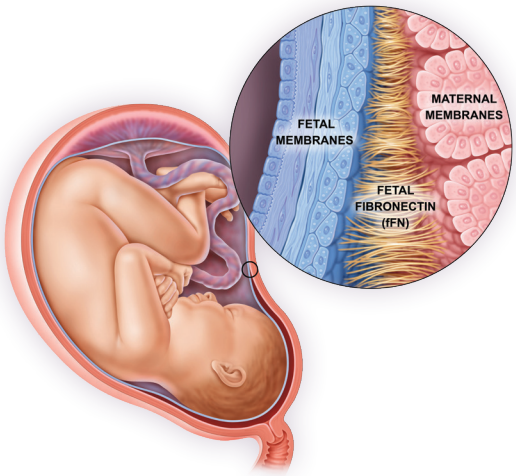
Fetal Fibronectin Testing to Assess the Risk of Preterm Birth

Frequently Asked Questions

HOLOGIC®

1. What is Fetal Fibronectin?

- Fetal fibronectin (fFN) is a "glue-like" protein that helps bond the baby to the uterus. Fetal fibronectin is detectable in vaginal secretions in the very beginning of pregnancy, when this bond is first forming, and then again at the end of pregnancy, when a woman's body is getting ready to deliver her baby. If fFN is detectable in vaginal discharge between 22 and 35 weeks, this could indicate the "glue" is leaking prematurely and preterm delivery is a real possibility.[1]



2. Where is the Rapid fFN® test used?

- In over 2,000 birthing hospitals across the United States.[2]

3. Which patients can receive a Rapid fFN test?

- Patients presenting with signs or symptoms of preterm labor are eligible to receive a Rapid fFN test.[1] These may include[3]:
  - Contractions every 10 minutes or more often
  - Change in vaginal discharge (leaking fluid or bleeding from the vagina)
  - Pelvic pressure (the feeling that your baby is pushing downward)
  - Abdominal cramps with or without diarrhea
  - Low, dull backache
- The Rapid fFN test can be used on symptomatic singleton ***and*** twin pregnancies.[1]

4. When can the test be performed?

- fFN testing is FDA approved in symptomatic patients between 24^0 and 34^6 weeks gestation.[1] The FDA has also approved fFN testing for asymptomatic patients at risk of preterm delivery between 22^0 and 30^6 weeks gestation.[1]

5. Why is the test performed?

- To determine a woman's risk of preterm delivery in the next 7-14 days.[1] Results can be useful when trying to determine whether to admit her to the hospital and when to administer antenatal corticosteroids.

6. How is the specimen collected?

- The specimen must be collected ***prior*** to other vaginal exams, without gels or lubricants.[4]
- During speculum exam, lightly rotate swab across posterior fornix of vagina for 10 seconds to absorb cervicovaginal secretions.[4]
- Remove swab and immerse polyester tip in buffer; break shaft at score even with top of tube.[4]
- Align the shaft with hole inside the tube cap and push down tightly over shaft, sealing tube; ensure shaft is aligned to avoid leakage. Write patient's name and other identifying information required on the specimen transport tube label.[4]

7. Can I collect a specimen if the patient has had sex in the last 24 hours?

- Yes. A negative fFN result is valid even if she's had sex in the last 24 hours.[1] Semen will not cause a false negative, but it can occasionally cause a false positive. So a positive result, in this situation, may not be valid and should be confirmed after 24 hours.

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8. What are contraindications for collecting/sending a specimen for an fFN test?

- Dilation > 3 cm
- Moderate or gross vaginal bleeding (spotting is OK)
- Placental abruption or placenta previa
- Rupture of membranes

If none of the above contraindications are present, it is appropriate to send the fFN sample to the lab according to instructions for use.[1,4]

9. How are fFN results interpreted?

- The Rapid fFN® test has an FDA-approved negative predictive value (NPV) of 99.2%, meaning that the patient has <1% chance of delivery with a negative result in the next 14 days.[1]
- The Rapid fFN test also has the best sensitivity available (86%) for ruling out preterm labor and is the only FDA-approved test to assess the risk of preterm delivery that has both a 7 ***and*** 14-day indication.[1,5]

10. How many patients will receive a negative result?

- The vast majority of patients, ~80%, will receive a negative result allowing you to focus on the 20% that really are at the highest risk.[1]

11. Can I use an AmniSure®, ROM Plus®, or Actim PROM® test instead of an fFN test to rule out imminent preterm birth?

- No, these are different tests with different purposes. Patients can be in active preterm labor but not yet ruptured, so a negative ROM test result does ***not*** rule out imminent preterm birth.[6]
- Leaking fFN can reveal her preterm birth risk long before her membranes actually rupture.

12. How long does it take to run the fFN test?

- Once the collected specimen arrives in the lab, it takes < 30 minutes for the $TLi_{IQ}^{®}$ analyzer to produce an fFN test result.[1]
- The lab can likely provide a test result within 1 hour if the fFN sample is sent immediately (check your internal process).

13. How long is the fFN specimen viable?

- The specimen can be stored at room temperature for up to 8 hours before testing or kept refrigerated for up to 3 days before testing.[4]
- While an fFN sample is typically collected in L&D when a patient presents with symptoms of preterm labor, this lengthy period of viability also gives providers the flexibility to collect the fFN sample in the office prior to conducting a digital exam and then sending it with the patient to L&D.

14. What does an fFN test cost?

- The cost of the Rapid fFN test itself is covered by many insurance policies; however, costs to patients will vary depending on their individual insurance.
- Remember to always collect an fFN specimen from each patient who presents with symptoms of preterm labor prior to doing a digital exam. Then, if the specimen cannot be sent to the lab due to a contraindication identified later during the exam, there is no charge since the **fFN COLLECTION SWABS ARE FREE**.

To request **FREE** Specimen Collection Kits & Educational Materials:

Website: www.fFNTest.com/HCP/OrderMaterials
Email: CustomerSupport@Hologic.com
Phone: 1-800-442-9892

AmniSure is a trademark of QIAGEN Group. ROM Plus is a trademark of Clinical Innovations. Actim PROM is a trademark of Cooper Surgical.

References 1. Rapid fFN for the TLi_{IQ} System [package insert]. AW-04196. Sunnyvale, CA; Hologic, Inc.: 2017. **2.** Hologic, Inc. Data on File. **3.** March of Dimes. Signs and symptoms of preterm labor. Reviewed August 2017. Accessed March 16, 2020. https://www.marchofdimes.org/complications/signs-and-symptoms-of-preterm-labor.aspx **4.** Rapid fFN for the TLi_{IQ} System Specimen Collection Kit [instructions for use]. AW-04194. Sunnyvale, CA; Hologic, Inc.: 2017. **5.** PartoSure Test [package insert]. PSPI-01-01-US, Rev. A. Boston, MA: Parsagen Diagnostics, Inc.; 2018. **6.** Aetna. Non-Invasive Fetal Membranes Rupture Tests. Clinical Policy Bulletin 0757. Last Reviewed November 6, 2020. Accessed January 21, 2021. http://www.aetna.com/cpb/medical/data/700_799/0757.html.

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