

**IWK Health Center
Halifax, N.S.
Clinical Policy and Objective Manual**

Fetal Fibronectin Testing for Preterm Labor

A. POLICY

All patients who present to the IWK Health Centre, with a diagnosis of threatened preterm labour and who meet the eligibility criteria as outlined in this document should be considered for fetal fibronectin testing.

Definition:

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 deciduas.

There is a strong association between the expression of fFN in cervical-vaginal secretions and preterm labor (PTL). Although it can be found in cervical-vaginal secretions until 22 weeks gestation, it is virtually never found in the window between 24 and 34 weeks gestation unless the cervix has undergone premature effacement and dilatation, usually in association with symptomatic uterine contractions.

B. PURPOSE

To outline the population of patients who present with threatened preterm labour, who are eligible for fetal fibronectin testing.

To provide guidelines for the collection of and interpretation of fetal fibronectin testing in patients with threatened preterm labor.

C. PROTOCOL

1. Indications for fFN testing:
 - a. 24-33 weeks gestation
 - b. Threatened preterm labour which include:
 - i. regular uterine contractions > 6/hour
 - ii. pelvic pressure
 - iii. low abdominal pain and/or cramps
 - iv. low backache

- c. Intact amniotic membranes
 - d. Cervix less than 3 centimeters dilated
 - e. Established fetal well being
2. Contraindications for testing
 - a. Estimated gestational age (EGA) < 24 weeks or >33 completed weeks
 - b. Preterm rupture of membranes
 - c. Cervix > 3 cm dilatation (known prior to current presentation)
 - d. Cervical cerclage
 - e. Active vaginal bleeding
 - f. Vaginal exam or sexual intercourse in the past 24 hours
 - g. fFN test within past 7 days
3. Explain procedure to patient and support person.
4. Provide support for patient, as this is a very stressful time.
5. Prior to a vaginal exam, a speculum exam will be performed by physician or registered nurse (who is certified in the competency for speculum exam) and a swab for fetal fibronectin collected as per physician order. (See Appendix B).
6. Specimen collection
 - a. Use only the Adeza Fetal Fibronectin Kit (swab, collection tube with tube cap)
 - b. Obtain additional supplies/equipment: sterile vaginal speculum, sterile gloves and light source.
 - c. Ensure that the swab and transport tubes are intact and have not leaked. Do not use if integrity of swab package or transport tube has leaked.
 - d. Position for speculum exam (Refer to policy # BU LDR - 13 Speculum Exam of Cervix).
 - e. Collect specimen during a speculum exam with special fFN swab using an unlubricated speculum (no lubricant except water).
 - f. Speculum must occur before a vaginal ultrasound, before digital examination and without the use of lubricants (all can alter predictability of the tests). If any of these has occurred, wait 24 hours and then obtain the test.
 - g. As the protein is found in high concentrations in amniotic fluid, the test is only advised in patients with symptomatic preterm labor (low abdominal pain, and/or cramps, low backache, pelvic pressure, regular uterine contractions) **without ruptured membranes**.
 - h. The swab is lightly rotated across the posterior fornix of the vagina for 10 seconds during sterile vaginal speculum exam. Take care not to break swab during the specimen collection. (See Appendix B).
 - i. Swab preparation (See Appendix B):
 - i. Remove lid from test tube

- ii. Insert swab into buffer in test tube
- iii. Carefully break the shaft of the swab at the score mark so that it is even with the top of the tube.
- iv. Align the shaft with the hole inside the tube cap and push the cap down tightly, sealing the tube.
- v. Label the tube and send to lab as soon as possible.
- j. If test cannot be performed within 8 hours of collection, refrigerate specimen until test can be performed.
- k. Perform test within three days of collection.

Note: Once the swab has been obtained, if subsequent physical exam does not indicate that there are sufficient signs of preterm labor (or if other contraindications are present i.e. ruptured membranes, cervical dilatation > 3 cm, etc.), the swab should be discarded and the test **NOT** performed.

