



Non-invasive Prenatal Test | Request Form

FOR THE DOCTOR

This test should be requested by the doctor responsible for medical management of non-invasive prenatal testing.

Patient details

First name _____ Surname _____
 Date of birth ____ / ____ / ____ Sex **Female - Pregnant**
 Address _____

 Phone (mobile) _____

Test/s requested

	SINGLETON	TWIN
Harmony Prenatal Test T21, T18, T13	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes
OPTIONS		
Fetal sex* (no charge)	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes
Monosomy X (no charge)	<input type="checkbox"/> Yes	N/A
Sex chromosome aneuploidy (no charge)	<input type="checkbox"/> Yes	N/A
22q11.2 deletion (additional charge)	<input type="checkbox"/> Yes	N/A

*Based on the presence or absence of the Y chromosome. For twin pregnancies this could indicate either two females (if absent) or at least one male.

Is this a RE-COLLECTION? Previous Lab ID _____

Staff ID/Location	<input type="checkbox"/> 2 x NIPT tube	Date re-collected / /	Time re-collected :	Re-collect PAY CAT SGUN
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Clinical information **REQUIRED**

ALL fields must be completed for testing to proceed.

Please note: Requested clinical information is essential for test accuracy. If any of the clinical information you provide below changes, please notify the laboratory immediately as this information is included in the test algorithm.

GESTATIONAL INFORMATION

LMP EDC ____ / ____ / ____ (date)

CONCEPTION DETAILS

Natural IVF (Patient egg) | Maternal age at egg retrieval ____ yrs
 IVF (Donor egg) | Maternal age at egg retrieval ____ yrs

MATERNAL INFORMATION

Maternal weight (kg) _____ Maternal height (cm) _____

Samples taken at less than 10 weeks' gestation will not be processed.

Harmony Prenatal Test is not validated:

- For three or more fetuses, or in the presence of a demised fetus
- If the maternal age is less than 18 at EDC
- In the presence of maternal aneuploidy, maternal transplant or maternal malignancy

NIPT is not a test of fetal viability and it may provide a valid result despite fetal demise.

22q11.2 may be added as an extra test, for an additional fee, within 14 days of the trisomy report. Specific exclusions are detailed at www.sonicgenetics.com.au. Please note that the requested clinical information is essential for test accuracy.

Requesting doctor

Name _____
 Address _____

 Phone _____ Provider No _____
 I confirm that this patient has been counselled about the purpose, scope and limitations of the test and has given consent.

Signature **DOCTOR SIGNATURE** Date _____

Copy reports to

Name _____
 Address _____

FOR THE PATIENT - Patient Consent

I consent to the Harmony Prenatal Test being performed and confirm that I have been informed about the purpose, scope and limitations of the test. Sources of information that I can access include my doctor, the Sonic Genetics website and brochures, a genetic counsellor and the reverse of this request form. I have had the opportunity to ask questions and understand that I can request further information or genetic counselling before or after the test.

I understand that the test is a screen for an extra copy of chromosomes 21, 18 and 13, that the test can also optionally identify fetal sex, screen for microdeletions of 22q11.2 and changes in the number of sex chromosomes, that the result should be reviewed by my doctor in the light of other findings, that a 'high probability' result should be confirmed by fetal karyotype, that a second collection may be required, and that 1-2% of tests do not yield a result due to biological factors. Should there be no result for chromosomes 21, 18, and 13, plus 22q11.2 if requested, a refund is available.

I consent to my result being used with Government birth records solely to audit the Harmony test, and understand that I would not be identified in reports of such audits.

Tick here if you do not consent to releasing your result for audit purposes.

Signature **PATIENT SIGNATURE** Date _____

Patient sample collection and payment

Full payment is required prior to sample collection and Medicare benefits do not apply. To finalise the order of your Harmony test, please visit www.sonicgenetics.com.au/payment. Alternatively, you may call us on 1800 010 447 to pay and book for your test. You will then receive an email and SMS confirmation of your booking.

Please make sure to bring this request form and booking confirmation with you on the day. Please record your payment receipt number here: _____

FOR THE COLLECTOR

I certify I established the identity of the patient named on this request, collected and immediately labelled the accompanying specimen(s) with the patient's name, DOB and date/time of collection.

