# >66,000 Pregnancies Screened Between 8-10 Weeks Gestation: The Impact of Fetal Fraction Amplification on Prenatal Cell-Free DNA Screening


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## Purpose

- Performance of prenatal cell-free DNA (pcfDNA) screening at gestational ages <10 weeks has been challenging to implement due in part to the lower fetal fractions (FF) at earlier gestational ages impacting screen failure rates.
- Fetal fraction amplification (FFA) enables reliable screening at gestational ages as early as 8 weeks while maintaining low failure rates[1].
- Here we describe the lab experience for over 66,000 screens performed for pregnancies in the early gestational age period (EGA) of 8w0d to 9w6d.

## Methods

- Data from pcfDNA screens completed between 11/19/2024 and 03/31/2026 were considered for analysis. The following were reported:
  - Number of orders received
  - Screen-positive results
  - Screen failures
- FF medians and first and third quartiles (Q1, Q3) for the 8- and 9-week gestational age period were calculated.
- Where provided, BMI information was analyzed.


1. Dugoff L, Mabey B, Bordwell J, Pierson S, Johansen Taber K, Muzzey D. Prenatal Cell-Free DNA Screening With Fetal Fraction Amplification at 6-9 Weeks of Gestation. Obstet Gynecol. 2026 Aug 1;148(2):149-156. doi: 10.1097/AOG.0000000000006324. Epub 2026 May 21. PMID: 42166774; PMCID: PMC13361953.


## Results

- 66,643 orders were completed for patients between 8w0d and 9w6d.
  - 1,645 (2.47%) were screen-positive (**Table 1**).
    - Of 647 rare autosomal aneuploidies, 563 were trisomies.
    - 50 samples were screen-positive for two or more autosomal abnormalities.
    - Results could not be generated for 238 samples, resulting in a screen-failure rate of 0.36% (**Table 2 and Table 3**); 64 samples (0.1%) failed due to insufficient FF (**Table 2**).

**Table 1.** Screen positive results of week 8 and 9 combined

| Result type | 1,645 screen-positive reports (2.47% screen-positive rate) |
|---|---|
| **Aneuploidies** | |
| **Trisomy 21** | **341** (20.73%) |
| **Trisomy 18** | **121** (7.36%) |
| **Trisomy 13** | **103** (6.26%) |
| **Sex chromosome aneuploidy** (SCA) | **531** (32.38%) |
| **Rare autosomal aneuploidies** (RAA) | **647** (39.33%) |
| **Microdeletions** | |
| **1p36** | **14** (0.85%) |
| **22q11.2** | **9** (0.55%) |
| **15q11.2** | **8** (0.49%) |
| **5p** | **7** (0.43%) |
| **4p** | **3** (0.18%) |

