Discussion

Two clinical uses of the fetal fibronectin test are to assess risk of preterm delivery in women with signs and symptoms of preterm labor, who present at 24 weeks 0 days to 34 weeks 6 days gestation (cervical dilatation less than 3 cm) and in asymptomatic women during routine obstetric visits, who are 22 weeks 0 days to 30 weeks 6 days gestation. Fetal fibronectin is normally elevated in cervicovaginal secretions during the first half of pregnancy. Therefore, a specimen collected during this time may show a positive result because the specimen was collected too early. Furthermore, a number of preanalytical specimen and/or patient factors may cause increased fetal fibronectin in the cervicovaginal fluid unrelated to imminent preterm delivery. The value of a given fetal fibronectin result may be significantly compromised if certain factors related to the specimen itself or to the patient's clinical status are present. The laboratory should be aware of these test limitations in order to inform clinicians about the appropriate utilization of this test.

The following are two case vignettes of obstetric patients who present as possible candidates for fetal fibronectin testing, one has signs and symptoms of preterm labor and the other is asymptomatic.

Note: There was an excellent response rate to this voluntary educational exercise by FF-B 2014 Survey participants with 78.5% of the laboratories also submitting answers to the following questions.

Case 1:
A 31-year-old woman with a 33 week pregnancy arrives at the hospital with signs and symptoms of preterm labor. Speculum exam shows that the cervix has dilated to two centimeters and there is evidence of rupture of amniotic membranes.

Which of the following statements is correct?	Participants Number	%
A. Fetal fibronectin testing is inappropriate because patient presents too early in her pregnancy.	4	0.3
B. Fetal fibronectin testing is inappropriate because patient presents too late in her pregnancy.	14	1.0
C. Fetal fibronectin testing is contraindicated because the cervix is dilated.	39	2.9
D. Fetal fibronectin testing is contraindicated because the amniotic membranes are not intact.	1121	83.7
E. There are no contraindications to fetal fibronectin testing in this patient.	162	12.1

Correct statement is D:

Nearly eighty-four percent of respondents chose the correct answer. Fetal fibronectin testing is contraindicated because the amniotic membranes are not intact.

Testing is not indicated when there is rupture of amniotic membranes since fetal fibronectin is present in amniotic fluid. Furthermore, there is already a high likelihood of imminent delivery under these circumstances. Additional diagnostic testing is usually not necessary to assess risk of preterm delivery in such patients. Other contraindications to fetal fibronectin testing in symptomatic women include: advanced cervical dilatation (greater than 3 cm), cervical cerclage or moderate or gross vaginal bleeding.[1]

Case 2:
A 19-year-old woman with no signs and symptoms of preterm labor presents at 23 weeks gestation for a routine prenatal visit. During a speculum examination, a specimen of cervical/vaginal secretions was obtained for fetal fibronectin testing as part of an assessment for risk of premature delivery.

Which of the following statements is correct?	Participants Number	%
A. Fetal fibronectin testing is inappropriate because patient presents too early in her pregnancy.	269	20.1
B. Fetal fibronectin testing is inappropriate because patient presents too late in her pregnancy.	0	0
C. Fetal fibronectin specimen is compromised because it was obtained during a speculum examination.	74	5.5
D. Fetal fibronectin testing is contraindicated for assessment of the risk of preterm delivery in a woman who has no signs or symptoms of preterm labor.	380	28.3
E. There are no contraindications to fetal fibronectin testing in this patient.	618	46.1

There are two acceptable answers (D or E) depending upon prevailing clinical practice regarding utilization of fetal fibronectin testing to assess for risk for preterm delivery in asymptomatic women.

Nearly half of the respondents, 46%, chose answer E which states that there are no contraindications to fetal fibronectin testing. According to the manufacturer's product information, the fetal fibronectin test, in conjunction with other clinical information, can be utilized as an aid in the assessment of the risk of preterm delivery in asymptomatic women who are at 22 weeks 0 days to 30 weeks 6 days gestation. Note: This patient's gestational age of 23 weeks is appropriate for this test indication.

Another twenty-eight percent of the respondents chose answer D which states that fetal fibronectin testing is contraindicated because the woman has no signs or symptoms of preterm labor. This is also an acceptable answer. A recent practice bulletin (2012) published by the American College of Obstetricians and Gynecologists does not recommend the use of fetal

fibronectin screening of asymptomatic women because interventional studies have not demonstrated that such testing improved perinatal outcomes.[2]

This patient's specimen was obtained during a speculum exam which is the recommended collection technique. However, this procedure should be performed prior to digital cervical examination or vaginal probe ultrasound, since manipulation of the cervix before specimen collection may cause a falsely elevated fetal fibronectin result.[1]

References

1. Fetal Fibronectin Enzyme Immunoassay and Rapid fFN,
   Information for Health Care Providers
   Hologic, Inc
   250 Campus Drive
   Malborough, MA 01752

   Rapid fFN Cassette Kit REF 01200
   Rapid fFN Specimen Collection Kit REF 71738-001
   Hologic, Inc
   1240 Elko Drive
   Sunnyvale, CA 94089-2212

   www.hologic.com

2. Committee on Practice Bulletins—Obstetrics, The American College of Obstetricians and Gynecologists. Practice bulletin no. 130: prediction and prevention of preterm birth. *Obstet Gynecol* 2012; 120:964.

Glynnis B. Ingall MD, PhD, FCAP
Chemistry Resource Committee