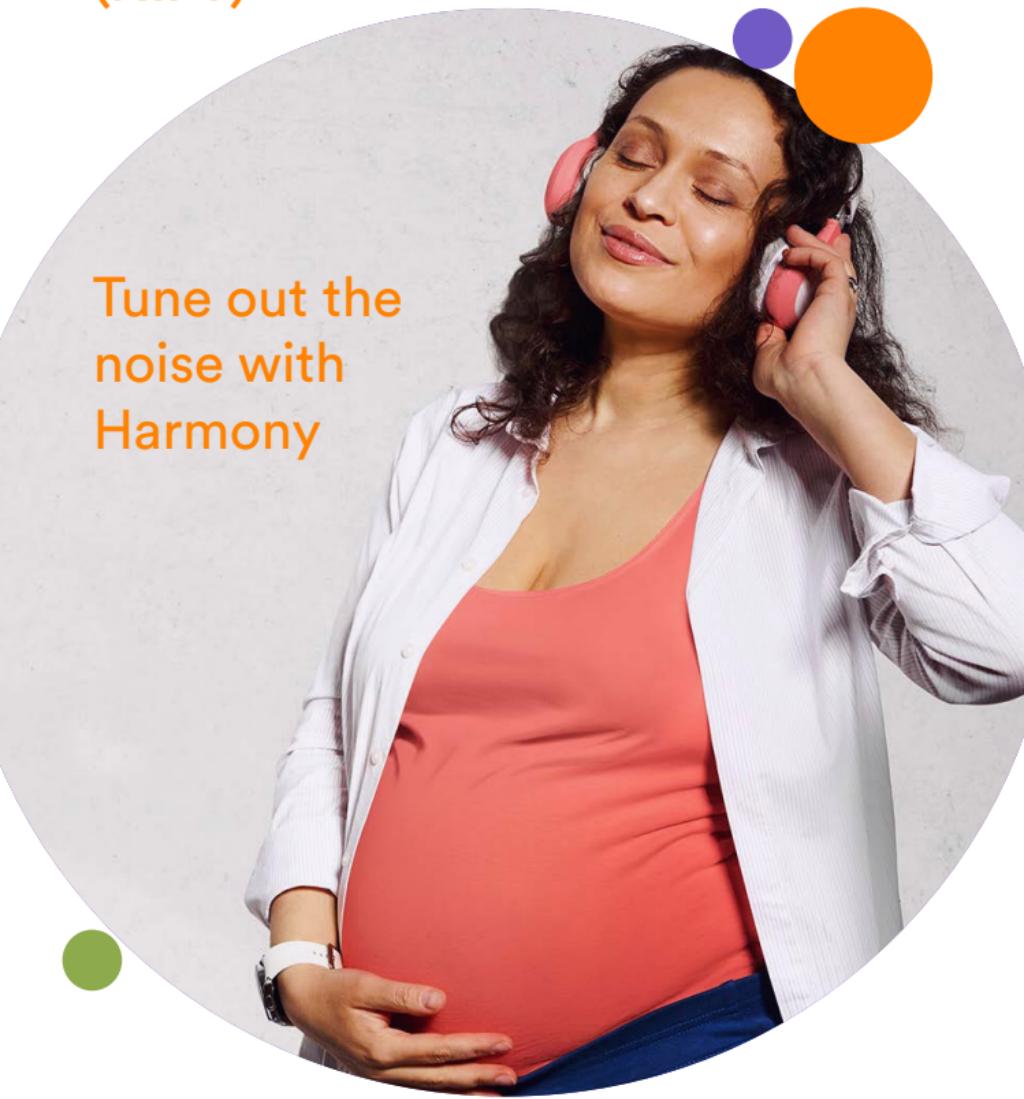


# harmony®



## NON-INVASIVE Prenatal Testing (NIPT)

Tune out the  
noise with  
Harmony



AUSTRALIAN  
 **Clinical labs**

Australia's only provider of  
Harmony NIPT including DiGeorge  
and Down syndromes.

[antenatal.clinicallabs.com.au](http://antenatal.clinicallabs.com.au)



During pregnancy, healthcare providers will offer various screening tests to help assess a baby's health.

As part of the care, options will be given to screen for Down syndrome, a genetic condition that affects physical and mental development.

## Why is screening for Down syndrome recommended?

Some genetic conditions run in families. Others, like Down syndrome, typically do not. They can happen in any pregnancy. Although the risk of Down syndrome increases with age, most babies with Down syndrome are born to women under 35 years of age.<sup>1</sup>

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) recommend that doctors provide all pregnant women with information regarding screening for Down syndrome.<sup>2</sup>

## Why is NIPT for DiGeorge syndrome important?

DiGeorge syndrome (22q11.2 deletion) is the second most common cause of congenital heart disease and developmental delay after Down syndrome<sup>9</sup>, affecting approximately 1 in 1,000 newborns.<sup>3</sup> Conventional screening methods, such as first-trimester screening, do not reliably detect DiGeorge syndrome in the prenatal period.<sup>3</sup> Additionally, maternal age is not a risk factor for microdeletions, meaning that DiGeorge syndrome can occur in any pregnancy.<sup>9</sup>

**Harmony NIPT with 22q11.2 is the most affordable and highly accurate prenatal screening choice for DiGeorge and Down syndromes in Australia.**

A doctor can add DiGeorge syndrome screening to a Harmony NIPT for an additional cost, but they cannot order it as a stand-alone test.

