harmony™
PRENATAL TEST

Testing Services by Ariosa Diagnostics

Clear ANSWERS to Questions that Matter

The Harmony Prenatal Test is a cell-free DNA test that evaluates the risk for trisomies 21, 18, 13.

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.

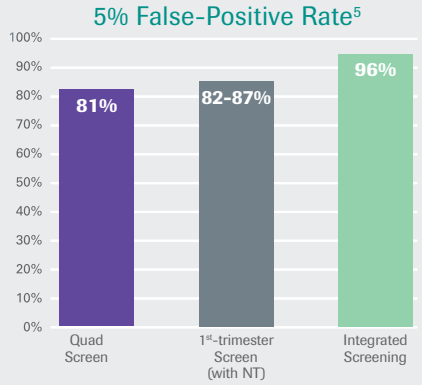
Exceptional Performance

The HARMONY PRENATAL TEST assesses your patients risk for trisomies 21, 18, 13 as early as 10 gestational weeks and validated for use in pregnant women, of any age* or risk category.[1]

Combined Harmony Performance Across All Clinical Studies[1]

	DETECTION RATE	FALSE-POSITIVE RATE
Trisomy 21	>99%	<0.1%
Trisomy 18	97.4%	<0.1%
Trisomy 13	93.8%	<0.1%

Detection Rate of Conventional Trisomy 21 Tests[5]

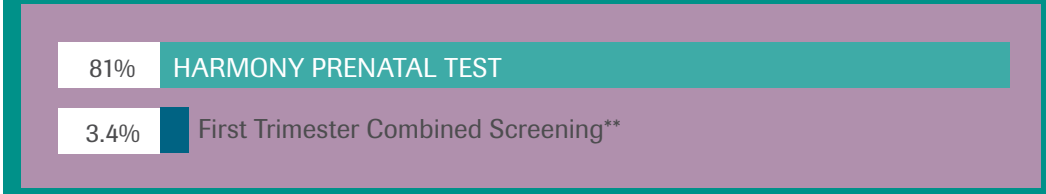


1 in 20 women experience false-positive results with conventional trisomy 21 tests[5]

The SUPERIOR ACCURACY and low false-positive rate of Harmony compared to traditional screening tests may minimize anxiety and invasive procedures caused by false-positive results.[2-4]

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.[2]



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.

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

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

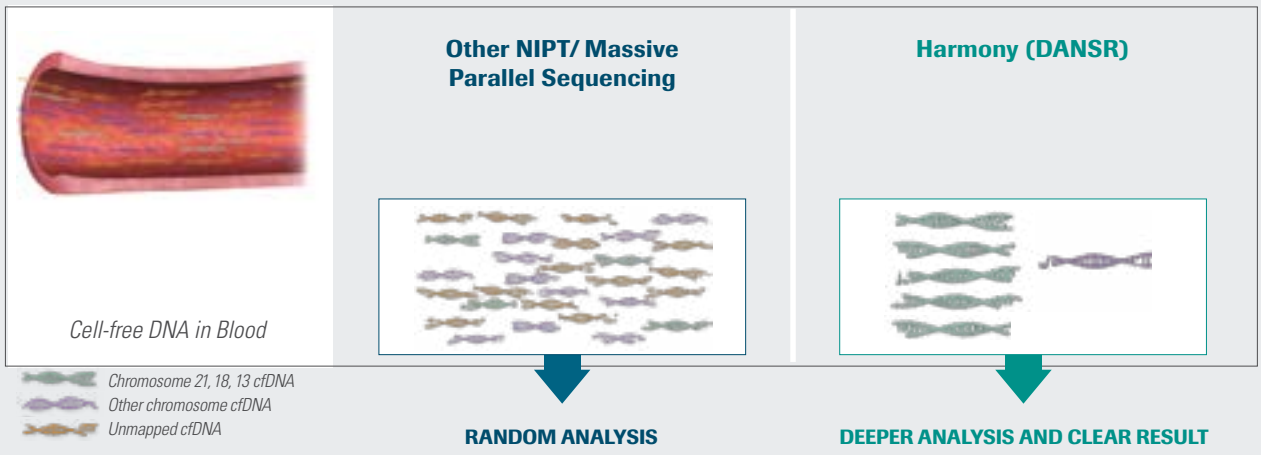
Targeted Technology

The HARMONY PRENATAL TEST uses proprietary, targeted DNA-based technology (DANSR™, FORTE™)[6-8]

Depth of Analysis

- DANSR assay targets fragments from the specific chromosomes of interest.[6]
- SNPs are used to quantify fetal DNA percentage[7]
- DNA microarray enhances speed and quality[8]

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.[6,8,9,10]

Accurate Measurement of Fetal Fraction

FORTE algorithm accurately distinguishes between high and low probability results even at low fetal fraction[7,8]

