HOLOGIC®

Don’t wonder

if sending her home is the right decision...

Be confident

that it is.

With a

99.5% NPV,

fFN testing can help you identify who you can confidently send home.[1]

RapidfFN™

20% of Patients Discharged Delivered within 3 Days[7]

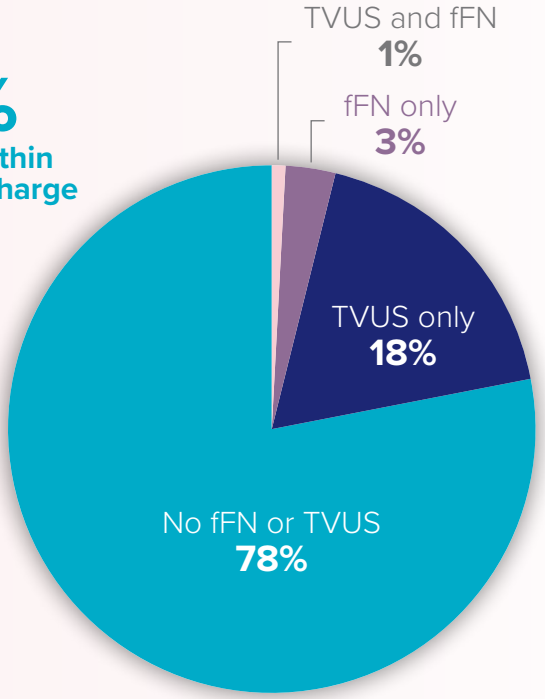
23,062
patients with PTL symptoms

24%
admitted
n = 5,550

76%
discharged home
n = 17,512

80%
delivered > 3 days later
n = 13,995

20%
delivered within 3 days of discharge
n = 3,517



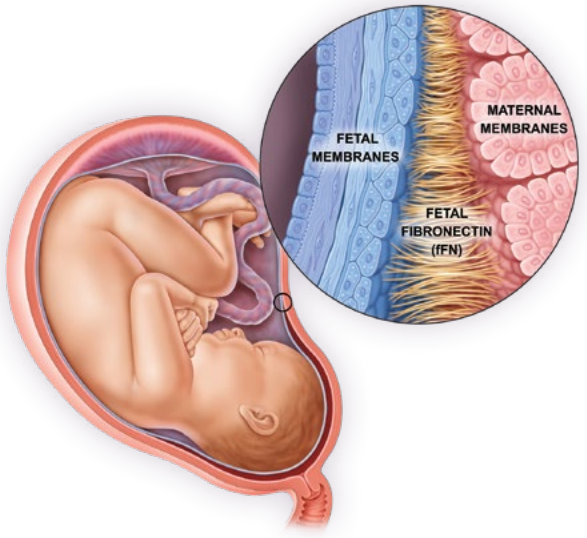
- TVUS and fFN **1%** (n = 41)
- fFN only **3%** (n = 106)
- TVUS only **18%** (n = 620)
- No fFN or TVUS **78%** (n = 2,750)

Underutilized fFN testing and subjective TVUS results led to **missed critical care opportunities**.

fFN testing can help **rule out 80% of patients** with symptoms of preterm labour.[1]

80% of patients with threatened preterm labour will receive a negative result allowing you to focus on the patients who really are at a higher risk of preterm birth.[1]

And with a **99.2% NPV**, a negative result means there is a **< 1%** chance she will deliver in the next **14 days**.[1]



Determining who is really at risk for preterm birth continues to be a major challenge. Rapid fFN can help rule out those who are not.

Fetal fibronectin (fFN) is a biomarker for preterm delivery.

It is highly correlated with the risk of preterm delivery when present in cervicovaginal secretions.

Before doing a digital exam or transvaginal ultrasound, collect a specimen for fFN testing.

Rapid fFN in symptomatic patients

High NPV[1]:

NPV for delivery within:
7 days = 99.5%
14 days = 99.2%
Less than 37 weeks = 84.5%

The benefits of a negative result include:

- Fewer unnecessary interventions
- Reassurance for physicians and patients
- Reduction of unnecessary admissions and costs

Useful PPV[1]:

PPV for delivery within:
7 days = 12.7%
14 days = 16.7%
Less than 37 weeks = 44.7%

The benefits of a positive result include:

- Identification of women who can be targeted for intervention
- Opportunity for antenatal steroids
- Opportunity to transfer to tertiary care center and preparation for optimal neonatal care

Deliver steroids to the patients who will benefit most.