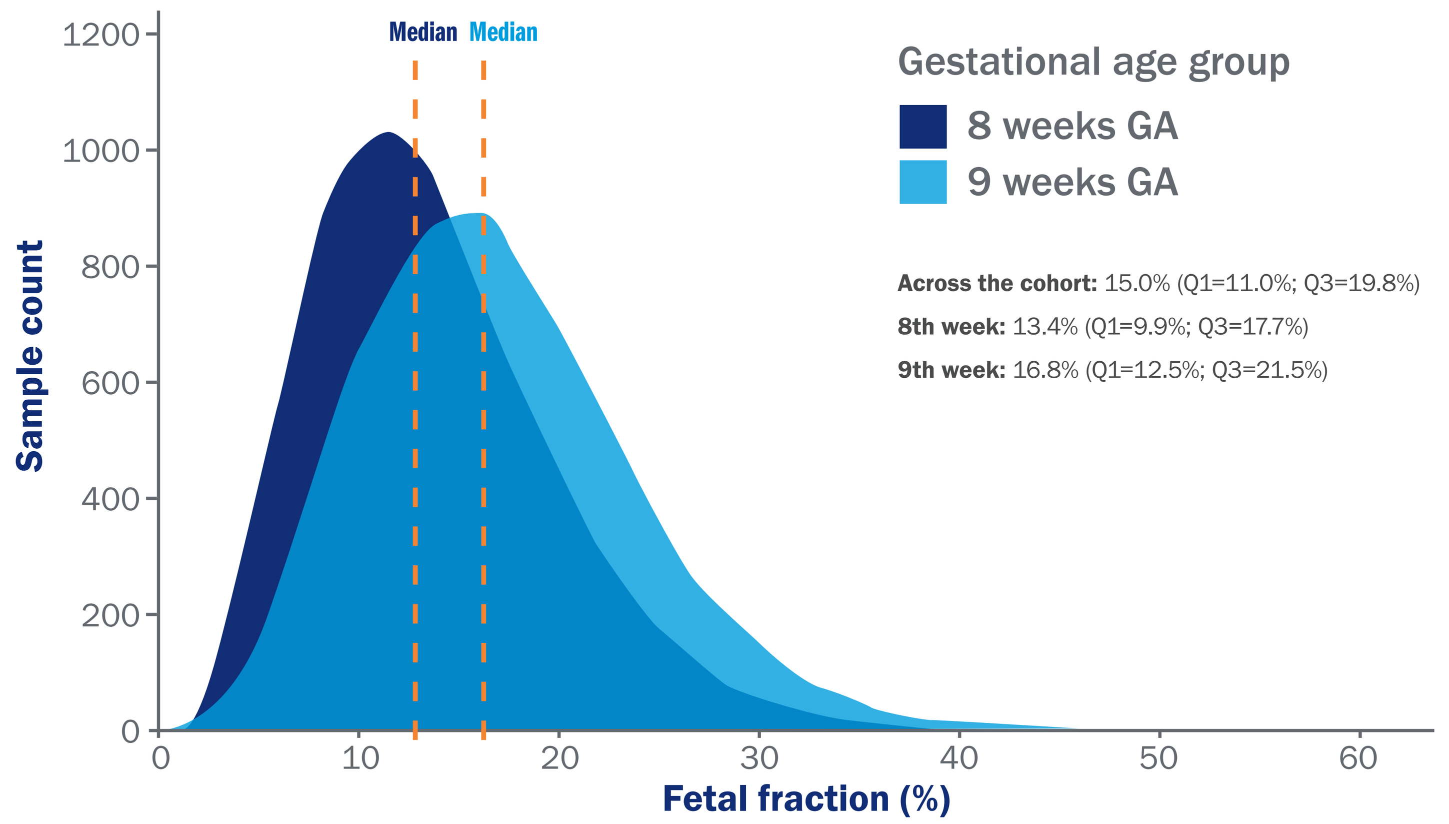
- Median FF across the cohort was 15.0% (Q1=11.0%; Q3=19.8%). For samples in the 8th week of pregnancy, median FF was 13.4% (Q1=9.9%; Q3=17.7%) and for samples in the 9th week of pregnancy, median FF was 16.8% (Q1=12.5%; Q3=21.5%) (**Figure 1**).

**Table 2.** Screen failure rates for weeks 8 and 9 combined

| Reason for failure | 238 total no call reports |
|---|---|
| **Insufficient FF** | **64 Samples** (0.10%) |
| **Other QC metrics** | **174 Samples** (0.26%) |