## What is the Harmony prenatal test?

When pregnant, the blood contains fragments of the baby's DNA. Harmony non-invasive prenatal testing (NIPT) is a screening test that analyses this DNA in a sample of blood to assess the risk of Down syndrome (trisomy 21), Edwards syndrome (trisomy 18), and Patau syndrome (trisomy 13) in a developing baby.

## How effective is Harmony NIPT in accurately detecting Down syndrome?

### HARMONY NIPT<sup>4</sup>

**DETECTION RATE\*\***  
Greater than 99%

**FALSE-POSITIVE RATE\***  
Less than 0.1%

### COMBINED

First-Trimester Screening\*\*\*<sup>5</sup>

**DETECTION RATE\*\***  
85-90%

**FALSE-POSITIVE RATE\***  
3-5%

\*Reports a high risk for Down syndrome when it is NOT actually present

\*\*Correctly indicates a high risk for Down syndrome when it IS present

\*\*\*Serum PAPP-A, total or free  $\beta$ -hCG & Nuchal Translucency

## How does Harmony NIPT reduce the need for invasive follow-up procedures?

The greater accuracy and lower false-positive rate of Harmony NIPT, compared to traditional tests, can reduce the likelihood of needing additional testing due to a false-positive result.<sup>6</sup> Follow-up testing may include invasive procedures, such as amniocentesis.





## What additional information can Harmony NIPT provide?

The Harmony prenatal test can screen for conditions caused by having an extra or missing copy of the X or Y chromosomes, including Turner and Klinefelter syndromes. Additionally, Harmony provides the option to find out the sex of the baby.<sup>7,8</sup>

## Who can have Harmony NIPT?

Women who are at least 10 weeks into their pregnancy with a single baby or twins, whether conceived naturally or through IVF, are eligible for Harmony NIPT. However, the additional sex chromosome aneuploidy analysis and DiGeorge syndrome screening can only be performed in singleton pregnancies. The Harmony prenatal test is approved for use in women 18 years and older.

## When is the Harmony prenatal test available?

Harmony NIPT is **ideally performed between 10 and 14 weeks of pregnancy**. The referring doctor will receive the results within 5-10 business days of the receipt of the sample at our lab.



## **Take the HARMONY NIPT TEST from 10 weeks pregnant.**

**Simply follow these 4 easy steps:**

1. Obtain a Harmony Request form from the referring doctor. Get the form early to be ready to have the test once 10 weeks of pregnancy is reached.
2. Visit any of our 1,300+ Clinical Labs collection centres ([clinicallabs.com.au/location](http://clinicallabs.com.au/location)) with the request form. There's no need to book.
3. Pay for the test while at the collection centre using our online payment portal. Our collector can assist if required.
4. The referring doctor will receive the results within 5-10 business days.

## **Is genetic counselling available?**

Genetic counselling will be offered to all women whose test results indicate a pregnancy with a high probability of chromosomal abnormality, within 48 hours. Please visit [antenatal.clinicallabs.com.au](http://antenatal.clinicallabs.com.au) to view our genetic counselling policy.



For frequently asked questions about Harmony NIPT testing, please visit our website at [antenatal.clinicallabs.com.au/patient/harmony/faq](http://antenatal.clinicallabs.com.au/patient/harmony/faq) or scan the QR code.

For more information about the test, its limitations, and our testing policy, please visit [antenatal.clinicallabs.com.au](http://antenatal.clinicallabs.com.au)

### References

1. The California Prenatal Screening Program March 2009. Provider Handbook 2009.
2. RANZCOG Guideline (C-Obs 59) July 2018.
3. Grati et al. *Prenat Diagn.* 2015 Aug; 35(8): 801-9.
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5. Norton et al. *New England J of Medicine.* 2015; 372(17): 1589-1597.
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7. Nicolaides et al. *Fetal Diagn Ther.* 2014; 35(1): 1-6.
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9. Rauch et al. *Am J Med Genet A.* 2006 Oct 1; 140(19): 2063-74.



Harmony NIPT is a highly accurate prenatal screening test with high specificity and sensitivity. It is important to note that while rare, false-positive and false-negative results may occur. Before making any treatment decisions, all women should discuss their results with their healthcare provider, who can recommend confirmatory, diagnostic testing where appropriate. The Harmony Prenatal Test is developed by Ariosa Diagnostics and it is performed in Australia. **ALWAYS FOLLOW THE DIRECTIONS FOR USE.**

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