harmony™
PRENATAL TEST

performed in Australia

AUSTRALIAN Clinicalabs

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

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 women, of any age or risk category.*[1-3]

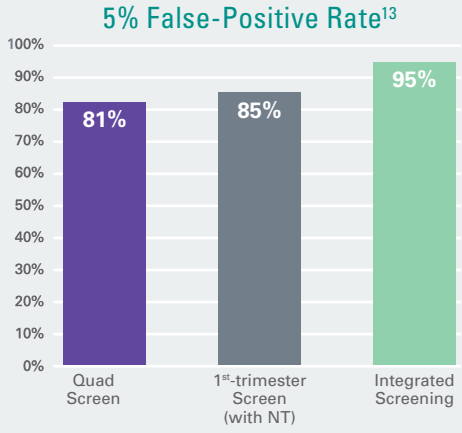
Harmony is Validated for Pregnant Women of All Ages* and Trusted by Clinicians Worldwide

- 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 Tests[13]



1 in 20 women experience false-positive results with conventional trisomy 21 tests[13]

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

A Proprietary, Targeted Technology

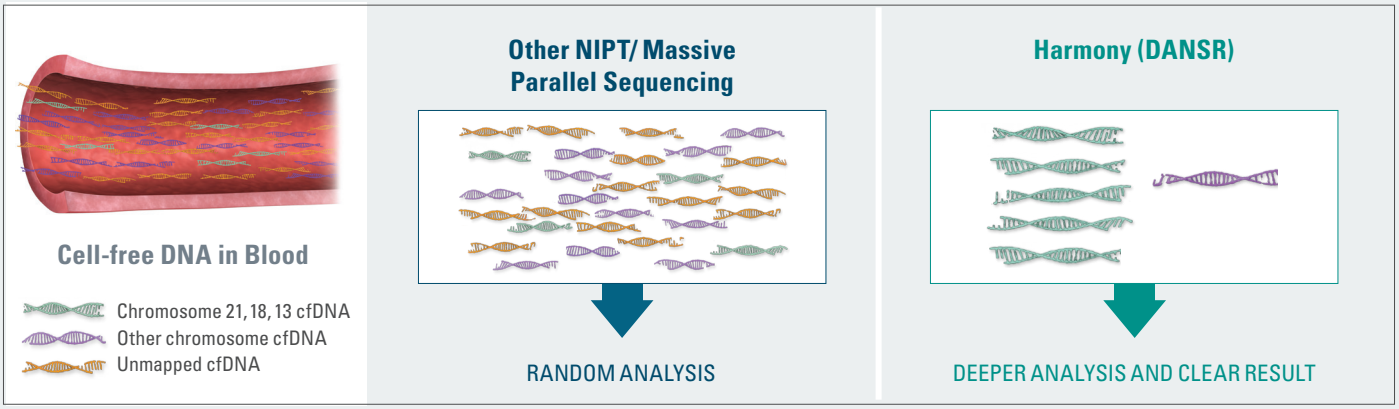
Only the **HARMONY PRENATAL TEST** uses proprietary, targeted DNA-based technology: (DANSR™, FORTE™)[4-5, 12]

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 quality[12]

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

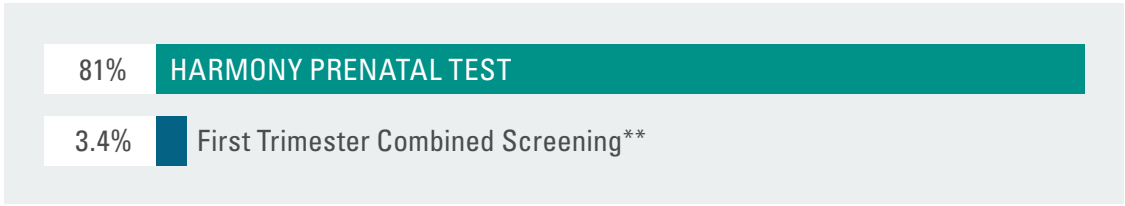
Clear Answers Early to Reduce Follow-up

The **SUPERIOR ACCURACY** and low false-positive rate of Harmony compared to traditional tests may minimise 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 Population[1]



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 ß-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.*

Landmark *New England Journal of Medicine* Study[1]

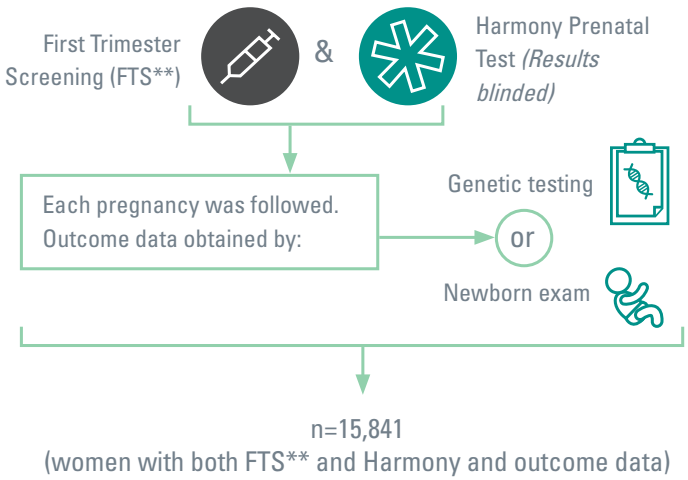
HARMONY SIGNIFICANTLY OUTPERFORMS First Trimester Combined Screening (FTS**) in both trisomy 21 detection and false-positive rate in a blinded, prospective head-to-head comparison.

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 ß-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

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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 [1-3, 5-9, 12, 19]
- Trusted by clinicians worldwide, over 500,000 pregnancies screened and available in over 100 countries [19]
- Performed as early as 10 weeks
- May minimise invasive procedures caused by false-positive results [16]

Three Simple Steps to Clarity

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

2. Submit sample directly to Australian Clinical Labs.

3. Receive results in 5 - 7 days after sample receipt.

Visit Us at www.clinicallabs.com.au

For assistance email **harmony@clinicallabs.com.au** or call **1300 750 610**

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.

Roche

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