harmony®

AUSTRALIAN Clinicallabs

Pregnancy Screening

for Chromosomal Abnormalities

Non-invasive prenatal testing for any practice

Clinical Labs is proud to be the exclusive Australian provider of Harmony NIPT, the most accurate non-invasive prenatal test, including 22q11.2 microdeletion.

Patients are asking — and clinicians need to be equipped with the right knowledge

Harmony® is the most broadly studied non-invasive prenatal test (NIPT) for Down syndrome (trisomy 21), Edwards syndrome (trisomy 18) and Patau syndrome (trisomy 13).[1] The Harmony prenatal test uses a proprietary, targeted DNA-based technology to provide you and your patients with a greater level of assurance, simply requiring a maternal blood sample.[2,3,4] Harmony NIPT not only screens for trisomies 21, 18, and 13, but it can also evaluate foetal sex, sex chromosome aneuploidy conditions, and 22q11.2 deletion syndrome.

Actionable results you can trust

Combined first trimester screening (cFTS) can detect 85-90% of pregnancies with trisomy 21 with a false-positive rate of 3-5%. [2] Harmony has been shown in clinical testing to identify greater than 99% of Down syndrome cases and to have a false-positive rate of less than 0.1%.[2,5] Clinicians in more than 100 countries have trusted Harmony.[6] Harmony can be ordered for all naturally conceived or in vitro fertilisation singleton or twin pregnancies, including those with egg donors, although only singleton pregnancies can undergo the sex chromosome aneuploidy and 22q11.2 deletion syndrome analysis. Harmony NIPT is a highly accurate prenatal screening test, not a diagnostic test, so false positive and negative results, although rare, may occur.

Harmony can be ordered from 10 weeks gestation

The Harmony prenatal test is validated for use in women ≥ 18years, suitable for women of any risk category*, available from 10+ weeks gestation, and is performed in-house at Australian Clinical Labs.
Patient's results will be available 5-10 business days from sample receipt at our labs.
To learn more about Harmony, please visit antenatal.clinicallabs.com.au/doctor.

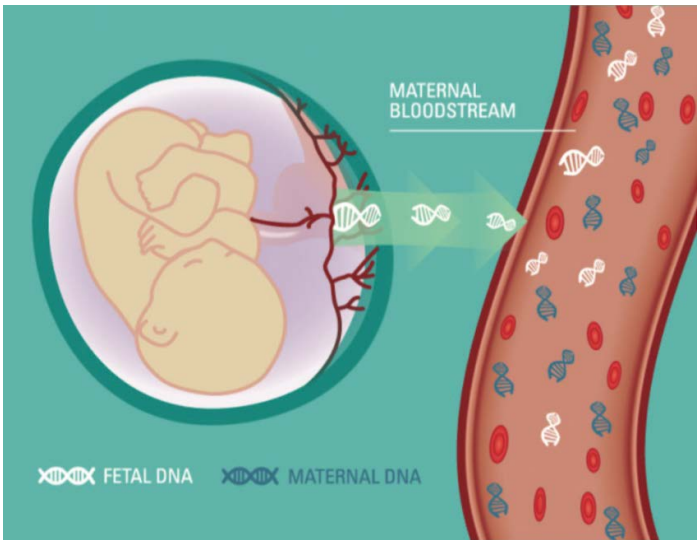
*Any risk refers to the average-risk population (age < 35) and high-risk population (age > 35).

A more accurate test

The Harmony prenatal test uses a proprietary, targeted DNA-based technology to provide accurate results.[3,4] Harmony is not like other trisomy screening tests. Its methodology is different and provides a greater level of assurance for you and your patients.[2,3,4]

NIPT involves testing millions of short fragments of DNA in maternal plasma. Some of these fragments will have come from the placenta, and most will be from the mother.

Using state-of-the-art, cell-free DNA (cfDNA) technology, the Harmony test carries a >99% accuracy rate for Down syndrome with a low false-positive rate of 0.1%.[2] NIPT reduces the need for invasive diagnostic testing and, thus, the risk of procedure-related miscarriage. Compared to conventional screening tests, NIPT is the most accurate and specific screening test with higher detection rates of chromosomal aneuploidies including trisomies 21, 18, and 13.[1,2,5]



What does Harmony NIPT screen for?

Harmony is viewed as a reliable screening test and can be seen as the first universal-tier antenatal screening test for the most common chromosomal conditions, making up approximately 80% of all chromosomal conditions. Please see the table below for a summary of the key abnormalities that are screened by Harmony.

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)recommend that NIPT should be discussed with all pregnant women.[7]

	HARMONY
Down Syndrome (Trisomy 21)	✓
Edwards Syndrome (Trisomy 18)	✓
Patau Syndrome (Trisomy 13)	✓
Klinefelter Syndrome (47,XXY)	✓ OPTIONAL
Turner Syndrome (Monosomy X)	✓ OPTIONAL
Jacob Syndrome (47,XYY)	✓ OPTIONAL
Triple X Syndrome (47,XXX)	✓ OPTIONAL
DiGeorge Syndrome (22q11.2 Deletion)	✓ OPTIONAL

Targeted versus genome-wide non-invasive prenatal testing

By Associate Professor Mirette Saad

This is an abridged version of A/Prof Mirette Saad's article in the March 2021 edition of Pathology Focus Medical Newsletter. To read the full article, visit antenatal.clinicallabs.com.au/doctor/resources.

