Introduction

During your pregnancy, your healthcare consultant will offer various tests to help you assess your health

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

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.

What is Harmony?

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

Harmony Prenatal Test is a new type of 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 all women

Traditional screening tests can miss as many as 15% of Down syndrome cases in pregnant women.[1]

Harmony was developed to be a more accurate prenatal Down syndrome screening test for all women, regardless of age or risk. It is a new DNA-based blood test that has been extensively tested in pregnant women both over and under 35.[1,2]

A more accurate test

Conventional screening will detect approximately 70-80% of pregnancies with Down syndrome.

The Harmony test will detect over 99%.

Harmony has a false positive rate of less than 0.1% compared to 5% with conventional screening.

This means that Harmony test detects more pregnancies with Down syndrome but also reduces the risk of unnecessary amniocentesis.

Clarity early

Harmony Prenatal Test requires a single blood sample from your arm and can be done as early as 10 weeks or later in pregnancy. Results are usually available within a week. Other commonly used tests for Down syndrome are performed later in pregnancy and require multiple clinic visits.

Minimises need for follow-up tests

The greater accuracy and low false-positive rate of Harmony compared to the traditional tests minimises the number of high risk results. Therefore fewer women will need follow up testing using an invasive procedure, such as amniocentesis.

Fetal sex chromosomes

Harmony Prenatal Test can also be used to evaluate X and Y sex chromosomes as early as 10 weeks.[3,4]

You have the option to test for conditions caused by having an extra or missing copy of the X or Y chromosomes, including Turner and Klinefelter syndromes (This is only available for singleton pregnancies).

Harmony versus Traditional Down Syndrome Tests[1]

	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 ß-hCG & Nuchal Translucency

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.
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.