Collector's name: _____

Signature **COLLECTOR SIGNATURE** Date _____

Staff ID/Location code Collection type (stamp)	<input type="checkbox"/> 2 x NIPT tube Date collected / / Time collected :	PAY CAT SGU
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Non-invasive Prenatal Test

Information for patients

Purpose

The primary purpose of the Harmony Prenatal Test is to screen for common chromosome disorders which can affect the health of a baby, i.e. Down syndrome (trisomy 21), Edwards syndrome (trisomy 18), and Patau syndrome (trisomy 13), plus microdeletions of chromosome 22, if requested (22q11.2). The Harmony Prenatal Test can also screen for common disorders of the sex chromosomes, i.e. Turner syndrome (45,X), Klinefelter syndrome (47,XXY), Triple X syndrome (XXX) and Jacobs syndrome (47,XYY) in singleton pregnancies. The Harmony Prenatal Test is not primarily intended as a test of fetal sex.

Limitations

There are rare occasions in which an NIPT result is incorrect. All NIPTs rely on fragments of DNA found in the mother's bloodstream; these fragments come from the placenta. On rare occasions, the DNA status of the placenta may not be the same as that of the fetus and, as a result, the NIPT result may not reflect the actual situation in the developing baby. In the case of fetal demise, NIPT may still provide a valid result based on analysis of residual fetal DNA. An ultrasound scan prior to NIPT is recommended to confirm viability, number of fetuses and gestation. For these reasons, an NIPT result should be carefully reviewed by your doctor, together with other information about your pregnancy before basing any decision on that result. Please also note that NIPT is a test for the conditions noted above; it is not a test for every possible fetal disorder. These considerations apply to any form of NIPT; they are not specific to the Harmony Prenatal Test.

Fetal fraction

The quantity of fetal (placental) DNA circulating in the mother's bloodstream is known as the fetal fraction. During the first 10 weeks of pregnancy, the fetal fraction is too low for NIPT to be reliable. The Harmony Prenatal Test has been developed and tested on patients at greater than 10 weeks' gestation. For these reasons, **we do not offer the Harmony Prenatal Test before 10 weeks' completed gestation**. Numerous factors, including high maternal weight, can lower the fetal fraction, even after the 10th week of pregnancy. The Harmony Prenatal Test also measures the fetal fraction in your blood sample, and will not provide a result unless there is sufficient fetal DNA to provide a reliable result for trisomy 13, 18 or 21, or 22q11.2 deletion, if requested. In this situation, we will not assume that your test result is normal, and you may be offered a repeat test (once) at no additional charge; if the second collection is also unreportable, we will refund the cost of your test on request.

Fetal sex and sex chromosomes

For biological reasons, it is more difficult to count the numbers of sex chromosomes (X and Y) than other chromosomes. We do not routinely report fetal sex or analysis of sex chromosomes, but will do so at no additional charge on request. Please note that the request should be made by your doctor on the initial request form. Analysis of sex chromosomes is only available for singleton pregnancies.

In less than 1% of samples, a definite result can be provided regarding the chance of trisomy 13, 18 or 21 (and 22q11.2 deletion, if requested) but not for fetal sex or sex chromosome disorders (or both). The fetal fraction in these samples is often at the low end of the acceptable range. Other factors may also make it difficult to provide accurate sex chromosome analysis, including poor quality of DNA in the sample, uncommon normal variations in the sex chromosomes, and a mixture of normal and abnormal cells in the placenta or mother. In these situations, we will report that a result is not possible for fetal sex or screening for a sex chromosome abnormality. We do not recommend repeat testing as the biological factors responsible for the lack of a result are unlikely to have changed. We do not offer a refund, as the primary purpose of the Harmony Prenatal Test (screening for trisomy 13, 18 or 21, plus 22q11.2 deletion, if requested) has been achieved.

Genetic counselling

Various forms of prenatal screening tests have been available in Australia for more than 30 years. Your doctor will be able to provide you with information and advice regarding this test, and can help you decide if this is the right test for you. Your doctor may also recommend that you seek genetic counselling before or after the test; we can provide contact details for genetic counselling services nationally.

If you have a result indicating a high chance of a chromosome condition, a genetic counselling consultation by telephone is available through Sonic Genetics at no charge. This must be requested by your doctor, and is only available to women who have paid Sonic Genetics directly for their test.

If you have any questions regarding your test result, we recommend that you discuss these with your doctor or genetic counsellor. Your doctor will know your situation and have the results of other tests and assessments. Your doctor can also contact our senior scientists and genetic pathologists to discuss technical aspects of your result.

Results

Your results will be delivered to your doctor typically within 5-8 business days.

Sonic Genetics

We are part of Sonic Healthcare which is Australia's largest pathology provider and the third largest pathology provider in the world. We employ highly qualified genetic pathologists, genetic scientists and molecular biologists and operate out of fully accredited laboratories throughout Australia, using state-of-the-art equipment. The laboratory performing the test in Australia has achieved NATA accreditation specifically for the Harmony Prenatal Test.