

Landmark *New England Journal of Medicine* Study¹

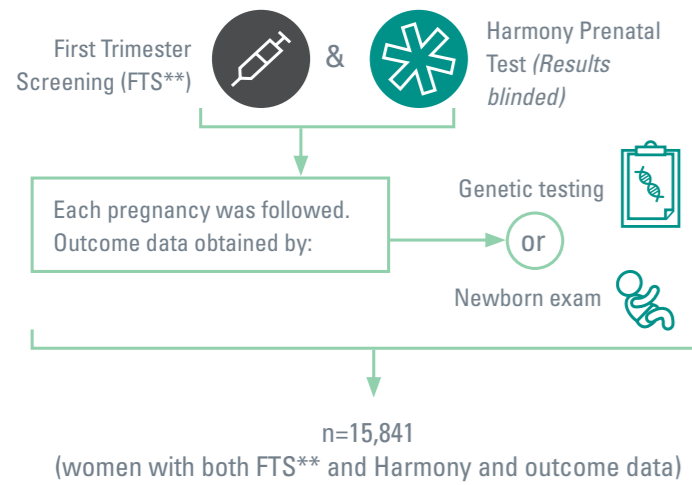
HARMONY SIGNIFICANTLY OUTPERFORMS First Trimester Combined Screening (FTS**) in both trisomy 21 detection and false-positive rate in a blinded, prospective head-to-head comparison.

Study Population

Women (age 18-48, mean age 31) with singleton pregnancies between 10 to 14 weeks' gestation.

Study Design

18,955 enrolled and each woman received both:



Study Results

(n=15,841)

	FTS**	Harmony Prenatal Test	p-value
DETECTION RATE (affected pregnancies correctly identified as high risk)	79%	100%	0.008
FALSE-POSITIVE RATE (unaffected pregnancies incorrectly identified as high risk)	5.4%	0.06%	<0.001

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

Reducing False Positives by Over 90-fold

854 of 15,803 False positives with FTS**

9 of 15,803 False positives with Harmony

Exceptionally Accurate Results

- More than 1 out of 5 affected pregnancies may go undetected with FTS. Harmony was far superior to FTS.

30 of 38 Sensitivity of FTS** in detecting Down syndrome

38 of 38 Sensitivity of Harmony in detecting Down syndrome

Why Choose Harmony?

- Exceptional accuracy for any age or risk^{1-12, 19}
 - Blinded studies in over 22,000 women of all ages^{1,2,6,7,9}
 - Less than 0.1% false-positive rate for trisomies 21, 18, 13^{3, 5-9, 12, 19}
- Trusted by clinicians worldwide, over 500,000 pregnancies screened and available in over 100 countries¹⁹
- Performed as early as 10 weeks
- May minimize invasive procedures caused by false-positive results¹⁶

Three Simple Steps to Clarity



1. Draw a maternal blood sample at 10 weeks or later in pregnancy.



2. Submit sample directly to Ariosa Diagnostics or through one of our clinical laboratory partners.



3. Receive results in as little as 3 days, most in 5 days after sample receipt.

Visit Us at harmonytest.com

For help, email nipt@tdlpathology.com or call +44 (0)20 7307 7409

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Non-invasive prenatal testing (NIPT) based on cell-free DNA analysis is not diagnostic; results should be confirmed by diagnostic testing. Data have not been submitted to or evaluated by Federal regulatory agencies and the test is not for sale as an In Vitro Diagnostic (IVD) in the US or the EU.



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- Data on file.
- Benn P et al. <http://www.ispdhome.org/public/news/2015/PositionStatementFinal04082015.pdf>. 2015 Apr.
- Estimate based on an average-risk population with prevalence for T21, T18, and T13 of 1 in 700, 1 in 5000, and 1 in 16000 respectively.



performed in the UK
Clear answers to questions that matter.



performed in the UK



Clear **ANSWERS** to Questions that Matter

HARMONY PRENATAL TEST is a cell-free DNA test that evaluates the risk for trisomies 21, 18, and 13.

The Harmony Prenatal Test is developed by Ariosa Diagnostics. Ariosa Diagnostics is a laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA). As with other laboratory-developed tests, this test has not been cleared or approved by the US FDA.

Exceptional Performance

AS EARLY AS 10 WEEKS, the Harmony Prenatal Test evaluates the risk of trisomy 21, 18, and 13 and is validated for use in pregnant woman, of any age or risk category.*¹⁻³

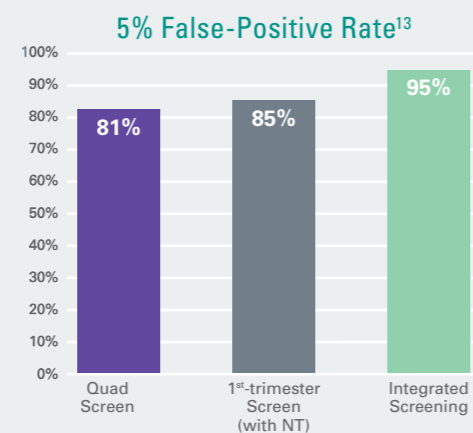
Harmony is Validated for Pregnant Women of All Ages* and Trusted by Clinicians Worldwide

- Studied extensively in blinded prospective published trials including >22,000 pregnant women.^{1,2,6,7,9}
- Clinicians in more than 100 countries have trusted Harmony to screen more than 500,000 pregnancies.¹⁹

