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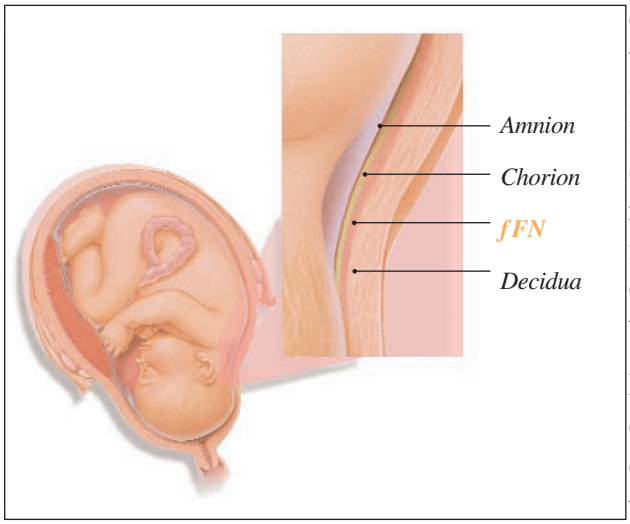
# ADEZA'S FETAL FIBRONECTIN (fFN) TEST IDENTIFIES WOMEN AT RISK OF PRETERM BIRTH

*Diagnosing the Signs and Symptoms of Preterm Labor*

The leading cause of neonatal morbidity and mortality in the United States continues to be premature birth, a statistic that grows more urgent, given its increasing rate—from 9.4% in 1965 to 11.9% in 2002 (*1*). Exposing the risk of preterm birth (PTB) provides the greatest opportunity to positively affect perinatal outcomes.




**Adeza Biomedical Corporation** (Sunnyvale, CA) has developed a safe, non-invasive test that helps identify women at increased risk of PTB. FDA-approved and cited by ACOG's committee on Obstetric Practice (*2*) as a strong indicator of PTB, the **Rapid fFN** for the TLiQ® System is an objective measure of fetal fibronectin that allows any certified laboratory to report results in less than one hour. Fetal fibronectin, a direct measure of preterm delivery risk, is a protein located in the choriodecidual interface that can be sampled in cervicovaginal secretions. This single objective test encompasses all etiological pathways, and if necessary, the Rapid fFN enables the obstetric provider to make important outcome decisions with confidence in a faster and more clinically relevant time frame.

Adam Duhl, MD, perinatologist and Director of Maternal-Fetal Medicine at the Mercy Hospital (Pittsburgh, PA), notes that there are many variable aspects that weigh into his clinical decision-making about preterm birth, including specific symptoms and adverse reproductive history. Says Dr. Duhl: "The fFN test is a very good diagnostic test, a helpful addition in my evaluation of the patient. I often use a coupling of the fFN test and cervical length measurement (CLM) when time permits; however, if there isn't time, or only one can be done, I choose the fFN test."

Dr. Duhl goes on to explain, "The benefits of the fFN test are twofold. Because it is a qualitative measurement, the results are the same wherever the test is done, unlike the CLM that may vary from one physician to another." He continues that the other benefit is immeasurable—a negative test result reassures physician and patient alike, is cost-effective, and allows the patient in most cases to resume activities while continuing with prenatal monitoring. Dr. Duhl adds that the fFN test is a milestone for rural physicians without quick accessibility to ultrasound equipment. Decisions relating to referrals and emergency transfers are made easier with fFN results.

**Factors elevating the risk of PTB include:**

- previous history of PTB,
- history of second trimester miscarriage,
- multiple gestation,
- previous neonatal death or stillbirth,
- extremes of weight or age,
- body mass index of <19.8,
- second trimester vaginal bleeding,
- internal os dilation,
- gestational diabetes,
- pulmonary disorder, and
- hypertension.

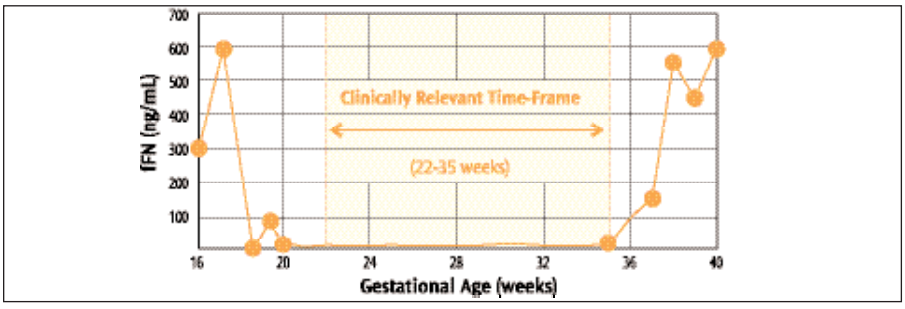
In the largest body of data on fFN in women without symptoms screened during prenatal care, fFN testing is identified as the strongest independent predictor of preterm delivery (*3*). And, an article in the Spring 2002 publication of the *Clinical Laboratory Science Journal* concludes that *evaluation of sensitivity and specificity studies document that the fetal fibronectin test predicts preterm delivery. For symptomatic women, a sensitivity of 89% and a specificity of 86% were found* (*4*).

**Monitoring High-Risk Pregnancy**

With the incidence of PTB increasing, close monitoring during pregnancy has become critical. These women may be at risk and the physician faces a dilemma. Because the fFN specimen can be collected in-office or clinic and sent to a local laboratory, it mitigates the time, cost, and disruption of hospital admission.

Appropriate action for a positive fFN test in a woman at increased risk includes: a) counseling the patient, b) monitoring for signs and symptoms of PTB, c) recommending lifestyle changes, d) determining possible causes of abnormal fFN, e) considering referral to a maternal fetal medicine specialist, and f) retesting for fFN.

If signs and symptoms occur in an fFN-positive patient, other interventions may include: a) hospitalization, b) corticosteroids, c) antibiotics, and d) tocolytics. After a positive test result, two negative fFN results are required before the risk of spontaneous preterm birth returns to baseline (*5*).




Normal fFN Expression by Gestational Age

**First-Time Pregnancy**

Of all deliveries, 45% are first-time pregnancies without medical or reproductive history. A negative fFN result at 24-26 weeks provides assurance that 27 out of 28 women are unlikely to deliver before 35 weeks (*6*). This assurance is valuable to manage a successful pregnancy, and repeat testing is only required if signs or symptoms occur.

When signs of preterm labor occur, the fetal Fibronectin (fFN) test is a proven marker for suspected preterm delivery—a negative test result is 99.2% accurate in determining that *delivery will not occur* within two weeks (*7*).

For more information concerning the fFN test, contact Adeza Biomedical at 1-408-745-0975 or 1-877-945-0208, visit Adeza Biomedical's Web site at www.adeza.com.

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