

Harmony NIPT Request Form

Patient Information	
Patient Name (Surname, Given)	
Date of Birth / / <small>Please format DD / MM / YY</small>	
Address	
City	
State	Post Code
Phone	

Patient Signature for Informed Consent	
<p>My signature on this form indicates that I have read, or had read to me, the informed consent and the limitations of this test 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. In the rare circumstance that Australian Clinical Labs is unable to perform the test, I give permission to Ariosa Diagnostics to perform the Harmony Prenatal Test. 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 may be required. I know that if I wish, I may obtain professional genetic counselling before signing this consent. I will follow the refund or repeat testing policy of Clinical Labs and understand that test results can be delayed in unusual circumstances.</p>	
Patient Signature	
Date / / <small>Please format DD / MM / YY</small>	

Test Menu Options	MANDATORY
<input type="checkbox"/> Harmony Prenatal Test (T21, T18, T13) <i>(please pay online)</i>	
<input type="checkbox"/> Harmony Prenatal Test (T21, T18, T13) + 22q11.2 ^{1,*} <i>(please pay online)</i>	
Optional Add On Tests - Please mark any additional test options requested:	
<input type="checkbox"/> Fetal Sex ^{**}	<input type="checkbox"/> Monosomy X ^{1,2,**}
<input type="checkbox"/> Sex Chromosome Aneuploidy Panel ^{1,2,**}	
<small>¹ Singletons only ² Fetal sex not reported *Additional charge applies **No extra charge</small>	

Payment Information	MANDATORY
<p>Harmony must be paid prior to your collection. Please scan the QR Code or visit the website link below to pay for your test online.</p>	
	pay.clinicallabs.com.au/harmony

Referring Clinician	
Name	
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	
Date / / <small>Please format DD / MM / YY</small>	

Copy Doctor	
Name	
Address	
City	
State	Post Code
Phone	
Fax	

Clinical Information		MANDATORY
Gestational Age (10 weeks or above):		
<input type="checkbox"/> LMP	DD / MM / YY	
<input type="checkbox"/> EDD	DD / MM / YY	
Number of Fetuses <input type="checkbox"/> 1 <input type="checkbox"/> 2		
Conception information:		
<input type="checkbox"/> Natural		
<input type="checkbox"/> IVF (Patient Egg) Age at egg retrieval: ____ Years		
<input type="checkbox"/> IVF (Donor Egg) Age at egg retrieval: ____ Years		
Maternal information:		
Maternal weight (kg) ____ Maternal height (cm) ____		
History of high probability of chromosomal abnormality: YES / NO		

Important Collector Instructions	
<ul style="list-style-type: none"> Confirm pre-payment prior to collection. Add the Receipt Number to box on right hand side. Invert tube 10 times - do not shake. 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: 	<p>Write patient receipt number in box below</p> <div style="border: 1px dashed orange; padding: 5px; min-height: 40px;">Receipt Number</div>
 <small>Name: Jane Doe, DOB: 1979-04-18</small> Is this a recollect? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>If yes, please collect a gel tube as well as 2x Harmony tubes if patient is <14 weeks</i>	<p>ACC Stamp</p> <p>Time of collection: _____ Collection Date: DD / MM / YY</p> <p>Collector Name (please print): _____</p> <p>Collector Signature: </p>

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. Harmony NIPT has not been validated in demised or vanished twins. False negative or positive results may occur.

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, triploidy, 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. This could be a LOW PROBABILITY result does not guarantee an unaffected pregnancy due to the screening limitations of the test. NIPT screening and confirmatory testing discrepancies are usually due to placental mosaicism. 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 a small percentage of cases, it will not be possible to generate a Harmony Prenatal Test result. If your first test does not produce a result, you will be asked if you would like to provide a new blood sample for testing. If you choose not to proceed, you are entitled to a full refund. If you decide to supply a new sample for testing, there will be no additional cost to you, and it will be covered by your initial payment. If the second sample does not produce a conclusive result, then a cost recovery may be charged to you. This partial refund will be processed automatically upon a second time fail. **Any refund issued by Australian Clinical Labs will be processed within 2-3 weeks back to the credit card used to pay at the initial testing stage.** For pregnant women who still wish to undergo the test for a third time, a full test fee will be incurred, and there will be no entitlement to a refund if the test fails.

Results will be made available to you through your nominated doctor. Genetic counselling will be offered to all women whose test result indicates a pregnancy with high probability of chromosomal abnormality, within 48 business hours. Upon referral from your requesting clinician, an initial telephone consultation with a certified genetic counsellor is available at no additional cost.

Collection Centres

For a current list of centres, please visit our website antenatal.clinicallabs.com.au

All of our collection centres across Victoria, New South Wales, Queensland, South Australia, Western Australia, the Northern Territory and the Australian Capital Territory can collect a blood sample for the Harmony prenatal test. For our collection centres in South Australia and the Northern Territory, we recommend calling ahead.



For frequently asked questions about Harmony NIPT testing, please visit our website antenatal.clinicallabs.com.au/patient/harmony/faq or scan the QR code.

