harmony®
PRENATAL TEST

*performed in Australia*

# Clear ANSWERS
## to Questions that Matter

HARMONY PRENATAL TEST is a DNA-based blood screening test for Down syndrome. Harmony is more accurate than traditional tests and can be performed as early as 10 weeks in pregnancy.[1,2]

AUSTRALIAN Clinicallabs

www.clinicallabs.com.au

VIC NSW SA NT
1300 453 688

Western Australia
1300 367 674

## Who can have the Harmony Prenatal Test?

Pregnant women who are at least 10 weeks gestational age with a singleton or twin pregnancy resulting from natural conception or IVF are eligible for this analysis. However, the additional fetal sex chromosome analysis and 22q11.2 deletion can only be performed in singleton pregnancies.

## How much does the test cost?

Currently neither Medicare nor Private Health Insurers cover the cost of the test. For current pricing, please contact us on 1300 750 610 or email harmony@clinicallabs.com.au

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

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

## Where can I have the test done?

Your doctor will provide you with a Harmony test request form. All of our collection centres across Victoria, New South Wales and Western Australia collect for the Harmony Prenatal Test. Collection centres in South Australia and Northern Territory require appointments. For a current list of our centres, please visit our website www.clinicallabs.com.au or contact us on 1300 453 866 or 1300 367 674 (WA only).

## Is genetic counselling available?

Genetic counselling will be offered to all women whose test result is high risk. The service may be provided, at your doctor's discretion, in one of the following ways:

- Your doctor may choose to provide the genetic counselling themselves;
- By the Australian Clinical Labs allied genetic counselling service (no additional fee applies);
- By referral from your doctor to a local genetic counselling service.

## Experts support Down syndrome screening

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.[6]

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) recommends that all pregnant women be provided with information regarding screening for Down syndrome.[7]

## What is the Harmony Prenatal Test?

When you're pregnant, your blood contains fragments of your baby's DNA.

Harmony Prenatal Test is a type of screening test that analyses this DNA in a sample of your blood to assess the risk of Down syndrome (trisomy 21) and two other genetic conditions, trisomy 18 (Edwards syndrome) and trisomy 13 (Patau syndrome).

## For woman of any age or risk category

Traditional blood tests can miss as many as 20% of Down syndrome cases in pregnant women.[2]

The Harmony Prenatal Test was developed to be a more accurate prenatal Down syndrome screening test for women of any age or risk category.

It is a DNA-based blood test that has been extensively tested in both the under 35 and over 35 age groups, studies have included pregnant women ages 18-48 for trisomy 21.[1-3]

## A more accurate test

Harmony has been shown in clinical testing to identify greater than 99% of Down syndrome cases and to have a false-positive rate of less than 0.1%.[1-2]

# Harmony versus traditional Down syndrome tests[2]

| HARMONY Prenatal Test | TRADITIONAL First Trimester Screening*** |
|---|---|
| FALSE-POSITIVE RATE* Less than 1 in 1,600 | FALSE-POSITIVE RATE* 1 in 20 |
| DETECTION RATE** More than 99 in 100 | DETECTION RATE** 79 in 100 |

* 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 ß-hCG & Nuchal Translucency

## Minimises need for follow-up tests

The greater accuracy and low false-positive rate of Harmony compared to traditional tests may minimise the chance that further testing would be recommended due to a false-positive result.[8] Follow-up testing might include an invasive procedure, such as amniocentesis.

## Clarity early

Results are usually available in about seven business days. Other commonly used screening tests for Down syndrome are performed later in pregnancy and may require multiple office visits.

## Fetal sex chromosomes

The Harmony Prenatal Test can also screen for conditions caused by having an extra or missing copy of the X or Y chromosomes, including Turner and Klinefelter syndromes. You also have the option to obtain information about the sex of your baby.[4,5]

## 22q11.2 deletion syndrome

The Harmony® Prenatal Test can include an assessment for 22q11.2 deletion syndrome. 22q11.2 deletion is the most common microdeletion syndrome, occurring in as many as 1 in 1,000 pregnancies[9] and is the second most common genetic cause of developmental delay and congenital heart disease after Down syndrome. Please discuss with your clinician if you wish to include the 22q11.2 deletion option (extra fee applies).

# 3 simple steps to CLARITY

1. At 10 weeks or later, you get a simple blood screening test.
2. Your blood sample is sent to Australian Clinical Labs, where it is analysed.
3. Your results are sent to your healthcare provider in about seven business days.

## Your results

The test result will give you a clear answer about the risk to your pregnancy of having any of the genetic conditions included in the test.

Once you have your Harmony test results, you can discuss your pregnancy care with your healthcare provider.


1. Stokowski et al. Prenat Diagn. 2015;35:1-4.
2. Norton et al. N Engl J Med. 2015 Apr 23; 372(17): 1589-97
3. Norton et al. Am J Obstet Gynecol. 2012 Aug;207(2):137.e1-8.
4. Nicolaides et al. Fetal Diagn Ther. 2014;35(1):1-6.
5. Hooks et al. Prenat Diagn. 2014 May;34(5):496-9.
6. The California Prenatal Screening Program. March 2009. Provider Handbook 2009.
7. RANZCOG Guideline (C-Obs59) Amended May 2016
8. Wax et al. J Clin Ultrasound. 2015 Jan;43(1):1-6.
9. Grati et al. Prenat Diagn. 2015 Aug; 35(8): 801-9
10. Rauch et al. Am J Med Genet A. 2006 Oct 1; 140(19): 2063-74.


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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. 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. The Harmony Prenatal Test is performed in Australia.




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