Harmony™ PRENATAL TEST

An advanced blood test to assess the risk of fetal trisomies and evaluate the X and Y chromosomes

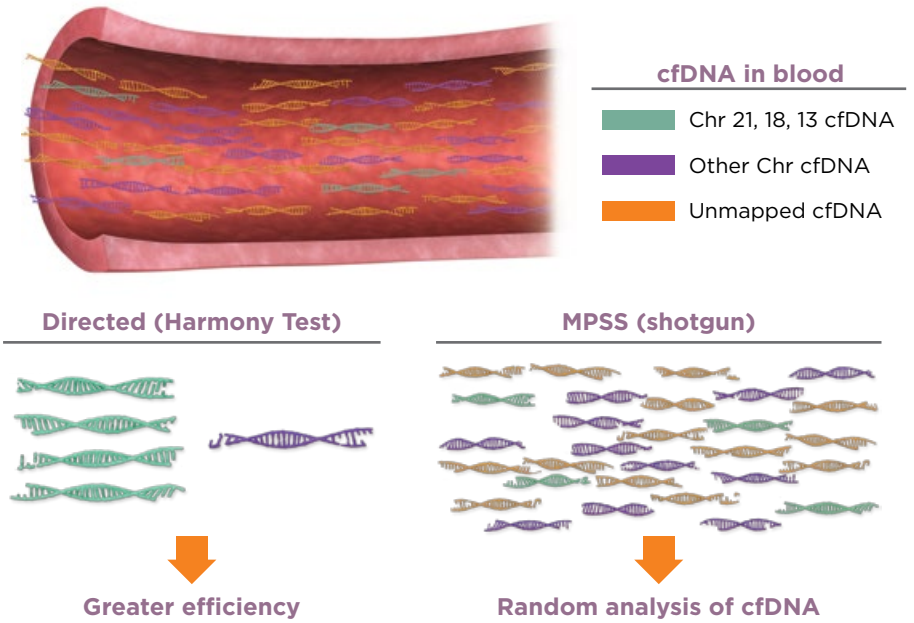
A simple, safe blood test

- Highly accurate, individualized results for you, your practice and patients[1-6]
- Performed anytime after 10 weeks' gestation
- Lowest cumulative false positive rate[1-6]

www.harmonytest.com

Advanced Technology Behind the Harmony Test

The Advantages of Directed Analysis



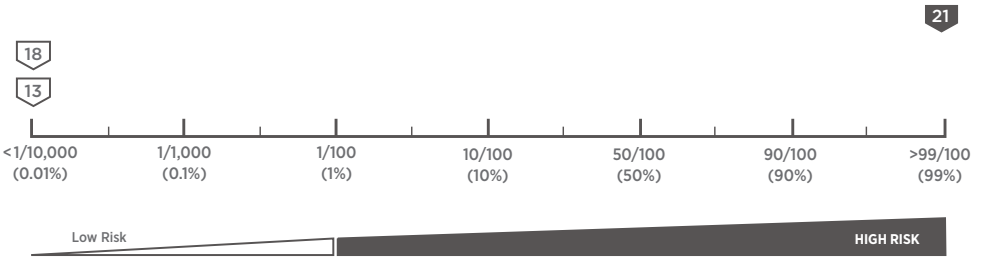
- Cell-free DNA are short DNA fragments from chromosomes found in circulation
- In pregnancy, cell-free DNA from the fetus and mother are both present in maternal blood[3]
- The Harmony test uses efficient, directed analysis for accurate trisomy detection

Informative Results

- Easy interpretation: Simple "High-Risk" or "Low-Risk" reporting for each trisomy
- Personalized risk results incorporate chromosome counts, fetal DNA fraction, gestational age, and maternal age
- 99.5% of risk score values are at either risk cutoff (<1/10,000 or >99%) for autosomal trisomies
- X and Y Analysis with the Harmony Prenatal Test offers >99% accuracy for fetal sex[7]