Combined Harmony Performance Across All Clinical Studies^{1-3, 5-9, 12, 19}

	DETECTION RATE	FALSE-POSITIVE RATE
Trisomy 21	>99%	<0.1%
Trisomy 18	97.4%	<0.1%
Trisomy 13	93.8%	<0.1%
Combined Performance (Trisomies 21, 18, 13)²¹	99%	<0.1%

Detection Rate of Conventional Trisomy 21 Tests¹³



1 in 20 women experience false-positive results with conventional trisomy 21 tests¹³

* Both under 35 and over 35 age groups, studies have included women ages 18-48

A Proprietary, Targeted Technology

Only the **HARMONY PRENATAL TEST** uses proprietary, targeted DNA-based technology: (DANSR™, FORTE™)^{4-5, 12}

Depth of Analysis

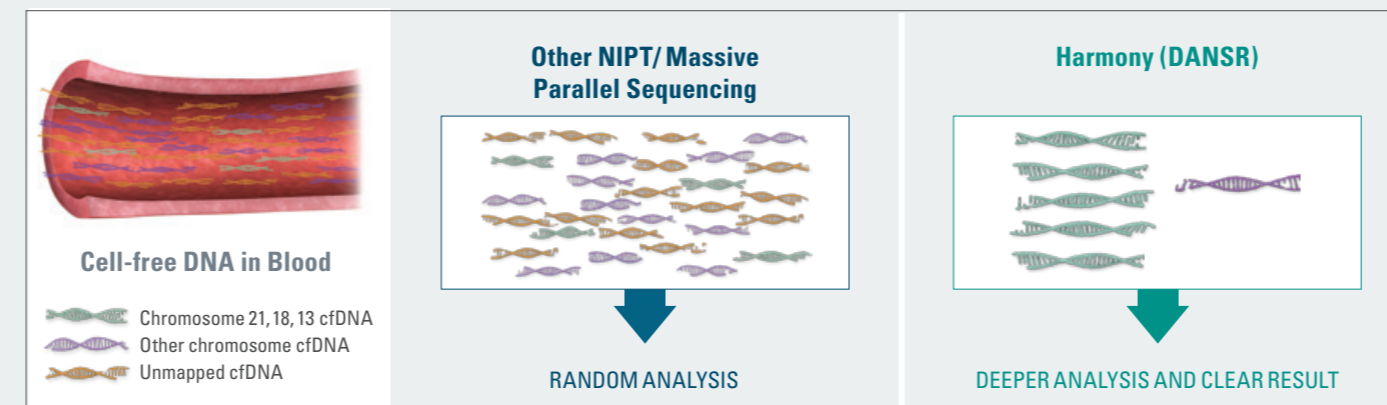
DANSR assay targets fragments from the specific chromosomes of interest.⁴

- SNP analysis distinguishes maternal from fetal DNA and quantifies the fetal DNA^{5, 12}
- DNA microarray enhances speed and quality¹²



From receipt, most in 5 days

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.^{4, 12, 14-15}

Accurate Measurement of Fetal Fraction

FORTE algorithm accurately distinguishes between high and low risk results even at low fetal fraction^{5, 12}

- Incorporates maternal risk factors and precise fetal DNA measurements
- Individual risk scores provided for each patient

Harmony Sample Test Report

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

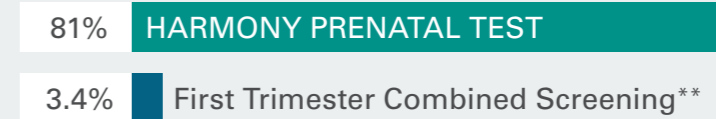
Clear Answers Early to Reduce Follow-up

The **SUPERIOR ACCURACY** and low false-positive rate of Harmony compared to traditional tests may minimize anxiety and invasive procedures caused by false-positive results.^{1,16-17}

Exceptional Positive Predictive Value for the General Population

Positive Predictive Value (PPV) is the likelihood that a positive test result is a true-positive. PPV varies by population. Harmony's extremely low false-positive rate of less than 0.1% gives it a high PPV for trisomy 21.¹

PPV in the General Population¹



Calculated using the Harmony *New England Journal of Medicine* study across 15,841 patients, ages 18-48. Trisomy 21 prevalence in this population was 1/417.



Professional medical societies support offering aneuploidy screening, including cell-free DNA screening, to all pregnant women^{13, 18, 20}

ACOG/SMFM Committee Opinion Number 640: "... any patient may choose cell-free DNA (cfDNA) analysis as a screening strategy for common aneuploidies regardless of her risk status..."

ISPD Position Statement from the Aneuploidy Screening Committee, April 2015:

"The following protocol options are currently considered appropriate:

1. cfDNA screening as a primary test offered to all pregnant women.
2. cfDNA secondary to a high risk assessment based on serum and ultrasound screening protocols..."

Options for Ordering***

Harmony Prenatal Test: Evaluates the risk for fetal trisomy 21, trisomy 18, trisomy 13

Additional Test Offerings:

- Fetal sex (singletons and twins)
- Monosomy X (singletons only)
- Sex chromosome aneuploidy panel (singletons only)

Validated for use in twin and IVF pregnancies, including self and non-self egg donor pregnancies.⁹

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

*** For New York State, test options are as follows: Harmony Prenatal Test, Harmony with Y analysis, Harmony with X, Y analysis. Test options for Fetal Sex, Monosomy X, and Sex Chromosome Aneuploidy Panel are not available in New York State.