

Landmark NEJM Study Shows Harmony Delivers Unsurpassed Accuracy for the General Pregnancy Population

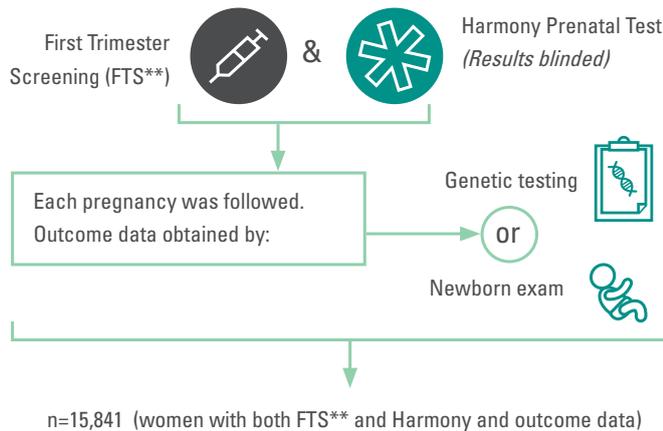
In the first and only blinded prospective study of its kind, the Harmony Prenatal Test proved superior to traditional first trimester screening for the detection of trisomy 21 (Down syndrome). Nearly 19,000 women, regardless of the age of risk, were enrolled in this unique study that compared the performance of two prenatal tests. The results, published recently in the *New England Journal of Medicine*¹, show Harmony Prenatal Test significantly outperforms the current screening standard for trisomy 21.

Study Population

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

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Sensitivity of FTS** in detecting Down syndrome

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Sensitivity of Harmony in detecting Down syndrome



Behind Harmony's unsurpassed Accuracy

- DANSR™ is a proprietary targeted assay for deeper analysis.
- FORTE™ algorithm incorporates fetal fraction, maternal age and gestational age to provide an individualised risk score.



Visit www.clinicallabs.com.au for more information.

Considerations in Selecting the Highest Quality NIPT| for Your Practice

To ensure the highest quality NIPT for your patients and practice, there are a number of critical quality standards to consider.

1. Can You Rely on the Performance Claims of Your NIPT?

- Harmony is the most broadly studied NIPT, documented in prospective, blinded validation trials in **over 22,000** pregnant women.^{1,3-10}

Why is this important?

- Without extensive blinded prospective clinical validation studies, performance claims may not be reliable. The Harmony test performance is based on such studies and not registries or internal datasets lacking confirmed clinical outcomes.

2. Does Your NIPT Result Represent the Fetus or the Woman?

- A recent report shows that three of five commercial NIPT tests reported a normal female fetus in samples from women who were not even pregnant. For this same set of samples, Harmony test appropriately reported insufficient fetal cfDNA and as a result did not provide a risk assessment.²
- Harmony accurately measures, incorporates, and reports fetal DNA percentage in each patient sample analysed and will only report a result if sufficient fetal DNA is present.

Why is this important?

- In some samples, there is very little or no detectable fetal DNA. If fetal DNA is not accurately measured, results may be based solely on the DNA of the mother. This may lead to increased risk of “false negative” results and discordant calls for fetal sex, with a documented error rate for fetal sex as high as 2.6%.¹²

Why Choose Harmony?

- Unsurpassed accuracy for any age or risk
 - Blinded studies in over 22,000 women of all ages
 - Less than 0.1% false-positive rate for trisomy 21
- Most widely used test – in over 500,000 pregnancies and over 100 countries
- Performed as early as 10 week
- May minimise invasive procedures caused by false-positive results.

For further information regarding the benefits of the Harmony Prenatal Test, please contact us at **1300 750 610** or visit our website at www.clinicallabs.com.au

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