- 7. Test results
 - Positive ≥ 50 ng/ml
 - Negative < 50 ng/ml
- 8. Factors affecting accuracy of the test
 - a. False positive tests may be caused by:
 - i. Digital exam prior to the speculum collection of the sample
 - ii. More than a minimal amount of blood in the specimen (fFN is present in the plasma).
 - iii. The presence of amniotic fluid in the specimen (amniotic fluid contains high levels of fFN)
 - iv. Intercourse within the previous 24 hours (fFN is present in seminal fluid).
 - b. False negative tests may be caused by:
 - i. Presence of a lubricant on the speculum.
- 9. Once test results are known, provide additional information, reassurance, and ongoing management as required.
- 10. Positive Test Result
 - a. In association with symptoms of preterm labor and cervical change indicates a higher risk of preterm delivery
 - b. Consider:
 - i. Administration of corticosteroids as indicated
 - ii. Administration of tocolytics as indicated
- 11. Negative Test Result
 - a. Indicates that delivery will not take place within 7-14 days (95% accuracy)

- b. Discharge home with instructions for return if symptoms worsen and limit activities that aggravate her symptoms if geographical, weather and other medical circumstances permit.
- c. Close follow up care may include a vaginal ultrasound to assess cervical length (If cervical length is > 2.5 cm it provides further reassurance that delivery will not occur preterm) +/- a swab for bacterial vaginosis
- d. Re-evaluate in 7-14 days

12. Complete documentation of the following:

- a. Maternal Assessment Form (Form # 5055)
- b. Partogram (Form #5047)– if in active labor
- c. Nurses notes – ongoing assessment and interventions, if not in active labor.
- d. Fetal monitoring tracing and interpretation.

D. SUPPLEMENTAL REFERENCES

Adeza Biomedical (2003). Adeza Biomedical Fetal Fibronectin Enzyme Immunoassay and Rapid fFN for the TLI-IQ System: Information for Health Care Providers. Sunnyvale, California: Author.

Bernhardt, J. & Dorman, K. (2004). Preterm birth assessment tools. *AWHONN Lifelines*, 8(1), 38-4.

British Columbia Reproductive Care Program (2005). Obstetric Guideline 2A: Preterm Labour. Vancouver, BC:BCRCP.

Child Health Network (2006). Fetal Fibronectin Guideline for Use in the Management of Preterm Labour; Practice Guideline. Child Health Network for the Greater Toronto Area: Toronto.

Farquharson, D., Lange, I., MacDonald, W.A., Morin, L., & Simard, F. (2005). SOGC Special report: Preterm Labour. The Society of Obstetricians and Gynecologists of Canada.

Gray, B.A. (2006). A ticking uterus: How nurses can identify , treat and prevent preterm labour. *AWHONN Lifelines*, 10(5), 380-389.

Lockwood, C.J. & Funai, E.F. (2006). Tests for prediction of preterm labor and delivery.

www.uptodate.com. Last accessed website 12/01/2007.

The Ottawa Hospital (2002). Fetal Fibronectin (fFN) Testing Policy. Ottawa: Author.

Plaut, M.M., Smith, W., & Kennedy, K. (2003). Fetal fibronectin: The impact of a rapid test on the treatment of women with preterm labor symptoms. *American Journal of Obstetrics & Gynecology*, 188(6), 1588-1595.

Reproductive Care Program of Nova Scotia (2006). Fetal Fibronectin Testing for Suspected Preterm Labour in Nova Scotia Telehealth Presentation. Nova Scotia: Author.

Ruiz, R.J., Fullerton, J. & Brown, C.E.L. (2004). The utility of fFN for the prediction of preterm birth in twin gestation. *JOGNN*, 33(4), 446-454.

