harmony®
Testing Services by Ariosa Diagnostics

Roche

Harmony Prenatal Test: Differentiating Data That Matters

Harmony: The NIPT for the average and high-risk pregnancy. Data published in the *New England Journal of Medicine*, using only the Harmony Prenatal Test[1]

General Population

15,841

Women age 18-48 with singleton pregnancies between 10 t0 14 weeks' gestation

First Trimester Screening*	Harmony Prenatal Test
79% Detection Rate (30 of 38)	100% Detection Rate (38 of 38)
5.4% False Positive Rate (854 of 15,803)	0.06% False Positive Rate (9 of 15,803)
3.4% Positive Predictive Value	81% Positive Predictive Value

* Serum PAPP-A, total or free β-hcg & Nuchal Translucency.

Average-risk Population

11,994

Women age 18-34 with singleton pregnancies between 10 t0 14 weeks' gestation

Harmony Prenatal Test

- **100%** Detection Rate (19 of 19)
- **0.05%** False Positive Rate (6 of 11,975)
- **76%** Positive Predictive Value

Harmony Twins Data

- **Validated for use in twin pregnancies,** with a higher detection rate and lower false positive rate compared to combined (serum) screening[2,3]
- **The only NIPT that uses the lower fetal fraction of the two fetuses,** rather than the total, to assess risk for fetal aneuploidies[4,5,6]
- **Minimizes possibility of false-negative results** in twin pregnancies where one twin has insufficient fetal fraction[4]

For patients that want NIPT it's easy to integrate Harmony into your practice

To start getting the Harmony Prenatal Test call 855-686-4363

otogenetics® corporation

Accurate measurement of fetal fraction

ACMG Position Statement...acknowledges that data suggests lower limit of fetal cfDNA for a reliable result is approximately 4%[10]

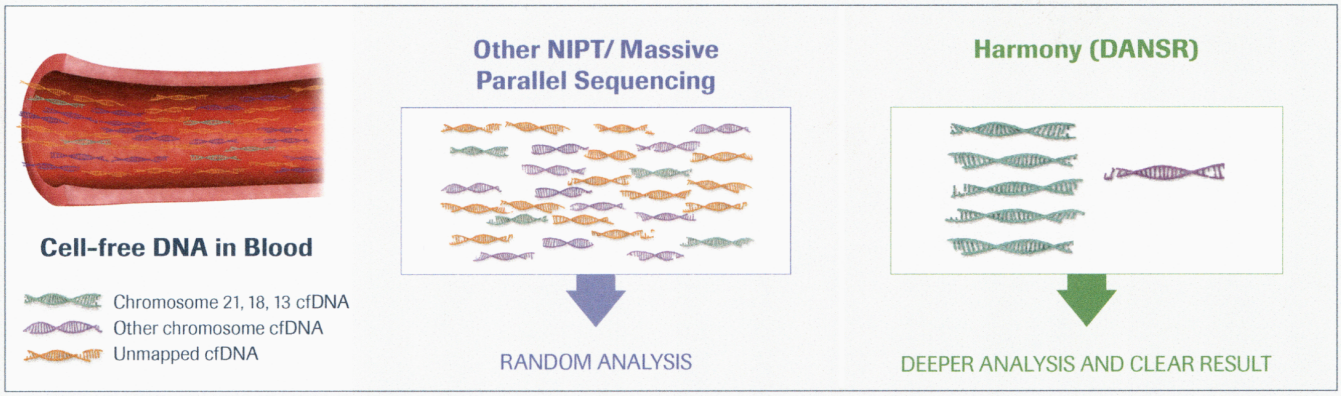
- The Harmony Prenatal Test has a 4% threshold for reporting results.
- Fetal fraction below 4% threshold may lead to an erroneous result of low-risk aneuploidy[7,11,12]
- Fetal fraction increases with gestational age and decreases with increasing maternal weight[13]
- FORTE algorithm accurately distinguishes between high– and low-risk results even at low fetal fraction[14,15]

A proprietary DNA-based technology

The HARMONY PRENATAL TEST uses proprietary, targeted DNA-based technology:

- (DANSR™, FORTE™) [7,8,9]
- DANSR™ analyzes fragments from the specific chromosomes of interest, rather than all chromosomes
- SNP analysis distinguishes maternal from fetal DNA and quantifies the fetal DNA

Targeted Approach Yields a Deeper Analysis versus Sequencing



Chromosomes 13, 18, and 21 together make up <10% of the genome. The directed approach therefore results in a much deeper analysis as only the chromosomes of interest are targeted.[8,9]

The Harmony Prenatal Test was developed by Ariosa Diagnostics, a CLIA-certified laboratory. As with other lab-developed tests, it has not been cleared or approved by the FDA and is not available for sale as an IVD in the US. Non-invasive prenatal testing (NIPT) based on cell-free DNA analysis is not diagnostic; results should be confirmed by diagnostic testing.

1. Norton et al. *N Engl J Med.* 2015 Apr 23,372(17):1589-97. 2. Bevilacqua et al. *Ultrasound Obstet Gynecol.* 2015 Jan;45(1):61-6. 3. Gil MM, Akolekar R, Quezada MS, Bregant B, Nicolaides KH. *Fetal Diagn Ther.* 2014;35(3):156-173. 4. Struble et al. *Fetal Diagn Ther.* 2013;35(3):199-203. 5. Sehnert et al. *Clin Chem.* 2011 Jul;57(7):1042-9. 6. Canick et al. *Prenat Diagn.* 2012 Aug;32(8):730-4. 7. Sparks et al. *Am J Obstet Gynecol.* 2012 Apr;206(4):319.e1-9. 8. Juneau et al. *Fetal Diagn Ther.* 2014;36(4):282-6. 9. Sparks et al. *Prenat Diagn.* 2012 Jan;32(1):3-9. 10. Gregg et al. Noninvasive prenatal screening for fetal aneuploidy. 2016 update. 11. Palomaki et al. *Genet Med* 2012;14:296-305. 12. Canick et al. *Prenat Diagn.* 2013 Jul;33(7):667-74. 13. Wang et al. *Prenat Diagn.* 2013;33:1-5. 14. Nicolaides et al. *Am J Obstet Gynecol* 2012 Nov.207(5):374.E1-9. 15. Ashoor G et al. *Am J Obstet Gynecol.* 2012 Apr;206(4):322.e1-5.