There are currently two major cfDNA NIPT technologies: "Genome Wide (GW)" and "Targeted" (eg. Harmony) detection methods.

The Harmony targeted cfDNA prenatal screening approach for the common trisomies provides the highest accuracy and sensitivity of this non-invasive screening test with high detection and a very low false-positive rate (<0.1%). The test offers high analysis depth across the clinically relevant chromosome alleles within the targeted region. Therefore, the focused NIPT screening approach reduces unnecessary follow-up invasive diagnostic techniques, which is the main advantage of cfDNA non-invasive screening compared to the conventional combined first trimester screening (cFTS).

There are some points of concern when using Genome Wide NIPT for aneuploidy screening;

Higher false-positive rates: Literature shows that using GW-cfDNA analysis may fail the main goal of a targeted screening method of antenatal screening. Wider, less targeted screening results in increased false-positive findings of rare chromosomal abnormalities, resulting in an increased rate of unnecessary invasive follow-up diagnostic procedures for conditions of unknown significance.

Higher failure rates and turn-around times: While both targeted and GW-cfDNA NIPT methods have overall similar sensitivity, the targeted NIPT test demonstrates a significant lower failure (no call) rate and shorter turn-around time than GW testing.

Guidelines: The HGSA/RANZCOG, along with international guidelines, recommend Down syndrome screening in the first trimester to all pregnant women by either cFTS or cfDNA NIPT, depending on local resources, patient demographics, and individual patient characteristics.

Currently, a broader GW-cfDNA NIPT approach is *not* *recommended by clinical guidelines* and may violate World Health Organization (WHO) screening principles. Updated guidelines by HGSA/RANZCOG 2018, state that *"routine population-based screening for genome-wide chromosome abnormalities are not recommended due to the absence of well-performed clinical validation studies".*

This is due to the uncertainty of the clinical significance of a heterogeneous set of chromosomal abnormalities and how best to manage a positive result. Therefore, follow-up care for positive cases has not been adopted by clinical guidelines.

Targeted NIPT is the preferred patients' choice: Large cohort surveys of pregnant women showed they would prefer the use of targeted over GW NIPT methods. False-positive results are always associated with inevitable anxiety that, in some cases, leads to pregnancy termination even after a normal diagnostic result is received.

References:
- Benn P. Clin Genet. 2016;90:477–485
- Benn et al. Prenat Diagn. 2015;35:725–734
- Benn et al. Ultrasound Obstet Gynecol. 2019;54(4):458-467
- Benn P and Grati F. Ultrasound Obstet Gynecol. 2018;51(4):429-433
- Di Renzo et al. Am J Obstet Gynecol. 2019 doi: https://doi.org/10.1016/j.ajog.2019.01.009
- Fiorentino et al. Prenat Diagn. 2017;37:1053–1054
- Grati FR and Benn P. Prenat Diagn. 2017;37:1050–1052
- Gregg et al. Genet Med. 2016; 18:1056–1065
- Malvestiti et al. Prenat Diagn. 2015;35(11):1117-27
- Prenatal screening and diagnostic testing for fetal chromosomal and genetic conditions. https://ranzcog.edu.au/RANZCOG_SITE/media/RANZCOG-MEDIA/Women%27s%20Health/Statement%20and%20guidelines/Clinical-Obstetrics/Prenatal-screening_1.pdf?ext=.pdf
- Stokowski et al. Prenat Diagn. 2015; DOI: 10.1002/pd.4686
- Van der Meij et al. Am J Hum Genet. 2019. pii: S0002-9297(19)30393-3. doi: 10.1016/j.ajhg.2019.10.005
- Van Opstal et al. Genet Med. 2018;20(5):480-485

Your quality choice for 22q11.2 deletion screening

As part of the Harmony screening test menu, Clinical Labs is now offering 22q11.2 deletion or Di George syndrome testing. 22q11.2 deletion syndrome affects an estimated 1 in 1,000 pregnancies.[8,9] The features of this syndrome vary widely, even among affected members of the same family. Common signs and symptoms include heart abnormalities and developmental delays.[10]

A 22q11.2 deletion may not be detected in all foetuses. Harmony NIPT 22q11.2 deletion testing is not validated for use in pregnancies with more than one foetus or for women with a known 22q11.2 duplication or deletion. Due to the limitations of the test, a NO EVIDENCE OF A DELETION OBSERVED result does not guarantee that a foetus is unaffected by a chromosomal or genetic condition. In cases of HIGH PROBABILITY results and/or other clinical indications of a chromosomal condition, confirmatory testing is necessary for diagnosis.