Test Results — Fetal cfDNA Percentage: 10.5%

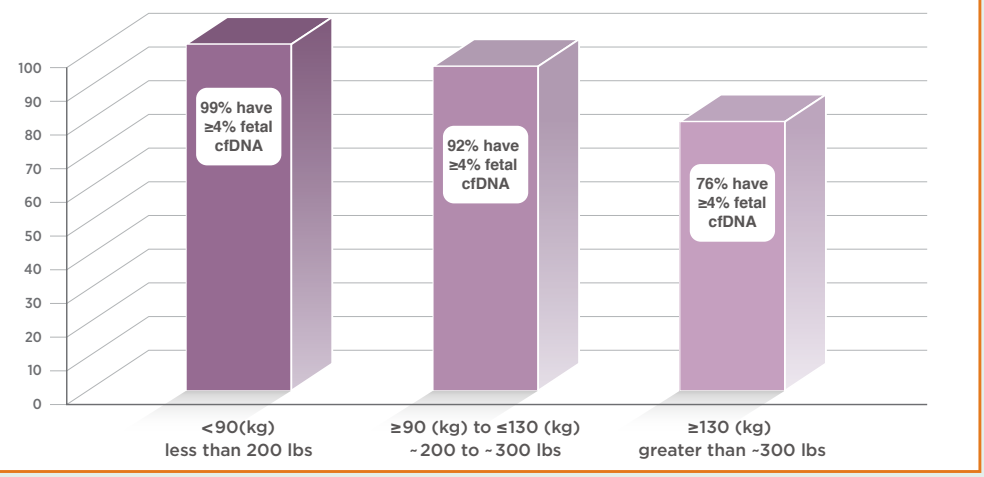
CHROMOSOME	RESULT	PROBABILITY	RECOMMENDATION
Trisomy 21 (T21)	**HIGH RISK**	**Greater than 99/100 (99%)**	**Genetic counseling and additional testing**
Trisomy 18 (T18)	Low Risk	Less than 1/10,000 (0.01%)	Review results with patient
Trisomy 13 (T13)	Low Risk	Less than 1/10,000 (0.01%)	Review results with patient
Y Analysis	Male Fetus	Greater than 99/100 (99%)	Review results with patient



Fetal fraction – key determinant for results

- A minimum amount of fetal cfDNA is necessary for reliable testing and quality results
- The Harmony test incorporates the measurement of fetal cfDNA into the analysis of ***every sample***
- Increased maternal weight and early gestational age may contribute to the presence of low fetal cfDNA (<4%)[7]

Effect of maternal weight as it correlates to ≥4% fetal cfDNA (%)



Accurate:
Enhanced Performance with Individualized Results[1-7]

Studied in over 6,000 patients, including >2,000 average-risk women[1-7]

