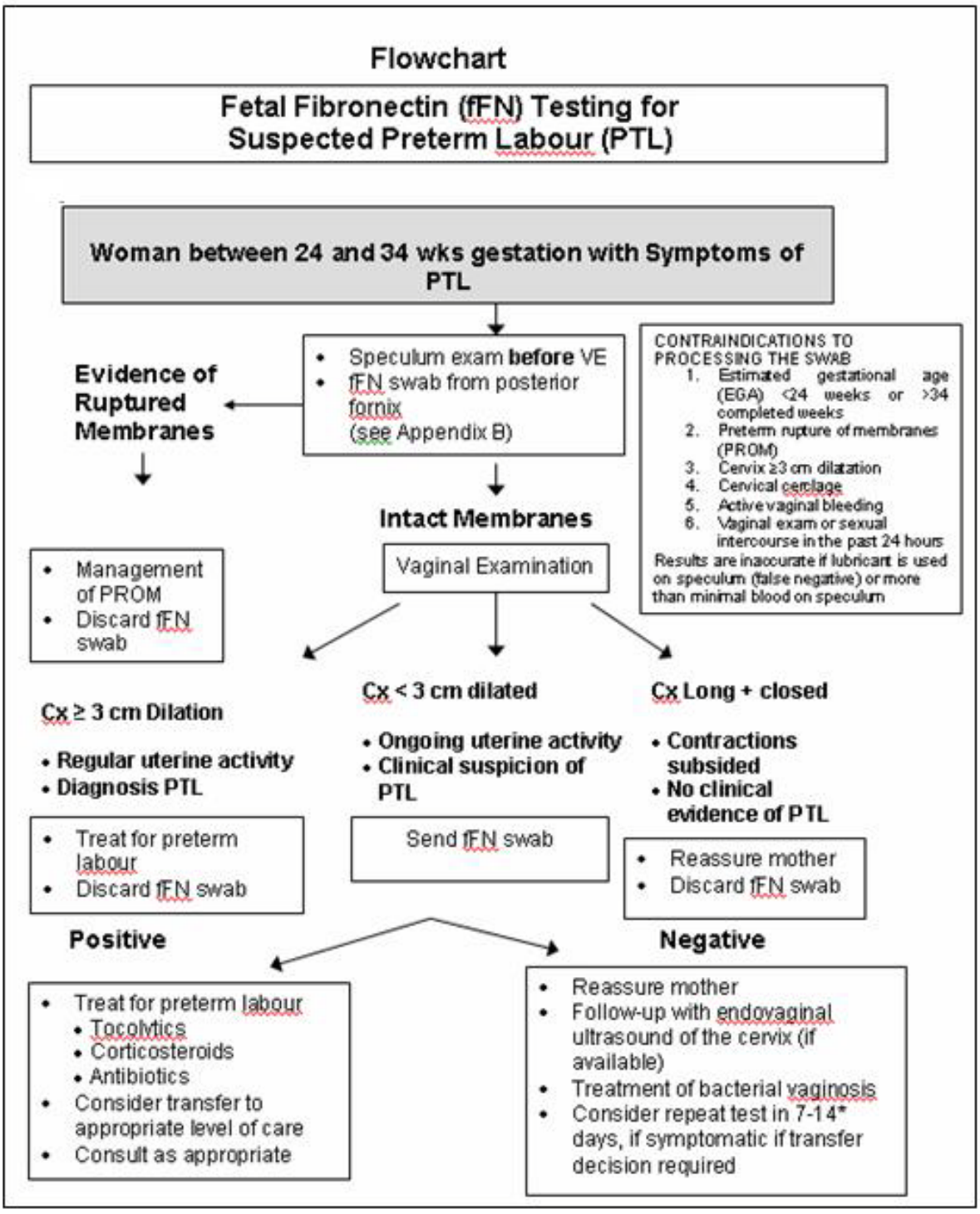
Joffe MJ, Jacques D, Bemis-Heys R, Burton R, Skram B, Shelburne P. Impact of fetal fibronectin assay on admissions for preterm labor. Am J Obstet Gynecol 1999; 180:581-6.

