

## What happens with a Harmony prenatal test:

# 1

At 10 weeks or later, your blood is drawn.

# 2

Your blood sample is sent to a laboratory where it is analysed.

# 3

Your results are sent to your healthcare provider in about 3-5 business days from receipt of sample in the laboratory.

## For clear answers

Screening with the Harmony test identifies more than 99% of pregnancies with Down syndrome, whereas traditional screening misses as many as 20% (1 in 5).<sup>3</sup>

## For fewer false alarms

The Harmony test performance is superior to traditional screening for Down syndrome.

With the Harmony test, there is less chance your doctor will recommend follow-up testing due to a false-positive result, and you can avoid needless anxiety.<sup>4</sup>

## For information you can trust

All results will be given to you by your healthcare provider and will be interpreted in the context of your medical details and family history. You should continue with your usual scan appointments before and following the testing.

The Harmony prenatal test offers a highly accurate and proven screening test<sup>1</sup>, giving confidence in the result.

## What to expect from Harmony results:

The Harmony test is a screening test. That means it looks for evidence of the conditions listed in this brochure, but like any screening test, it does not provide a diagnosis.

Your Harmony test results can guide the discussions you have with your doctor about your pregnancy care.

A small proportion of NIPT tests may not produce a test result, for example if a suitable amount of the babies DNA was not present in the mother's blood. Please talk to your healthcare provider on your options should this be the case.

## FOR MORE

information, talk to your healthcare provider or visit [www.harmonytest.co.uk](http://www.harmonytest.co.uk)



TDL  
GENETICS



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The Harmony non-invasive prenatal test is based on cell-free DNA analysis and is considered a prenatal screening test, not a diagnostic test. Harmony does not screen for potential chromosomal or genetic conditions other than those expressly identified in this document. All women should discuss their results with their healthcare provider who can recommend confirmatory, diagnostic testing where appropriate.

The Harmony prenatal test was developed and its performance characteristics determined by Ariosa Diagnostics, Inc. a CLIA-certified and CAP-accredited San Jose, CA USA. This testing service has not been cleared or approved by the US Food and Drug Administration (FDA). The assay is CE marked.

Roche Diagnostic Limited, Charles Avenue, Burgess Hill, West Sussex, United Kingdom. RH15 9RY. Registration number: 571546. Date of preparation: June 2018. Material number: RMS-SS-2018-013 © 2018 Roche Diagnostics Limited. All Rights Reserved. HARMONY is a trademarks of Roche. All other product names and trademarks are the property of their respective owners. TAP3900/10-08-2018/V5DL

\* Any risk refers to the average risk population (under age 35) and high risk population (over age 35). The Harmony test has been studied in women ages 18-48. Pregnancies with more than two fetuses, a history of vanishing twin, maternal organ transplant or maternal aneuploidy are not eligible for the Harmony test.

1. Demonstrated by 48 peer-reviewed published studies using the Harmony prenatal test as of Jan 2018. For the entire 48 references, please go to [harmonytest.com/references](http://harmonytest.com/references)
2. Data on file.
3. Norton EM *et al.* N Engl J Med. 2015 Apr 23;372(17):1589-97.
4. Wax *et al.* J Clin Ultrasound. 2015 Jan;43(1):1-6.
5. ACOG Practice Bulletin 163 Obstet Gynecol. 2016 May;127(5):e123-37.
6. The California Prenatal Screening Program. March 2009. Provider Handbook 2009.

## PRENATAL TEST

harmony  
PRENATAL TEST

**For You**  
it's a highly accurate and proven screening test<sup>1</sup>.

Clear answers to questions that matter.

# Clear answers to questions that matter

Clear answers are everything when you're pregnant, especially when it comes to your baby.

You want the best information, so you can make plans and have peace of mind for the months ahead.

**The Harmony test is the most proven brand of noninvasive prenatal test (NIPT) available.<sup>1</sup> It has been used in more than 1 million pregnancies worldwide.<sup>2</sup>**



## What is the Harmony prenatal test?

Harmony is a safe blood test that screens for specific chromosome conditions in a pregnancy as early as 10 weeks gestation.

When you're pregnant, your blood contains tiny amounts of your baby's DNA. The Harmony prenatal test looks at this DNA to provide accurate information about the likelihood for the most common chromosome conditions such as Down syndrome (trisomy 21), Edwards syndrome (trisomy 18), and Patau syndrome (trisomy 13).

## What else can the Harmony test do?

In addition to screening for the conditions listed above, you and your healthcare provider can talk about which of the following additional options might make sense for your pregnancy.

- Fetal sex – So you know whether your baby is male or female (also available with twins)
- Monosomy X – Also called Turner syndrome, a condition where a female is missing an X chromosome, and as a result, may have heart, endocrine, and learning problems
- Sex Chromosome Aneuploidy – Differences in the number of X and Y chromosomes which can result in certain learning and/or behavioral challenges in addition to other health issues

## Who should have this screening?

The Royal College of Obstetricians and Gynaecologists welcome the news that non-invasive prenatal testing has been recommended for high-chance women on the NHS and states that it reduces unnecessary invasive procedures.<sup>5</sup>

Down syndrome does not typically run in families and can happen in any pregnancy. Although the chance of having a baby with Down syndrome increases with age, most babies with Down syndrome are born to women under 35.<sup>6</sup>

## HARMONY VERSUS TRADITIONAL TESTS FOR DOWN SYNDROME<sup>3</sup>

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

<sup>\*</sup> Correctly indicates a high risk for Down syndrome when it IS present

<sup>\*\*</sup> Reports a high risk for Down syndrome when it is NOT actually present

## Why choose the Harmony test?

The Harmony prenatal test is better at identifying Down syndrome with fewer false positives than traditional screening tests for women of any age or risk.<sup>13</sup>

## Does a low risk result mean that the baby does not have Down Syndrome?

No, any screening test carries a risk of a 'false negative' however the risk of this happening with the Harmony is much lower than with conventional Down screening.

## If I have a high risk result does that mean that the baby's chromosomes are abnormal?

No, not necessarily. It means that there is a higher risk and you will be offered the option of amniocentesis to assess the chromosomes directly. You will be offered support and counselling to help you reach that decision.

## What if I have twins?

The Harmony Non Invasive Prenatal Test and technology can also be applied to twin pregnancies but is not suitable in the case of a vanishing twin.

## Will I always get a result?

3 out of 100 women will require a repeat test. When the test is repeated, we receive a result in approximately two thirds of these samples. Patients will not be charged if we are unable to obtain a result.

## Is this test available through the NHS?

Please refer to your healthcare provider for information about the price of this test and how you may need to pay for it. Samples will be processed at TDL Genetics in London, UK. This service is confidential and every effort has been made to ensure your personal information is held securely.

**FOR MORE**  
information, visit [www.harmonytest.co.uk](http://www.harmonytest.co.uk)