0.36% overall screen failure rate

**Figure 1.** Fetal Fraction distribution at 8 and 9 weeks



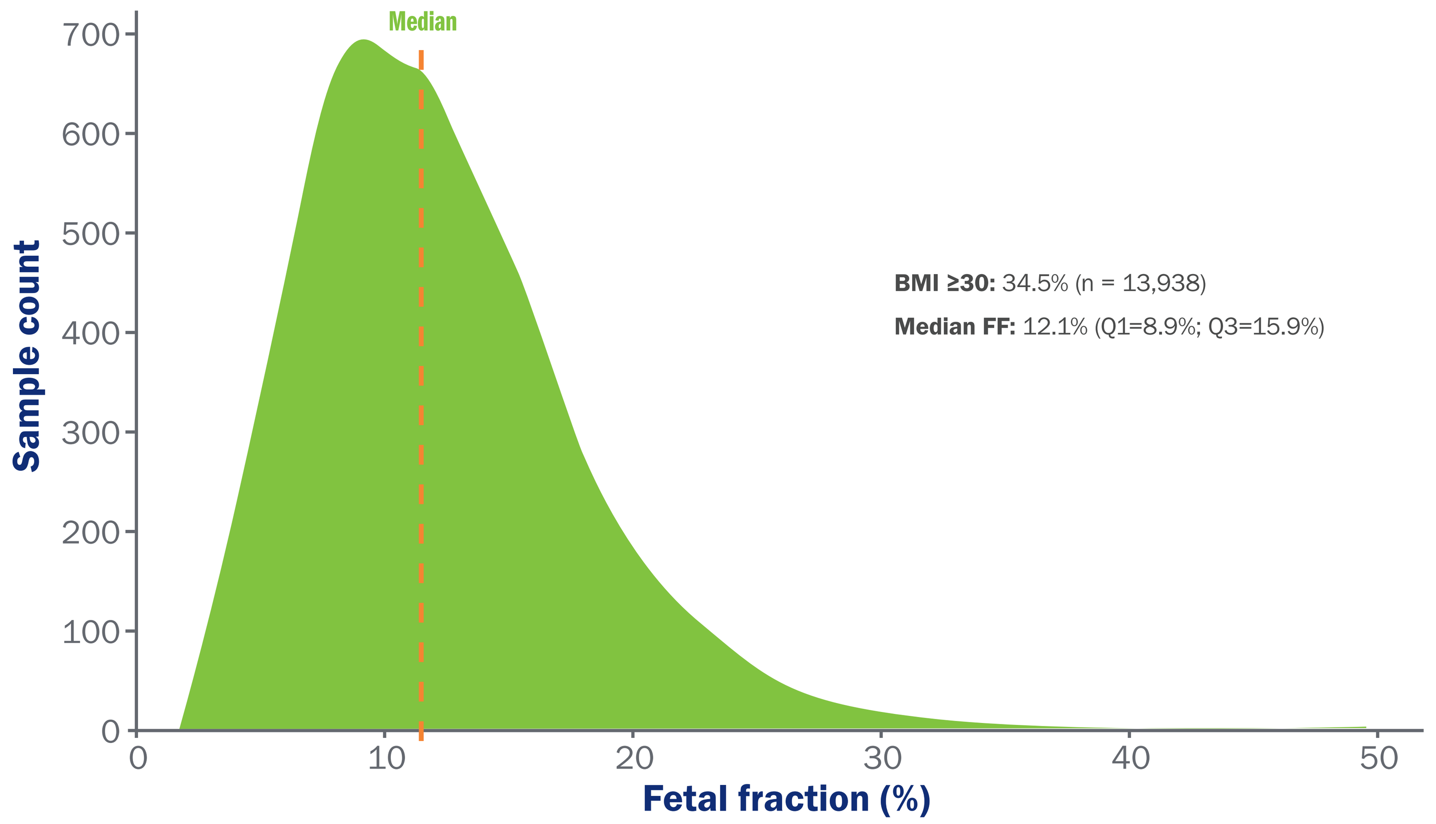
Median
Median
Gestational age group
8 weeks GA
9 weeks GA
Across the cohort: 15.0% (Q1=11.0%; Q3=19.8%)
8th week: 13.4% (Q1=9.9%; Q3=17.7%)
9th week: 16.8% (Q1=12.5%; Q3=21.5%)
Sample count
Fetal fraction (%)


- For samples in which BMI could be assessed (n=40,443), the proportion at BMI ≥30 was 34.5% (n=13,938). For those with BMI ≥30, median FF was 12.1% (Q1=8.9%; Q3=15.9%) (**Figure 2**).

**Table 3.** Failures due to insufficient FF

| Week | n (Rate) |
|---|---|
| **Week 8** | **48 Samples** (0.07%) |
| **Week 9** | **16 Samples** (0.02%) |

**Figure 2.** Fetal Fraction distribution at high BMI ≥30



Median
BMI ≥30: 34.5% (n = 13,938)
Median FF: 12.1% (Q1=8.9%; Q3=15.9%)
Sample count
Fetal fraction (%)


## Conclusions

- This pcfDNA assay with FFA demonstrates sufficient FF for pregnancies within the EGA period as well as a low FF failure of 0.1%, including pregnancies with higher BMIs.
- pcfDNA screening at an EGA offers a viable option for individuals who desire information earlier in pregnancy than what is typically available.


**Disclosures:** All authors were employees of Myriad Genetics, Inc. at the time of this study and received salaries and stock as compensation.



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