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Success of NIPT based on maternal weight and gestational age

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I. Introduction

The use of cell-free DNA (cfDNA) has increasingly become the standard of care for prenatal screening of fetal aneuploidy. NIPT has the potential to yield a non-reportable result. As such, it is important to understand the factors impacting the ability to obtain a clinical result. Maternal weight has an inverse relationship to fetal fraction, while fetal fraction has a direct relationship with gestational age. This study reviews the success rate of obtaining an NIPT result as a function of maternal weight and gestational age (GA).

II. Methods

A retrospective analysis of 139,995 consecutive maternal blood samples that were submitted to Sequenom Laboratories® (a wholly owned subsidiary of Laboratory Corporation of America® Holdings) for MaterniT® 21 PLUS laboratory developed testing were stratified by maternal weight and gestational age. The percent of NIPT samples that yielded a non-reportable test result was evaluated assuming both factors are independent. Samples were subjected to DNA extraction, library preparation, and whole genome massively parallel sequencing as described by Jensen et al.[1]

III. Results

Patients <125 lbs have 100% success rate at GA >22 weeks, the lowest success rate is in the highest weight population >300 lbs at 93.7% (ranging from 90.9-100% depending on GA). Stratifying these populations by GA shows only a minor impact in success rate across GA in the <200 lbs population, but a marked improvement as GA increases, matching the average population success rate in the heaviest population at 25 weeks GA.

Table 1.
Success rate by gestational age and maternal weight

Gestational Age	Maternal Weight (lbs)										
	<100	100 - 124	125 - 149	150 - 174	175 - 199	200 - 224	225 - 249	250 - 274	275 - 299	>300	Average
<12 weeks	99.72%	99.71%	99.54%	99.35%	98.97%	97.97%	97.00%	96.11%	95.02%	93.15%	99.03%
13-15 weeks	100.00%	99.85%	99.60%	99.29%	98.98%	98.48%	96.48%	97.65%	94.87%	90.86%	98.94%
16-18 weeks	100.00%	99.70%	99.48%	99.44%	99.14%	98.82%	97.59%	96.99%	95.79%	94.89%	99.06%
19-21 weeks	100.00%	99.62%	99.71%	99.65%	99.38%	98.90%	99.30%	99.02%	99.35%	96.00%	99.45%
22-24 weeks	100.00%	100.00%	99.82%	99.72%	99.73%	99.11%	99.23%	100.00%	100.00%	100.00%	99.70%
25-27 weeks	100.00%	100.00%	99.78%	99.44%	100.00%	99.62%	100.00%	97.40%	100.00%	100.00%	99.66%
28-30 weeks	100.00%	100.00%	99.64%	99.15%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	99.70%
>30 weeks	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	96.88%	100.00%	99.92%
Average	99.82%	99.74%	99.57%	99.39%	99.09%	98.37%	97.36%	97.05%	95.81%	93.67%	99.09%

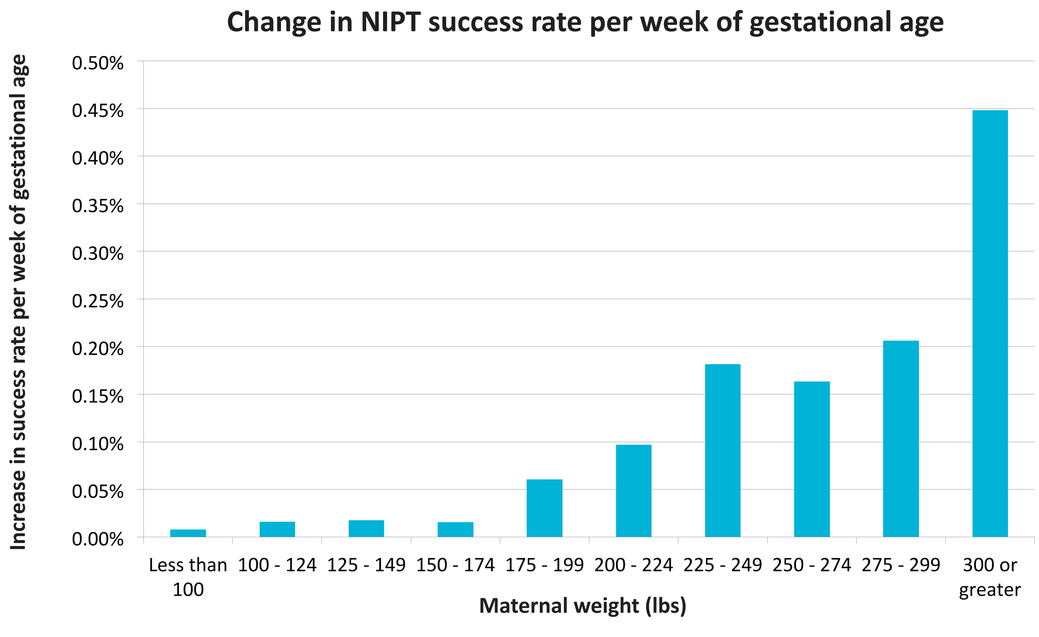
Table 2.
Success rate by maternal weight

Maternal Weight (lbs)	Total #	Success Rate
<100	1,339	99.85%
100-124	19,869	99.76%
125-149	42,231	99.57%
150-174	31,941	99.37%
175-199	19,821	99.08%
200-224	11,353	98.29%
225-249	6,706	97.36%
250-274	3,404	96.86%
275-299	1,701	95.71%
>300	1,580	93.48%
Total	139,945	99.09%

Table 3.
Success rate by gestational age

Gestational Age	Total #	Success Rate
<12 weeks	83,416	99.00%
13-15 weeks	25,860	98.90%
16-18 weeks	11,279	99.10%
19-21 weeks	10,276	99.40%
22-24 weeks	4,317	99.70%
25-27 weeks	2,044	99.70%
28-30 weeks	1,335	99.70%
>30 weeks	1,418	99.90%
Total	139,945	99.10%

Figure 1. Weekly increase in success rate by maternal weight



IV. Conclusions

Of the two factors studied, GA and maternal weight, the later has a larger impact on NIPT success rate but it can be improved with an increase in GA. Despite a reduced success rate at extreme maternal weights, especially at early gestational age, cfDNA testing delivers results for more than 93.6% of patients in the >300 lbs population. In this study we show that the non-reportable rate of maternal weight on NIPT results can be improved by waiting to test at a later GA for patients >200 lbs. NIPT can be considered a viable option for aneuploidy screening in obese patients.

V. References

1. Jensen TJ, Zwiefelhofer T, Tim RC, et al. High-throughput massively parallel sequencing for fetal aneuploidy detection from maternal plasma. *PLoS One*. 2013; 8(3):e57381. doi:10.1371/ journal.pone.0057381. Epub 2013 Mar 6.

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Poster presented at the 38th NSGC Annual Conference; 2019 November 5-8; Salt Lake City, UT.