Fetal Fibronectin (fFN) Assay Protocol

The purpose of this guideline is to establish a method of collecting fFN for patients in possible pre-term labor

Supportive Data:

The fFN is a test used to assess the risk for preterm delivery within 7-14 days from the time of vaginal sample collection. The strongest supportive data is for testing symptomatic patients between 24 and 34 and 6/7 weeks gestation.

Negative test results have a predictive value of up to 99% that delivery will not occur in within 7–14 days. The care provider will decide if the obtained specimen will be analyzed by the lab for fFN based on clinical signs and symptoms. In addition to the patient's clinical symptoms, the fFN result will enable the provider to further evaluate the need for admission and/or tocolysis, observation or discharge. The information obtained from the fFN testing may be enhanced by combining the results with transvaginal sonography for cervical length. A cervical length <2.5 cm and a positive fFN increases the concern for preterm delivery for that patient, whereas a cervical length >2.5 cm and a negative fFN is reassuring that preterm birth should not occur in the next 7 days.

CONTRAINDICATIONS:

- Less than 22 weeks gestation
- Greater than 34 6/7 weeks gestation
- H/O intercourse, vaginal exam or vaginal ultrasound within the last 24 hours
- Vaginal bleeding
- Spontaneous rupture of membranes
- $\geq$ 3cm dilated or 80% effaced
- Known previa (even if not bleeding)

Procedure:

MFM Staff RN or Provider will:

1. Obtain specimen collection tube and polyester swab.
2. Obtain specimen using sterile vaginal speculum. Lightly rotate Dacron swab for 10 seconds in posterior vaginal fornix. The swab must not be placed directly in the cervix. When the cervix is not directly visualized the specimen can be obtained from the posterior vaginal walls.
3. Immerse the specimen swab tip in the transport tube containing buffer solution. Break the shaft 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 tightly.
5. Label per protocol.

6. Following specimen collection vaginal exam may be done per protocol.
7. At completion of initial evaluation of patient, if test is indeed indicated, order the test in LIS and transport specimen to lab per protocol.

References:

1. Goldenberg, Robert L., The Management of Preterm Labor, ACOG, Vol. 100, NO. 5, Part 1, November 2002
2. Iams, Jay D., Prediction and Early Detection of Preterm Labor, ACOG, Vol 101, NO. 2, February 2003

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