Sonic Genetics
Clinpath Laboratories

SPECIALIST IMAGING PARTNERS

harmony™ PRENATAL TEST
performed in Australia

Laboratory number

LABORATORY COPY

Non-Invasive Prenatal Test | Request Form

Patient details

Name: _____

Date of birth: ____ / ____ / ____ Gender: **Female – Pregnant**

Address: _____

_____

Phone (home): _____ Phone (mobile): _____

Tests requested

Harmony™ Prenatal Test – T21, T18, T13 ☑

Options (Please ✔ any additional test options requested)	SINGLETON	TWINS
Fetal gender	☐	☐
Monosomy X	☐	N/A
Sex chromosomes aneuploidy panel	☐	N/A

MATERNAL INFORMATION

Maternal weight (kg) _____

Maternal height (cm) _____

NO. OF FETUSES *(please specify)*

☐ Singleton
☐ Twins

CONCEPTION

☐ Natural (or donor semen)

☐ IVF with:
- ☐ Patient's egg
- ☐ Donor egg

Age at retrieval ____ (yrs)

WHAT IS THE GESTATIONAL AGE?

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

or specify: ☐ LMP ☐ EDC ☐ IVF ____ / ____ / ____ (date)

CLINICAL NOTES

☐ **RECOLLECTION**

Lab ID _____

Patient information

This test must be pre-booked and pre-paid

Non-invasive prenatal testing (NIPT) is a specialist service that requires a pre-booked collection appointment so that we can ensure the best test outcomes. To finalise the order of your non-invasive prenatal test, please visit **www.sonicgeneticsnipt.com.au/locations** to find a suitable collection location, and then contact us on **(08) 8366 2000** to complete your booking and online payment. You will need to have this form and credit card details at hand.
Medicare benefits do not apply.

Alternatively, if you wish to have your blood test at Specialist Imaging Partners please contact:

SPECIALIST IMAGING PARTNERS

SPECIALIST IMAGING PARTNERS
LEVEL 2, 77 KING WILLIAM ROAD, NORTH ADELAIDE 5006
P 8361 6836 F 8361 6834
E admin@specialistimaging.com.au
www.specialistimaging.com.au

DATE_____/_____/_____ **TIME**_____

please take this form with you when attending your collection appointment

Patient consent

I consent to the Harmony Prenatal Test being performed and confirm that I have been informed about the purpose, scope, and performance of the test by my doctor, patient literature, and/or the Sonic Genetics website. I understand that the test is a screen for selected abnormalities of chromosomes 21, 18, and 13; that the test can also screen for less serious selected abnormalities of the sex chromosomes, and identify fetal gender; that the result should be reviewed by my doctor in the light of other findings; that a 'high risk' 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 (with prepaid tests for chromosomes 21, 18, and 13 being refunded). I have had the opportunity to ask questions and understand that I can request further information or genetic counselling.

I consent to my identified 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 [delete this sentence if you do NOT consent to releasing your result for audit purposes].

Signature ✘ PATIENT SIGNATURE Date

Requesting doctor

Name: _____

Address: _____

_____

Provider number: _____

REQUESTING DOCTOR'S SIGNATURE AND REQUEST DATE

Signature ✘ DOCTOR SIGNATURE Date

Copy reports to

Name: _____

Address: _____

_____

Collector details

PERSON COLLECTING SPECIMEN(S) TO COMPLETE

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 details.

Name: _____

Signature ✘ COLLECTOR SIGNATURE Date

Staff ID/Location code/Collection type (stamp)	Dedicated NIPT tube	
	Pay cat	
	Date collected / /	Time collected :

Harmony™ Prenatal Test is not validated for 3 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. Specific exclusions are detailed at www.sonicgenetics.com.au. Please note that the requested clinical information is essential for test accuracy.

PRIVACY NOTE The information provided will be used to assess any Medicare benefit payable for the services rendered and to facilitate the proper administration of government health programs, and may be used to update enrolment records. Its collection is authorised by provisions of the Health Insurance Act 1973. The information may be disclosed to the Department of Health and Ageing or to a person in the medical practice associated with this claim, or as authorised/required by law.

SONIC HEALTHCARE GENETICS PTY LTD, ABN 98 100 145 748, a subsidiary of Sonic Healthcare Limited APA ABN 24 004 196 909, 14 Giffnock Ave, Macquarie Park NSW 2113.

OCTOBER 2015

harmony™
PRENATAL TEST

Performed in Australia

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www.specialistimaging.com.au

Patient Informed Consent

The Harmony Prenatal Test and the available test options are laboratory-developed screening tests that analyze cell-free DNA (cfDNA) in maternal blood.
The tests aid in the risk determination of fetal chromosomal or genetic conditions, and fetal sex determination, if selected. In some cases, follow up comfirmatory testing based on these test results could uncover maternal chromosomal or genetic conditions.

For a full test description of the Harmony Prenatal Test and available test options, please visit: **www.harmonytest.com**

Who is eligible for the Harmony Prenatal Test?

Patients must be at least 10 weeks gestational age for any of the Harmony Test offerings. Patients who have received bone marrow or organ transplants, or those who have metastatic cancer are not eligible for the Harmony Prenatal Test. Please see below for additional eligibility criteria:

	Harmony (Trisomy 21, 18, 13) with or without Fetal Sex Option	Harmony with Sex Chromosome Aneuploidy Panel or Monomosy X
Singleton Pregnancies including IVF	✓	✓
Twin Pregnancies including IVF	✓	Not eligible
More than 2 fetuses	Not eligible	Not eligible

What are the limitations of the Harmony Prenatal Test?

The Harmony Prenatal Test is not intended nor validated for diagnosis or detection of mosaicism, partial trisomy or translocations. Certain rare biological conditions may also affect the accuracy of the test. Limited numbers of aneuploidy twin and egg donor pregnancies have been evaluated because these conditions are rare. Results for twin pregnancies reflect the probability that the pregnancy involves at least one affected fetus. For twin pregnancies, male results apply to one or both fetuses and female results apply to both fetuses.

Not all Trisomy fetuses will be detected. Some trisomy fetuses may have LOW RISK results. Some non-trisomy fetuses may have HIGH RISK results. False negative and false positive results are possible. A LOW RISK result does not guarantee an unaffected pregnancy due to the screening limitations of the test. Harmony provides a risk assessment, not a diagnosis, and results should be considered in the context of other clinical criteria. It is recommended that a HIGH RISK result and / or other clinical indications of a chromosomal abnormality should be confirmed through fetal karyotype analysis such as amniocentesis. It is recommended that results be communicated in a setting designed by your healthcare provider that includes appropriate counselling.

TO BOOK YOUR HARMONY BLOOD TEST APPOINTMENT WITH OR WITHOUT ULTRASOUND PLEASE CONTACT:

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