HARMONY NIPT REQUEST FORM

harmony® PRENATAL TEST
performed in Australia

Place barcode ID here

AUSTRALIAN Clinicallabs
www.clinicallabs.com.au
VIC NSW SA NT 1300 453 688 | Western Australia 1300 367 674

Patient Information

Patient Name (Surname, Given)

Date of Birth / / Please format DD / MM / YY

Address

City

State Post Code

Phone Medicare Number

Weight (kg) Height (m)

Patient Signature for Informed Consent

My signature on this form indicates that I have read, or had read to me, the informed consent on the back of this form. I understand the informed consent and give permission to Australian Clinical Labs to perform the laboratory Non-Invasive Prenatal Screening tests selected. I have had the opportunity to ask questions and discuss the capabilities, limitations, and possible risks of the test(s) with my healthcare provider or someone my healthcare provider has designated. I have been informed that 1-2% of tests do not yield a result due to biological factors; and that a second collection maybe required. I know that if I wish, I may obtain professional genetic counselling before signing this consent.

Patient Signature X

Date / / Please format DD / MM / YY

Billing Information MANDATORY

Please tick one: ☐ Cheque ☐ VISA ☐ Mastercard ☐ Money Order
☐ Commercial Client (Biller Code _____)
☐ Pay over phone (call centre) Receipt # _____

For Cheques and Money Orders, please make payable to Australian Clinical Labs

Patient relationship to person paying for test: ☐ Self ☐ Spouse ☐ Other

Please bill my credit card for $ _____

Card Number _____

Exipry Date _____/_____ Please format MM / YY

Cardhold Name (please print) _____

Cardholder Signature X _____

*additional charge applies for 22q11.2

Clinic Information

Referring Clinician

Address

City

State Post Code

Phone

Fax

Clinician Signature

I attest that my patient has been fully informed about details, capabilities, and limitations of the test(s). The patient has given full consent for this test.

Clinician Signature X

Date / / Please format DD / MM / YY

Clinical Information MANDATORY

Gestational Age:

_____ weeks _____ days measured on _____ / _____ / _____ (DD / MM / YY)

☐ LMP ☐ EDD ☐ IVF _____ / _____ / _____ (DD / MM / YY)

Number of Fetuses ☐ 1 ☐ 2

Conception information:

☐ Natural

☐ IVF (Patient Egg) | Age at egg retrieval: _____ Years

☐ IVF (Donor Egg) | Age at egg retrieval: _____ Years

Test Menu Options

☐ Harmony Prenatal Test (T21, T18, T13)

Optional Add On Tests - Please mark any additional test options requested:

☐ Fetal Sex **
☐ Monosomy X [1,2] **
☐ Sex Chromosome Aneuploidy Panel [1,2] **
☐ 22q11.2 [1] *(additional cost applicable)

[1] Singletons only [2] Fetal sex not reported **no extra charge

Important Blood Draw Information

Write the patient's full name and date of birth on tube barcodes.
Name, barcode, and date of birth must match the TRF.
Place labels lengthwise on the blood tubes as shown in the example.

Is this a recollect? ☐ Yes ☐ No

If yes, please collect a gel tube as well as 2 x Harmony tubes if patient is <14 weeks

Time of collection: _____ Collection Date: _____ / _____ / _____ (DD / MM / YY)

Collector Name (please print): _____

Collector Signature: X _____

Patient Informed Consent

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

Results from the Harmony Prenatal Test should be communicated in a setting designated by your healthcare provider that includes the availability of appropriate genetic counselling.

Who is eligible for the Harmony Prenatal Test?

Patients must be of 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. Patients who have been identified as having a pregnancy with a demised twin are not eligible for testing.

Please see below for additional eligibility criteria:

	Harmony (Trisomy 21, 18,13) with or without Fetal Sex Option	Harmony with Sex Chromosome Aneuploidy Panel, Monosomy X or 22q11.2
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 PROBABILITY results. Some non-trisomy fetuses may have HIGH PROBABILITY results. False negative and false positive results are possible. A LOW PROBABILITY result does not guarantee an unaffected pregnancy due to the screening limitations of the test. Harmony provides a probability assessment, not a diagnosis, and results should be considered in the context of other clinical criteria. It is recommended that a HIGH PROBABILITY result and/or other clinical indications of a chromosomal abnormality be confirmed through fetal karyotype analysis such as amniocentesis. It is recommended that results be communicated in a setting designated by your healthcare provider that includes appropriate counselling.

What are the limitations of the Harmony Prenatal Test for 22q11.2?

In addition to the limitations discussed above, the 22q11.2 option is not validated for use in pregnancies with more than one fetus or for women with a 22q11.2 duplication or deletion.

A 22q11.2 deletion may not be detected in all affected fetuses. Due to the limitations of the test, a NO EVIDENCE OF A DELETION OBSERVED result does not guarantee that a fetus is unaffected by a chromosomal or genetic condition . Some fetuses with a 22q11.2 deletion may receive a test result of NO EVIDENCE OF A DELETION OBSERVED. Some fetuses without the 22q11.2 deletion may receive a test result of HIGH PROBABILITY OF A DELETION. In cases of HIGH PROBABILITY results and/or other clinical indications of a chromosomal condition, confirmatory testing is necessary for diagnosis.

What is done with my sample after testing is complete?

No additional clinical testing will be performed on your blood sample other than those authorised by your healthcare provider. Australian Clinical Labs will disclose the test results only to the healthcare provider(s) listed on the front of this form, or to his or her agent, unless otherwise authorised by you or as required by laws, regulations, or judicial order.

Payment / Billing Information

In some infrequent cases, it will not be possible to generate a Harmony Prenatal Test result. Should this occur you may choose to provide a new blood sample for testing. No additional fees will be incurred for the second test. In the event that you decide not to submit an additional sample for testing, Australian Clinical Labs will refund the full test fee paid.

Results will be made available to you through your nominated doctor. In the event that you are found to have a high probability for one of the chromosome conditions tested for, details of a nominated genetic counselling service will be provided to your doctor. You or your doctor may contact the genetic counselling service to discuss your results.

Collections Centres

For a current list of centres, please visit our website **www.clinicallabs.com.au** or contact us on **1300 453 688 (VIC, NSW, SA & NT)** or on **1300 367 674 (WA only)**.

All of our collection centres across **Victoria, New South Wales** and **Western Australia** collect for the Harmony Prenatal Test.

Collection centres in **South Australia** and **Northern Territory** require appointments for the Harmony Prenatal Test. Please visit our website or contact us on **1300 453 688** to find your nearest collection centre and book an appointment.

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Roche

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