Accurate and timely delivery of steroids can reduce complications for the baby. SOGC recommends that one course of antenatal corticosteroid therapy should be routinely administered to women at 24^0 to 34^0 weeks gestation who are at high risk for preterm delivery **within the next 7 days**. This has been shown to significantly reduce perinatal death, respiratory distress syndrome and intraventricular hemorrhage.[2]

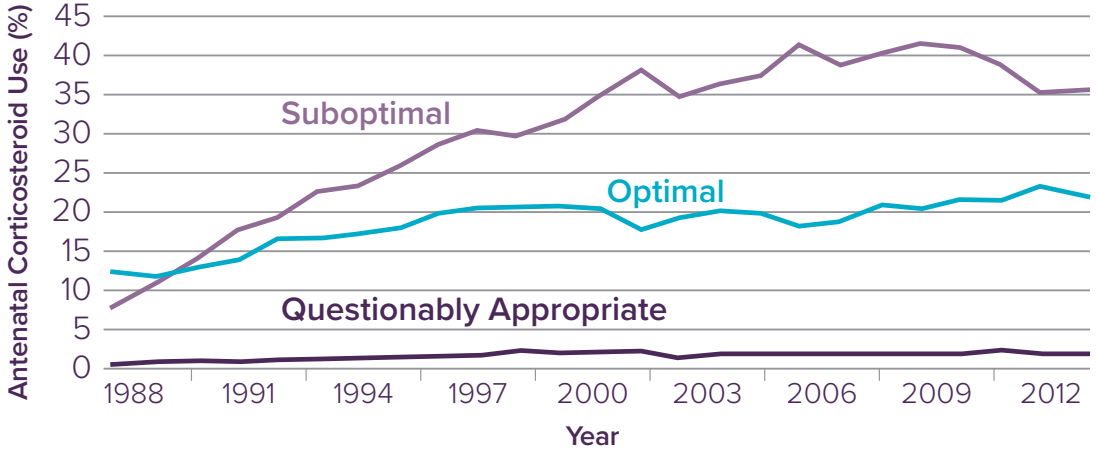
Antenatal Corticosteroids (ACS) administered earlier than the optimal < 7 day window before delivery resulted in higher morbidities compared to optimally timed administration.[3]

Neonatal Respiratory Morbidity and ACS-to-Delivery Interval

Compared to ACS administered within 7 days of delivery	ACS administered 8-14 days before birth	ACS administered 15-21 days before birth
Respiratory Distress Syndrome	2.7x	6.8x
Chronic Lung Disease	1.1x	8.0x
Intubation	5.1x	4.7x
Composite Outcome	.98x	6.8x

Odds ratio of babies born at 28-30 weeks compared with those that received steroids in optimal window, < 7 before birth.