- Incorporates maternal age, gestational age, fetal fraction and precise fetal DNA measurements
- Individual probablity scores provided for each patient

Harmony Sample Test Report

Test Results			Fetal cfDNA Percentage: 10.5%
CHROMOSOME	RESULT	PROBABILITY	RECOMMENDATION
Trisomy 21 (T21)	Low Probability	less than 1/10,000 (0.01%)	Review results with patient
Trisomy 18 (T18)	Low Probability	less than 1/10,000 (0.01%)	Review results with patient
Trisomy 13 (T13)	Low Probability	less than 1/10,000 (0.01%)	Review results with patient

Fetal Sex	**Female**
22q11.2	**High probability of a deletion - Recommend genetic counseling**

Clear Answers Early

22q11.2 deletion syndrome, also referred to as DiGeorge syndrome or Velo-Cardio-Facial syndrome, is the most common microdeletion, and affects as many as **1 in 1,000** pregnancies. It is the second most common cause of developmental delay after Down syndrome.[12-15]

Why Choose Prenatal Screening for 22q11.2

- Maternal age is not a risk factor for microdeletions[14]
- More than 90% of affected individuals have no family history of 22q11.2 deletion[14]
- 22q11.2 deletion is not reliably detected by routine screening[15]

Early prenatal screening for 22q11.2 deletion enables informed choices and appropriate obstetrical and neonatal management.[15]

Harmony Ordering options†

Trisomy 21, 18, and 13 (singleton and twins)
Fetal Sex (singleton and twins)
Monosomy X (singleton only)
Sex chromosomes aneuploidy panel (singleton only)
22q11.2 (singleton only)

The Harmony Prenatal Test has been validated for use in twins and IVF pregnancies, including self and non-self egg donor pregnancies.[16] 22q11.2 testing is not available to women that are known to have this deletion.

† For New York State, 22q11.2 is not available.

Professional medical societies support offering aneuploidy screening, including cell-free DNA screening to all pregnant women[11,17]

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…*"

ACMG recommends informing all pregnant women that Noninvasive Prenatal Screening is the most sensitive screening option for traditionally screened aneuploides.

Consistently Accurate Results

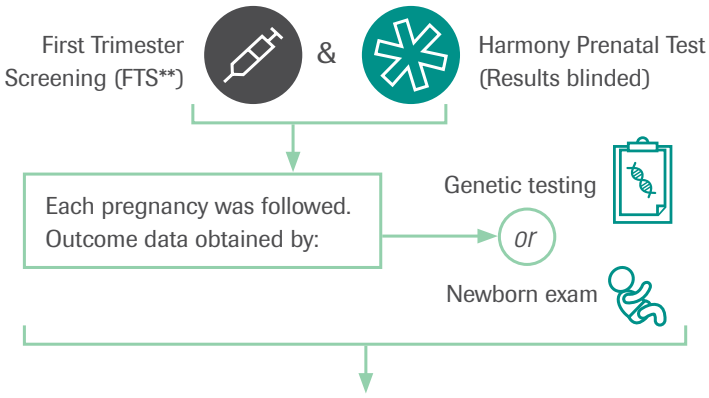
In the landmark New England Journal of Medicine NEXT study the Harmony Prenatal Test significantly outperforms First Trimester Combined Screening (FTS**) in both trisomy 21 detection and false-positive rate in a blinded, prospective head-to-head comparison.[2]

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:



n=15,841
(women with both FTS** and Harmony and outcome data)

General Population Study Results

(n=15,841)

	FTS**	Harmony Prenatal Test
DETECTION RATE (affected pregnancies correctly identified as high risk)	79% *(30 of 38)*	100% *(38 of 38)*
FALSE-POSITIVE RATE (unaffected pregnancies incorrectly identified as high risk)	5.4% *(854 of 15,803)*	0.06% *(9 of 15,803)*

More than 1 out of 5 affected pregnancies may go undetected with First Trimester.

Average Risk Population Study Results (women <35 years old)

(n=11,994)

	Harmony Prenatal Test
DETECTION RATE (affected pregnancies correctly identified as high risk)	100% *(19 of 19)*
FALSE-POSITIVE RATE (unaffected pregnancies incorrectly identified as high risk)	0.05% *(6 of 11,994)*

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

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PRENATAL TEST
Testing services from Ariosa Diagnostics

Why Choose Harmony?

- Exceptional accuracy for any age* or risk
  - Less than 0.1% false-positive rate for trisomies 21, 18, 13[1]
- Performed as early as 10 weeks
- May minimize invasive procedures caused by false-positive results

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 within 5-7 days from sample receipt.

For assistance email **sjc.clientservices@roche.com** or call **1-855-927-4672.**

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

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