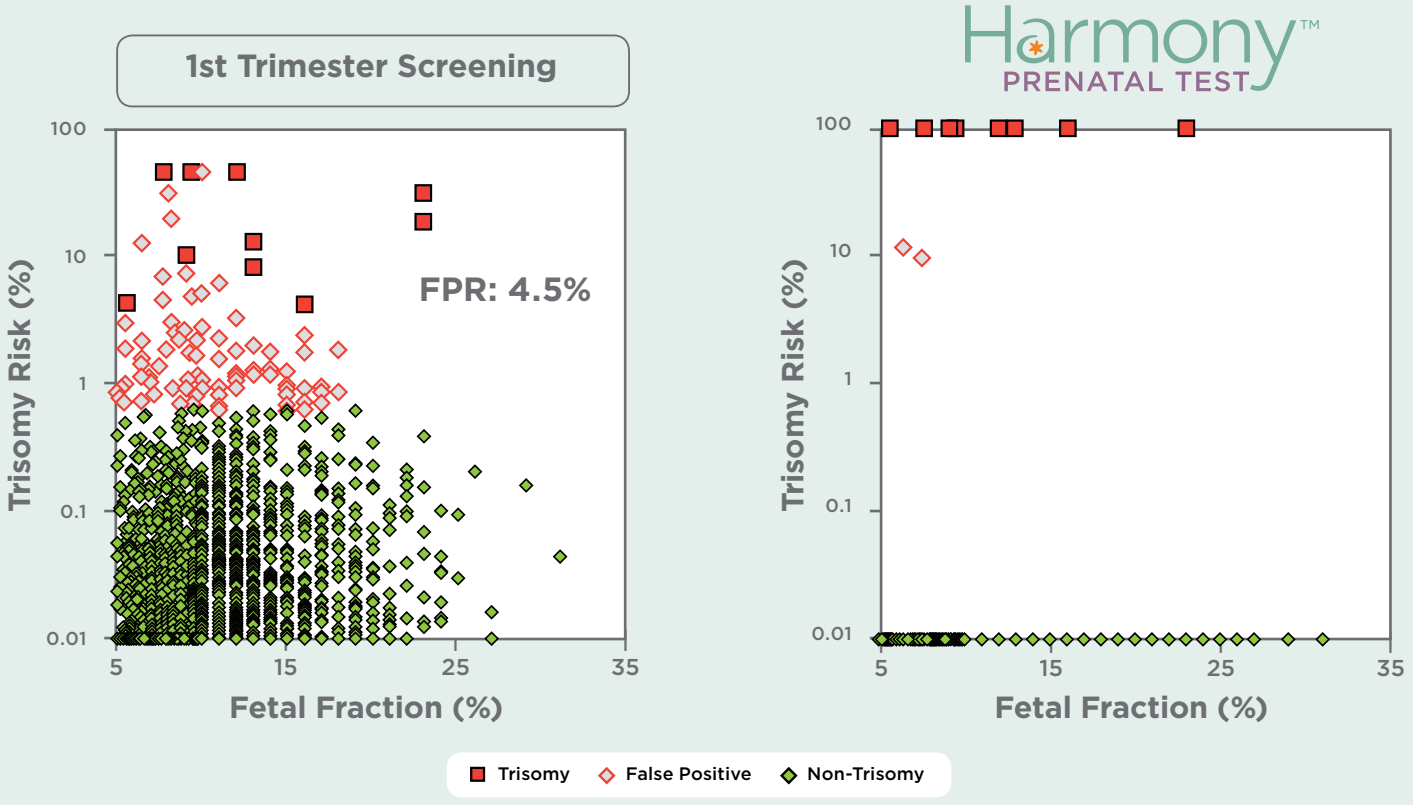
	Combined Sensitivity for Trisomies (T21, T18, T13)*	False Positive Rate
T21	>99% (231 of 232)	<0.1%
T18	>98% (103 of 105)	<0.1%
T13	8 of 10	<0.1%

X and Y analysis is >99% accurate for fetal sex. It can also assess risk for sex chromosome conditions with test performance varying by the type of condition detected.[7]

- Only non-invasive prenatal test (NIPT) that has been exclusively evaluated in 1st trimester pregnant women
- Results in 99% of your patients with proper sample collection
- 95% of results reported within 9 days of accessioning[7]

Clinical Utility in a General Screening Population[6]

Nicolaides K.H., Syngelaki A., Ashoor G, et al., Noninvasive prenatal testing for fetal trisomies in a routinely screened first-trimester population. *Am J Obstet Gynecol* (2012); 207:374.e1-6.