E. AUTHORS/CONSULTANTS/REVIEWERS

Maxine Bernard RNC – Clinical Educator Birth Unit
 BU Education Team
 Jeff Dempster
 Childbirth Care Team

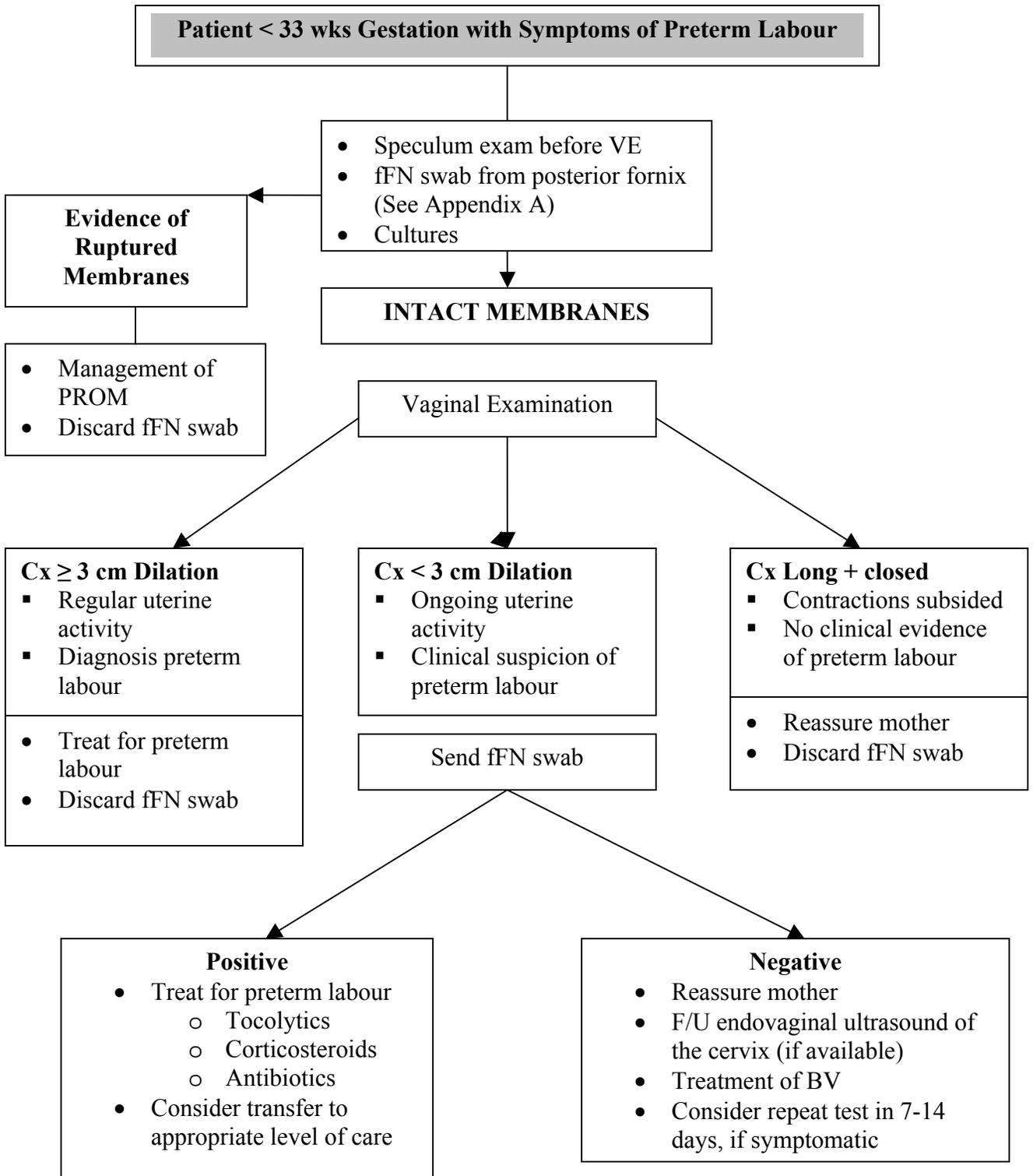
Responsibility Of:	Women's & Newborn Health Program	Effective Date:	March 2007
Last Review Date:	New	Next Review Date:	March 2010
Cross References:	Sterile Speculum for Fern testing: Policy #7150 Preterm Labour Policy #7140	Policy Number:	7065
Target Audience:	Birth Unit Registered Nurses and physicians	Policy (ies) Replaced:	N/A
Pages:	7	Approved By:	Childbirth Care Team

