Harmony™ Prenatal Test delivers unsurpassed accuracy when compared to any other trisomy 21 blood test.

Unsurpassed accuracy

Harmony™ Prenatal Test is clinically validated for use in women of any age or risk category

Harmony™ Prenatal Test is validated in women of all ages

A recently published prospective 15,141 patient comparison, Risk Triage Combined Screening (FTS) with Harmony™ Prenatal Test is a general pregnancy population.**

The Harmony™ Prenatal Test test accuracy assessed at 36-10 weeks’ gestation at a cut-off 

The amount of fetal DNA in maternal plasma is too low prior to 10 weeks.

For further information, including examples of test reports, please refer to our website, www.sonicgenetics.com.au or call us on 1800 010 447.

The test can only be performed after 10 weeks’ gestation, and then at any time up to term. This test has not been validated at earlier gestations, as the concentration of fetal DNA in maternal plasma is too low prior to 10 weeks.

The test is only available at specific collection centres, and can sometimes only perform on specific days (please call either 1800 010 447 or 02) 4956 4040 for availability.

The difference in performance is clear

A study of 12,891 prospectively enrolled 1,741 patient comparison, Risk Triage Combined Screening (FTS) with Harmony™ Prenatal Test is a general pregnancy population.**

The Harmony™ Prenatal Test test accuracy assessed at 36-10 weeks’ gestation at a cut-off 34 out of 38 with FTS*. The difference in performance is clear

The quality and reliability of the Harmony™ Prenatal Test has been documented in more than 500,000 patient samples through the Ariosa international sites.

The HARMONY™ Prenatal Test in a prospective blinded cohort of more than 15,000 pregnant women of various ages and risk across multiple international sites.

FTS* produced 5.4% (n=854) false-positives, compared 0.06% (n=9) false-positives for trisomy 21 cases, versus 30 out of 38 with FTS*.

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How long does the test take?

We aim to provide you with the test result within 5–10 business days. On rare occasions, the NIPT test is unable to provide results.

Payment is required in advance. In the rare circumstance that a sample is required, the repeat test is performed at no additional cost.

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What does the test cost?

NIPT is currently not covered by Medicare or covered by private health insurance.

Please view noninvasivediagnostic.com.au to find out the current price or call us on either 1800 010 447 or 02) 4956 4040.

The Harmony™ Prenatal Test evaluates the risk for trisomies 21, 18 and 13 in women of any age or risk category

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What is NIPT?
NIPT is a non-invasive screening test for common chromosomal abnormalities. It is more accurate than most other screening tests for detecting Down syndrome, Edwards syndrome (trisomy 18) and Patau syndrome (trisomy 13). NIPT is primarily designed to screen for the common trisomies (21, 18 and 13) and sex chromosomal abnormalities. In addition, the presence of Y chromosome and abnormalities in the number of X chromosomes can be tested for using the Harmony™ Prenatal Test for NIPT. Sonic Genetics recommends the Harmony™ Prenatal Test for NIPT.

What does NIPT screen for?
NIPT is designed to screen for chromosomal abnormalities. It is not a diagnostic test. Abnormal results should be confirmed by invasive testing before making any important clinical decisions, e.g. termination of pregnancy. An unplanned normal result, e.g. a Down syndrome screen, may also warrant invasive testing.

How does NIPT work?
NIPT involves testing a small fragment of DNA in maternal plasma. Some of these fragments may have come from the placenta. NIPT involves testing millions of short fragments of DNA in maternal plasma. Some of these fragments will have come from the placenta, whilst others may have come from the fetal cells, with the proportion of fetal fragments varying with the prior risk that the woman has an affected fetus. This proportion is used to calculate the risk of an affected fetus.

NIPT is more accurate than conventional first trimester screening. In over 99.5% of normal fetuses, NIPT is a very good screening test, but it is not perfect. Abnormal results should be confirmed by invasive testing before acting on that result. Invasive testing is not always necessary. This leaflet provides a brief overview of these issues. More detailed information can be found in the Sonic Genetics leaflet which patients receive when the test is ordered.

Can NIPT be used for twins pregnancies?
NIPT can be used for women who are pregnant with twin pregnancies. In this case, the woman will receive one result for each twin, with the proportion of fetal DNA from each twin being calculated. This may apply to an older woman, or a woman with an increased risk result from conventional first trimester screening. In a twin pregnancy, the accuracy of NIPT to correctly identify a normal fetus is the main clinical benefit of NIPT. It is likely but not definite that the result is correct, and that the fetus does not have any of the chromosomal abnormalities tested. This is because the result of the twin is not independent of the result of the other twin.

How does NIPT work?

What is Not Included in the NIPT test?
NIPT does not detect every genetic abnormality in the fetus, or every developmental problem that might occur during pregnancy. It will detect the following conditions.

• Less common or ‘atypical’ chromosomal abnormalities. These may include 45,X, 47,XXX, 47,XXY and 47,XY, or abnormal numbers of sex chromosomes. These abnormalities are often clinically milder than other chromosomal abnormalities. Testing for sex chromosomal abnormalities will also reveal the fetal gender. It is important to note that chromosomal abnormalities are very unlikely in the absence of the chromosomal abnormalities that we test for. NIPT is also being extended to detect small deletions in specific areas of certain chromosomes (microdeletions) to increase the number of conditions detected. It has also reduced accuracy.

Can NIPT be used for women who are at high risk of having a chromosomal abnormality?

NIPT is highly likely that the result is correct, and that the fetus does not have any of the chromosomal abnormalities tested. NIPT is a powerful investigation that carries major clinical implications for the mother and baby. Please contact us on either 1800 310 413 or info@sonicgeneticsnipt.com.au if you require further information.

How should the NIPT result be interpreted?
The accuracy of NIPT varies with the prior risk that the woman has an affected fetus. Three general scenarios are considered below.

Key Points

• NIPT is a non-invasive screening test: it is not a diagnostic test. Abnormal or unexpected results should be reviewed carefully with diagnostic invasive testing of the fetus performed before changing the management of the pregnancy.
• NIPT is primarily designed to screen for the common trisomies of 21, 18 and 13 and sex chromosomal abnormalities.
• NIPT does not detect screen for all chromosomal abnormalities (numerical or structural) or for abnormalities of the placenta, although it does not screen for other genetic disorders or birth defects.
• NIPT is not related to Medicaid or by private health insurance. Please visit www.sonicgeneticsnipt.com.au to find out all the costs or call us on either 1800 310 413 or 040 085 5300.

Before undergoing NIPT, please ensure that adequate genetic counselling has been provided. A negative NIPT result from conventional first trimester screening does not generally warrant or exclude further invasive testing, e.g. amniocentesis or chorionic villus sampling. This is because the result of the twin is not independent of the result of the other twin. It is not uncommon for NIPT to be normal for one twin but abnormal for the other twin.

References

Estimate based on an average-risk population with prevalence for T21, T18, and T13 of 1 in 700, 1 in 5000, and 1 in 16000 respectively.