

Let's Assess Clinical Assessment

Less than 10% of women with the clinical diagnosis of preterm labor **give birth within 7 days** of presentation.¹

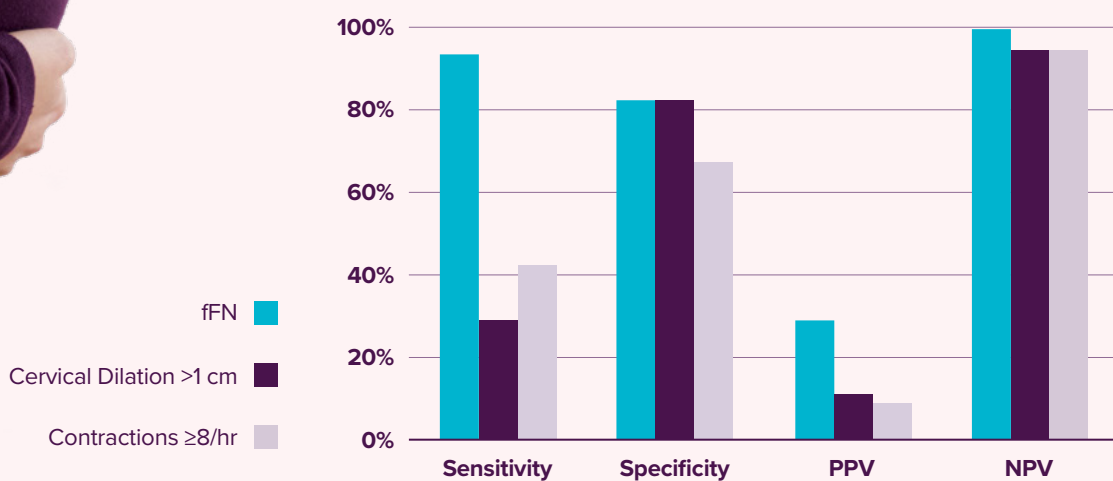
Minimally Dilated Patients Can be at Significant Risk of Delivery.

16% - 32% of patients who were <2cm delivered in <7 days.²

Cervical Dilatation, cm	Deliveries by Time from Admission %				
	<24 h	24-48 h	3-7 d	<7 d Total	>7 d Total
0-1 (n=104)	6	5	6	16	84
2 (n=54)	13	9	9	32	68
3 (n=29)	21	7	14	41	59
4 (n=22)	50	9	23	82	18
5 (n=16)	50	12	0	62	38
6-10 (n=19)	89	11	0	100	0

fFN Predicts Delivery More Accurately than Clinical Assessment³

Cervical dilatation and contractions have low sensitivity



Rapid fFN has the best sensitivity to help rule out preterm labor.^{4,5}

RapidfFN®
for the TLip® System

Dilatation measurements vary significantly between providers⁶

In a study of OBs, residents and L&D nurses, **only 56% provided accurate measurements.** There was no significant difference in accuracy among examiners by level of experience.

And even among the same provider.⁶

The study also found that **52% of providers reported different dilatation measurements** on identical simulations. There was no significant difference in intraobserver variability by level of experience, except for physicians with 10+ years of experience, who recorded higher variability. The authors hypothesize more senior physicians perform cervical examinations less often.

fFN testing can help
rule out 80% of patients
with symptoms of
preterm labor.⁴



~ 80% Patients
receive a negative result



~ 20% Patients
receive a positive result

Benefits of a Negative Result

A negative fFN result means the patient has a **<1% chance of delivery in the next 14 days.**

High NPV:

NPV for delivery within:

7 days = 99.5%

14 days = 99.2%

Benefits of a Positive Result

A positive result can help a physician decide whether a patient and her baby may benefit from interventions.

Useful PPV:

PPV for delivery within:

7 days = 12.7%

14 days = 16.7%

References: 1. ACOG Practice Bulletin No. 171: Management of Preterm Labor. *Obstet Gynecol.* 2016;128:e155-64. doi:10.1097/AOG.0000000000001711. 2. How H, et al. Cervical dilatation on presentation for preterm labor and subsequent preterm birth. *Am J Perinatol.* 2009;26:1-6. doi:10.1055/s-0028-1090586. 3. Iams J, et al. Fetal fibronectin improves the accuracy of diagnosis of preterm labor. *Am J Obstet Gynecol.* 1995;173(1):141-145. doi:10.1016/0002-9378(95)90182-5. 4. Rapid fFN for the TLI_Q System [package insert]. AW-04196-001, Rev. 004, Sunnyvale, CA: Hologic, Inc.; 2017. 5. PartoSure Test [package insert]. PSPI-01-01-US, Rev. A. Boston, MA: Parsagen Diagnostics, Inc.; 2018. 6. Phelps JY, et al. Accuracy and intraobserver variability of simulated cervical dilatation measurements. *Am J Obstet Gynecol.* 1995;173 (3 Pt 1):942-945. doi:10.1016/0002-9378(95)90371-2.

Rapid fFN[®] Test for the TLI_Q[®] System

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