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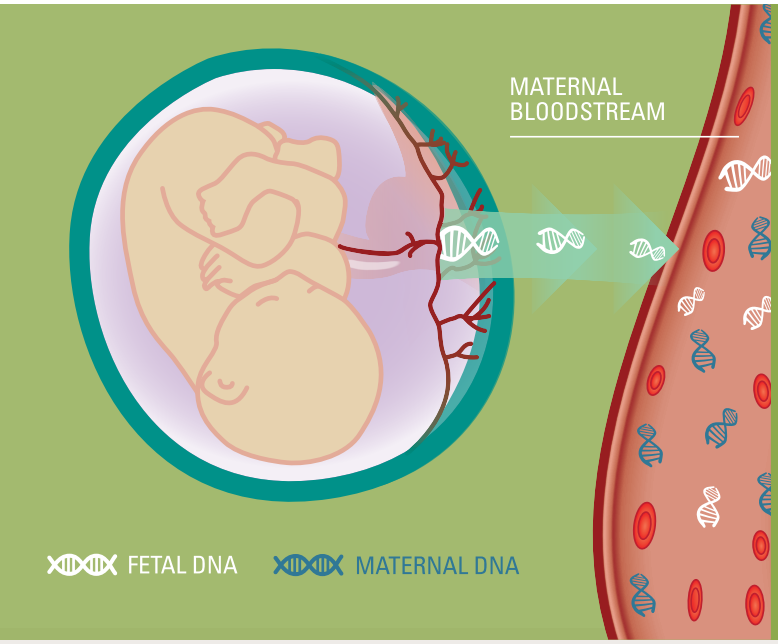
Choose the NIPT that you can trust

Experts agree that measuring fetal fraction* is important.[1-3]
How confident are you about your fetal fraction measurement?

Different methodologies used for measuring fetal fraction have shown varying degrees of accuracy.[4-6]



The Harmony prenatal test gives you confidence by:

- ✓ Determining fetal fraction accurately and reproducibly[7-9]
- ✓ Reporting fetal fraction to provide a confident result
- ✓ Incorporating fetal fraction into results to accurately distinguish high and low probability results (even at low fetal fraction)[10]

* Fetal fraction is the amount of fetal cell-free DNA circulating in the mother's blood compared the to total cell-free DNA

The Harmony prenatal test demonstrates accurate and reproducible fetal fraction[9]

Analysis of 47,500 patient samples showed **Harmony test determined fetal fraction with high accuracy.[9]**

In this analysis set, fetal fraction measurement using DANSR (digital analysis of selected regions) assay is not only accurate but also highly reproducible.[9] Reproducibility provides higher confidence in the quality of the measurement.

1. Jani J et al. Ultrasound Obstet Gynecol.2015 Nov;46(5):515-7.
2. ACOG-SMFM Committee Opinion No. 640. Obstet Gynecol. 2015 Sep;126(3):e31-7.
3. Benn et al. Prenat Diagn. 2015 Aug;35(8):725-34.
4. Nygren AOH, Dean J, Jensen TJ, et al. Clin Chem. 2010;56(10):1627-1635.
5. Yu SCY, Chan KCA, Zheng YWL, et al. Proc Natl Acad Sci U S A. 2014;111(23):4-10.
6. Kim SK, Hannum G, Geis J, et al. Prenat Diagn. 2015;35(8):810-815.
7. Sparks et al. Prenat Diagn. 2012 Jan;32(1):3-9.
8. Juneau K et al. Fetal Diagn Ther. 2014;36(4):282-6. d
9. Schmid et al. Ultrasound Obstet Gynecol. 2018 Feb DOI: 10.1002/UOG.19036.
10. Sparks et al. Am J Obstet Gynecol. 2012 Apr;206(4):319.e1-9.

The Harmony prenatal test was developed and its performance characteristics determined by Ariosa Diagnostics, Inc. a CLIA-certified and CAP-accredited clinical laboratory in San Jose, CA, USA. This testing service has not been cleared or approved by the US Food and Drug Administration (FDA). The Harmony non-invasive prenatal test is based on cell-free DNA analysis and is considered a prenatal screening test, not a diagnostic test. Harmony does not screen for potential chromosomal or genetic conditions other than those expressly identified in this document. All women should discuss their results with their healthcare provider who can recommend confirmatory, diagnostic testing where appropriate.

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When test results are this important... you want a reliable result — not just any result

Quality of NIPT is highly dependent on accurate determination of fetal fraction

The Harmony Test provides results you and your patients can trust – based on a minimum threshold of fetal fraction

- If very little cell-free DNA is present, result is likely based on maternal DNA. False reassurance may be provided in case of trisomy.
- If fetal fraction is not measured and reported, validity of individual result is not known.
- Data suggest that the lower limit of cell-free fetal DNA for a reliable result is approximately 4%. A no-call* may be reported if there is not a sufficient amount of fetal cell-free DNA in the maternal blood sample.[2]

*no call rate is the proportion of all samples submitted that do not receive a result. This includes samples that do not receive a result for low fetal fraction, and those that do not receive a result for other quality metrics.

Non-invasive prenatal test (NIPT) results for two non-pregnant women from five commercial laboratories[3]

LABORATORY[1]	RESULT REPORTED?	DETAILS
Harmony (Lab A)	No	Insufficient fetal cell-free DNA for accurate NIPT evaluation
Panorama (Lab B)	No	Unable to report due to low fetal fraction (fetal fraction reported as 0.6% in both samples)
MaterniT21 (Lab C)	Yes	Negative; consistent with female fetus (fetal fraction 4.3% and 3.9% reported on request)
verifi/Illumina-based NIPT (Lab D)	Yes	No aneuploidy detected, two sex chromosomes (XX)
verifi/Illumina-based NIPT (Lab E)	Yes	No aneuploidy detected, two sex chromosomes (XX)

1. One can deduce the laboratories by referring to the public information on their respective websites or in publications on how they report results. Therefore:
   Lab A is Ariosa Diagnostics which performs the Harmony test. Harmony reported insufficient cfDNA.
   Lab B is Natera which performs the Panorama test. Panorama test returned an inability to report while citing the fetal fraction.
   Lab C is Sequenom which performs the MaterniT21 test. The test doesn't report out fetal fraction. Fetal fraction of the study was requested by the author of the study.
   Lab D and E are verifi or an Illumina based NIPT test, which do not measure fetal fraction therefore returned test results with "No aneuploidy detected".
2. Gregg et al. Genetics in Medicine 2016 Oct; 18(10):1056-65
3. T. Takoudes*, B. Hamar "Performance of non-invasive prenatal testing when fetal cell-free DNA is absent" DOI: 10.1002/uog.14715