



ASK Your Prenatal Healthcare Provider

What can I learn from the Harmony test?

How does Harmony differ from other Down syndrome screening tests?

What are the advantages of using Harmony rather than traditional tests?

Do you offer the Harmony test in your office or through a laboratory?

How can I find out how much the Harmony test costs?

When and how will you notify me of the Harmony test result?



Understand your testing options by watching our educational video: harmonytest.com/video

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PRENATAL TEST
performed in Australia

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Visit us at www.clinicallabs.com.au where you can find more questions to ask your doctor about Harmony.

Clear **ANSWERS**
to Questions that Matter

Three 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.



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



1. Norton et al. *N Engl J Med.* 2015 Apr 23;372(17):1589-97
2. Nicolaides et al. *Am J Obstet Gynecol.* 2012 Nov;207(5):374.e1-6.
3. Nicolaides et al. *Fetal Diagn Ther.* 2014;35(1):1-6.
4. Hooks et al. *Prenat Diagn.* 2014 May;34(5):496-9.
5. The California Prenatal Screening Program. March 2009. Provider Handbook 2009.
6. ACOG Practice Bulletin 77. ACOG Committee on Practice Bulletins. *Obstet Gynecol.* 2007 Jan;109(1):217-27

Non-invasive prenatal testing services (NIPT) based on cell-free DNA analyses are 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

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CONGRATULATIONS

on your pregnancy! Now that you are pregnant, supporting your baby's development is your top priority.



| CLEAR ANSWERS TO QUESTIONS THAT MATTER

Harmony versus Traditional Down Syndrome Tests¹

	FALSE-POSITIVE RATE*	DETECTION RATE**
HARMONY Prenatal Test	Less than 1 in 1,600	More than 99 in 100
TRADITIONAL First Trimester Screening***	1 in 20	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 β -hCG & Nuchal Translucency

Introduction

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.

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.⁵

The American College of Obstetricians and Gynecologists (ACOG) now recommends that all pregnant women be offered screening and diagnostic testing for Down syndrome.⁶

What is the Harmony Prenatal Test?

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

Harmony Prenatal Test is a new 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 Women of Any Age or Risk Category

Traditional blood tests can miss as many as 20% of Down syndrome cases in pregnant women.¹

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 21.¹⁻²

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

Clarity Early

Harmony Prenatal Test requires a single blood draw and can be done as early as 10 weeks or later in pregnancy.

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.

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. Follow-up testing might include an invasive procedure, such as amniocentesis.

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.^{3,4}