Leitich H, Kaider A. Fetal-fibronectin-how useful is it in the prediction of preterm birth. Br J Obstet Gynaecol 2003; 110:66-70.

Peaceman Am, Andrews WW, Thorp JM, Cliver SP, Lukes A, Iams JD, Coultrip L, Eriksen N, Holbrook RH, Elliot J, Ingardia C, Pieterantoni M. Fetal Fibronectin as Predictor of Preterm Birth in Patients with Symptoms: A Multicenter Trial. Am . J. Obst Gynecol 1997; 177: 13-18.

Sullivan A, Hueppchen NA, Satrin AJ. Cost effectiveness of bedside fetal fibronectin testing varies according to treatment algorithim. J Mat Fetl Med 2001;10:380-384.

.


Flowchart
Fetal Fibronectin (fFN) Testing for Suspected Preterm Labour (PTL)
Woman between 24 and 34 wks gestation with Symptoms of PTL
Speculum exam before VE
fFN swab from posterior fornix (see Appendix B)
Evidence of Ruptured Membranes
Intact Membranes
CONTRAINDICATIONS TO PROCESSING THE SWAB
1. Estimated gestational age (EGA) <24 weeks or >34 completed weeks
2. Preterm rupture of membranes (PROM)
3. Cervix ≥3 cm dilatation
4. Cervical cerclage
5. Active vaginal bleeding
6. Vaginal exam or sexual intercourse in the past 24 hours
Results are inaccurate if lubricant is used on speculum (false negative) or more than minimal blood on speculum
Management of PROM
Discard fFN swab
Vaginal Examination
Cx ≥ 3 cm Dilation
Regular uterine activity
Diagnosis PTL
Cx < 3 cm dilated
Ongoing uterine activity
Clinical suspicion of PTL
Cx Long + closed
Contractions subsided
No clinical evidence of PTL
Treat for preterm labour
Discard fFN swab
Send fFN swab
Reassure mother
Discard fFN swab
Positive
Negative
Treat for preterm labour
Tocolytics
Corticosteroids
Antibiotics
Consider transfer to appropriate level of care
Consult as appropriate
Reassure mother
Follow-up with endovaginal ultrasound of the cervix (if available)
Treatment of bacterial vaginosis
Consider repeat test in 7-14* days, if symptomatic if transfer decision required

Fetal Fibronectin Test Datasheet

*This test is **ordered** for women where **admission is being considered** for symptoms of PTL*

Call Biochemistry lab prior to sending swab
Determines Technologist availability and turnaround time

This sheet must accompany swabs sent to the lab for processing
Place a photocopy in designated binder or indicate on audit sheet.

Patient ID

Date: _____/_____/_____ (YY MM DD) **Time Swab Taken:** _____

Ordered by : _____ **Performed by:** _____

G_____ **T**_____ **P** _____ **A**_____ **L**_____ **GA** ____weeks ____days

Reported in last 24 hrs. Vaginal Examination, Vaginal Bleeding, Vaginal Ultrasound, Lubricant Use
- ☐ No
- ☐ **Yes** – ***excluded from test***

TVS Cervical length (most recent) _____mm **Date:** _____/_____/_____ (YY MM DD) *(Leave blank if not done)*

fFN Performed at: ☐ Civic ☐ General ***IN*** ☐ OAU ☐ Birthing Unit ☐ Clinic ☐ B 4 ☐ 8 E ☐ Other _____

Exam findings:
Cervical dilated _____ cm (≤*2cm required for test processing*)
Cervical length _____ cm (*>1cm required for test processing)*
Effacement _____ % (*<80% required for test processing*)

Test result: ☐ Negative ☐ Positive ***Lab to call result to General OAU @ #78012***

Post test: ☐ Discharge ☐ ANHC program ☐ Admit

FOLLOW-UP:

TVS Cervical length (most recent) _____mm **Date:** _____/_____/_____ (YY MM DD) *(Leave blank if not done)*

Birth hospital: _____

Birth date: _____/_____/_____ (YY MM DD)

GA at birth: ____weeks _____days