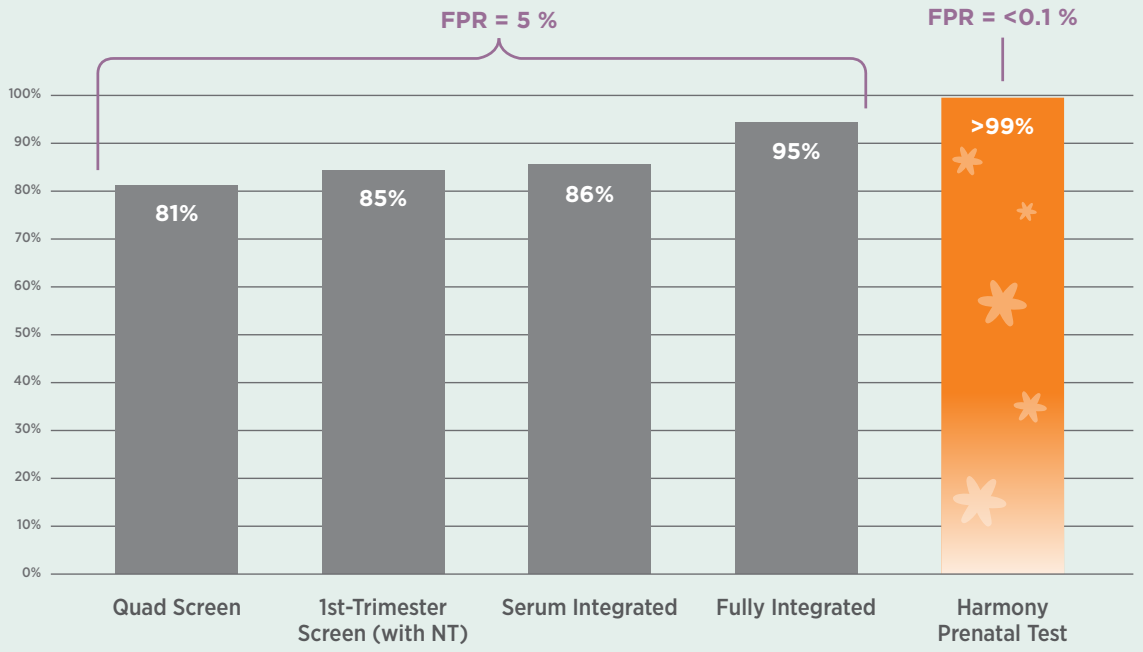


- Both figures have the same number of patients
- 10 cases of trisomy 21 or trisomy 18
- 1,939 non-trisomy cases

Flexible for Multiple Patient Populations

- The Harmony Prenatal Test detects >99% of fetal trisomy 21 cases at a false positive rate of <0.1%
- Optional X and Y chromosome analysis available for fetal sex and X,Y sex chromosome analysis
- This test does not assess risk for mosaicism, partial trisomies or translocations
- The Harmony test is available for all singleton and twin pregnancies, including those conceived by IVF

Performance of Screening Tests for Trisomy 21[4,7]



1. Sparks, A.B., Struble, C.A., Wang, E.T., Song, K., Oliphant, A., Non-invasive Prenatal Detection and Selective Analysis of Cell-free DNA Obtained from Maternal Blood: Evaluation for Trisomy 21 and Trisomy 18, *Am J Obstet Gynecol* (2012), doi: 10.1016/j.ajog.2012.01.030.
2. Ashoor, G., Syngelaki, A., Wagner, M., Birdir, C., Nicolaides, K.H., Chromosome-selective sequencing of maternal plasma cell-free DNA for first trimester detection of trisomy 21 and trisomy 18, *Am J Obstet Gynecol* (2012), doi: 10.1016/j.ajog.2012.01.029.
3. Sparks, A.B., Wang, E.T., Struble, C.A., Barrett, W., et al., Selective analysis of cell-free DNA in maternal blood for evaluation of fetal trisomy. *Prenat Diagn* (2012); 32(1):3-9. doi: 10.1002/pd.2922. Epub 2012 Jan 6.
4. Norton, M., Brar, H., Weiss, J., Karimi, A., et al., Non-Invasive Chromosomal Evaluation (NICE) Study: Results of a Multicenter, Prospective, Cohort Study for Detection of Fetal Trisomy 21 and Trisomy 18, *Am J Obstet Gynecol* (2012), doi:10.1016/j.ajog.2012.05.021.
5. Ashoor, G., Syngelaki, A., Nicolaides, K.H., et al., Trisomy 13 detection in the first trimester of pregnancy using a chromosome-selective cell-free DNA analysis method, *ULTRASOUND Obstet Gynecol* (2012), DOI: 10.1002/uog.12299.
6. Nicolaides K.H., Syngelaki A., Ashoor G, et al., Noninvasive prenatal testing for fetal trisomies in a routinely screened first-trimester population. *Am J Obstet Gynecol* (2012); 207:374.e1-6.
7. Internal data on file.

Ariosa® DIAGNOSTICS

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The Harmony Prenatal Test has been developed and is performed as a laboratory test service by Ariosa Diagnostics, a CLIA-certified clinical laboratory located in California, USA.

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