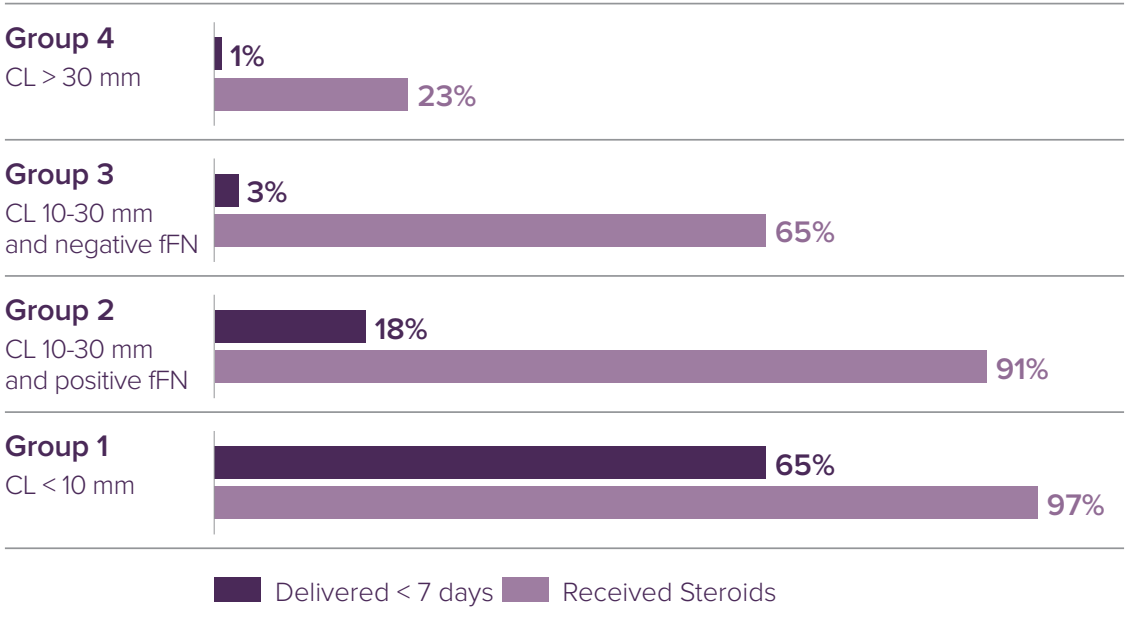
25-Year Trend in Steroid Administration



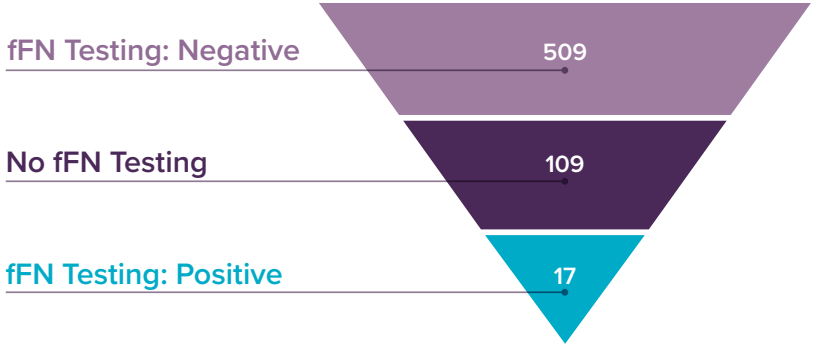
While therapy administration has increased, there are improvements to be made in terms of timing. A recent study showed that 52% of mothers who received steroids delivered > 35 weeks.[4]

RapidfFN™

Steroids are frequently administered to women with a low likelihood of delivery < 7 days.[5]

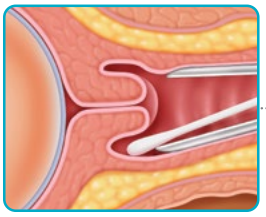


The number of patients who need to be treated with steroids to prevent 1 case of respiratory distress syndrome.[6]



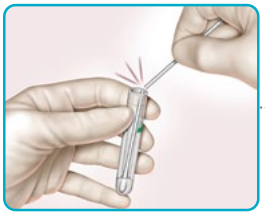
Clinician Collection Procedure

Collect specimen prior to digital examination or manipulation of the cervix to avoid sample contamination.



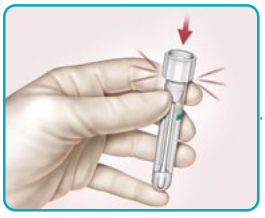
1

During speculum examination, lightly rotate swab across posterior fornix of the vagina for 10 seconds to absorb cervicovaginal secretions.



2

Remove swab and immerse polyester tip in buffer; break shaft at score even with top of tube.



3

Align the shaft with hole inside the tube cap and push down tightly over shaft, sealing tube; ensure shaft is aligned to avoid leakage. **Send fetal fibronectin sample to a lab near you.**

Website: www.fFNTest.com/HCP/OrderMaterials

Email: Canada2@Hologic.com

Phone: 1-877-209-7192

Hologic provides this collection procedure guide as a general informational tool only; it is not an affirmative instruction or guarantee of performance. It is the sole responsibility of medical professionals to read and understand the appropriate package insert and comply with applicable local, state and federal rules and regulations.

References: 1. Rapid fFN for the TLi$_{IQ}$ System [package insert]. AW-04196-001, Sunnyvale, CA: Hologic, Inc.; 2017 **2.** Skoll A, et al. No. 364-Antenatal Corticosteroid Therapy for Improving Neonatal Outcomes. *J Obstet Gynaecol Can*. 2018 Sep;40(9):1219-1239. doi: 10.1016/j.jogc.2018.04.018. PMID: 30268316. **3.** Wilms FF, et al. Relationship between the time interval from antenatal corticosteroid administration until preterm birth and the occurrence of respiratory morbidity. *Am J Obstet Gynecol*. 2011;205(1):49.e1-7. Doi:10.1016/j.ajog.2011.03.035. **4.** Razaz N, et al. Trends in optimal, suboptimal and questionably appropriate administration of antenatal corticosteroids prophylaxis. *Obstet Gynecol*. 2015;125(2):288-96. **5.** Wilms F, et al. Prescribing patterns of antenatal corticosteroids in women with threatened preterm labor. *Eur J Obstet Gynecol Reprod Biol*. 2015;192:47-53. doi:10.1016/j.ejogrb.2015.06.008. **6.** Honest H, et al. Accuracy of cervicovaginal fetal fibronectin test for predicting risk of spontaneous preterm birth: systematic review. *BMJ*. 2002;325(7359):301-4. doi: http://dx.doi.org/10.1136/bmj.325.7359.301. **7.** Blackwell, SC. Utilization of fetal fibronectin testing and pregnancy outcomes among women with symptoms of preterm labor. *Clinicoecon Outcomes Res*. 2017;9:585-594. doi: 10.2147/CEOR.S141061.

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Rapid fFN® Test for the TLi$_{IQ}$® System

For accurate patient results, follow these instructions.

Gestational age collection window:

- 24^0 weeks - 34^6 weeks

Specimens should be collected prior to:

- Digital cervical exam
- Collection of culture specimens
- Vaginal probe ultrasound exams

Do not contaminate swab or specimen with:

- Lubricants
- Soaps
- Disinfectants
- Creams

Do not test if patient has:

- Moderate or gross vaginal bleeding
- Advanced cervical dilation (3 centimeters or greater)
- Rupture of membranes
- Suspected or known placental abruption or placenta previa

If patient has had sex in the prior 24 hours:

- A negative result is still valid.
- A positive result may not be valid and should be confirmed > 24 hours.

RapidfFN™