PathWest LABORATORY MEDICINE WA

harmony® PRENATAL TEST

Sonic Genetics
Clinipath Pathology

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

- ☐ Harmony Prenatal Test T21, T18, T13
- ☐ Harmony Prenatal Test T21, T18, T13 + 22q11.2 (additional charge)

Optional tests (no additional charge)

- ☐ Fetal sex (based on presence or absence of Y chromosome)
- ☐ Monosomy X
- ☐ Sex chromosome aneuploidy panel

TWIN

- ☐ Harmony Prenatal Test T21, T18, T13

Optional tests (no additional charge)

- ☐ Fetal sex (can indicate either two females or at least one male)

Is this a ☐ **RE-COLLECTION?** Previous Lab ID _____

Staff ID/Location	☐ 2 x NIPT tube	Date re-collected / /	Time re-collected :	Re-collect PAY CAT **SGUN**

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 AGE

Either Weeks ____ Days ____ as at ___/___/___ (date)

or ☐ LMP ☐ EDC ☐ IVF ___/___/___ (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) _____

Harmony Prenatal Test is not validated for three or more fetuses, or in the presence of a demised fetus. The Harmony Prenatal Test examines for certain aneuploidies in viable singleton and twin pregnancies by natural or IVF conception after 10 weeks' gestation.

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

Collection appointment 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)	☐ 2 x NIPT tube	PAY CAT
	Date collected / /	**SGU**
	Time collected :	

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Non-invasive Prenatal Test

Information for patients

Purpose

The primary purpose of Harmony 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). Harmony 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. Harmony 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. For that reason, 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 Harmony.

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. For this reason, we do not offer Harmony before 10 weeks' completed gestation. Numerous factors, including high maternal weight, can lower the fetal fraction, even after the 10th week of pregnancy. Harmony 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 and 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 Harmony (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 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.