F. APPENDIX:

**Appendix A: Fetal Fibronectin testing for Suspected Preterm Labour
 Appendix B: Steps to collect fFN swab**

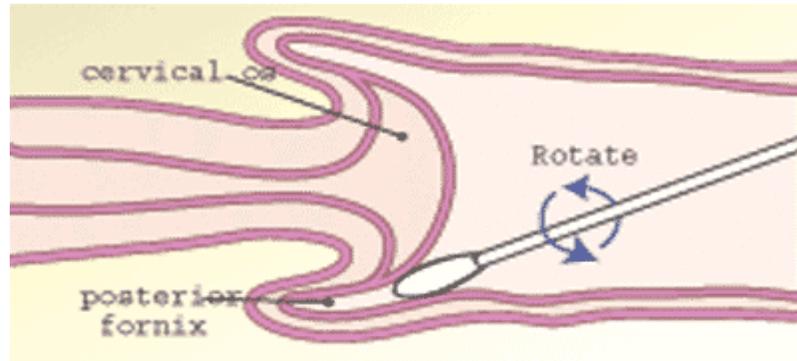
APPENDIX A

Fetal Fibronectin Testing for Suspected Preterm Labour

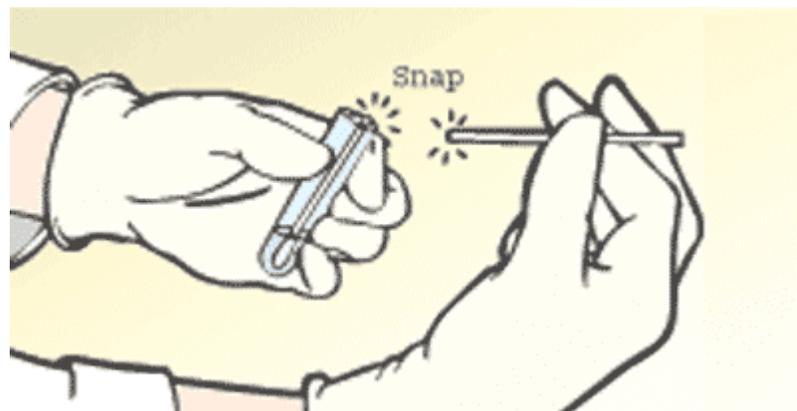


APPENDIX B

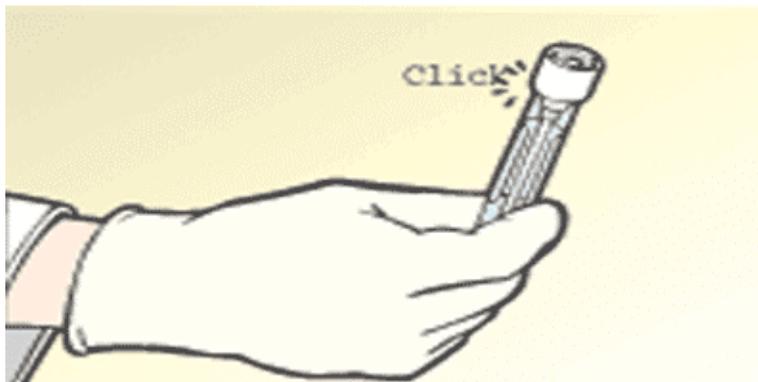
1. During speculum examination, prior to any examination or manipulation of the cervix or the vaginal tract, lightly rotate the swab across the posterior fornix of the vagina for 10 seconds to absorb cervicovaginal secretion.



2. Remove swab and immerse the polyester tipped swab in buffer. Break the shaft (at the score) even with the top of the tube.



3. Align the shaft with the hole inside the tube cap and push down tightly over the shaft, sealing the tube. Warning: The shaft MUST be aligned to avoid leakage.



4. Send the tube at room temperature to the laboratory for testing.
5. Specimens that are not tested within 8 hours of collection must be stored refrigerated at 2° to 8° C and assayed within 3 days of collection or frozen and assayed within 3 months.