"No call" or "Inconclusive Test" results

Between 0.5-2.9%[11] of women who undergo NIPT will not get a result, often due to insufficient foetal DNA in the sample (known as Low Foetal Fraction), high maternal body mass index (BMI), early gestational age, maternal aneuploidy, chromosomal mosaicism (maternal, foetal of placental), and unknown demised co-twin pregnancy, or the mother has had a transplant or transfusions. A sample can also show inconclusive results if the level of 'noise' in the sample (variance of genomic assays) was too great to reliably assess sex chromosomes. Due to testing complexity, in 1 in 100-200 tests, foetal gender or sex chromosomal assessment results cannot be reported. The manufacturer of the testing kit does not recommend that the Harmony test be repeated. Cumulative data showed that repeat testing is unlikely to provide a reliable result.

Genetic counselling is available for high probability cases within 48 business hours

When receiving a high probability Harmony prenatal test result, patients want access to accurate information. To assist your patient, an initial telephone consultation with a certified genetic counsellor is available at no additional cost. Follow-up consultations, if required, will incur an out-of-pocket fee. Genetic counselling is always recommended following a high probability result. Please note: the genetic counselling referral must be within two weeks of the reporting of high probability results.

How is the patient referred to our genetic counselling services?

1. Australian Clinical Labs will notify the referring clinician of a high probability Harmony prenatal test result and will provide details on how to access genetic counselling.
2. The patient or referring clinician will contact the genetic counsellor to set up an appointment.
3. Appointments are conducted via telephone and are generally available within 48 hours of request. If preferred, the consultation can be organised through the laboratory, which will contact the counsellor with the case details.

What will be discussed during the genetic counselling appointment?

The genetic counsellor will conduct a counselling session with the patient. (It is optional for the referring clinician to be involved in this call.) This initial consultation will be for a period of around 15 to 20 minutes.

During the appointment, the patient can expect to discuss their Harmony prenatal test result, including a comprehensive review of how the result should be interpreted, the specified condition, a discussion surrounding additional testing options, and a brief review of family history.

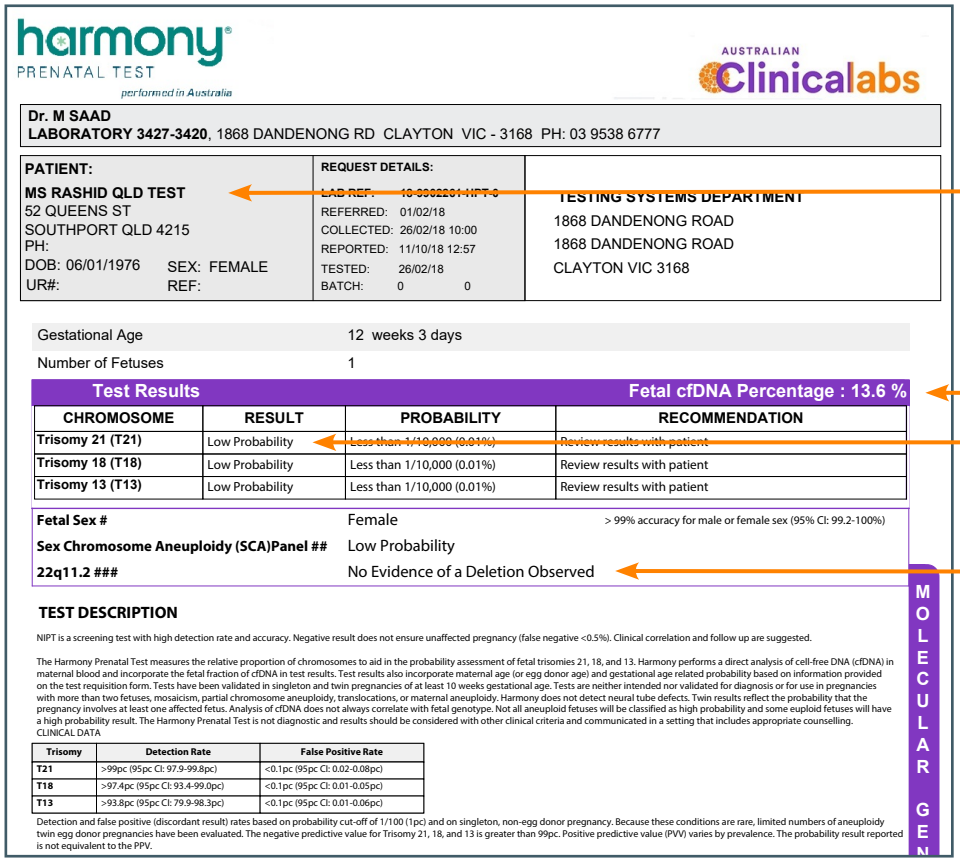
What will happen after the genetic counselling appointment?

Referring clinicians will receive a report from the genetic counsellor following the discussion, which will serve as a summary.

This summary can further aid in the discussions between clinician and patient. Please note that the Harmony prenatal test is a screening test and a high probability Harmony result should always be confirmed by amniocentesis/CVS before any major clinical decision is made regarding the patient's pregnancy.

How to interpret Harmony test results

Low probability result



harmony PRENATAL TEST performed in Australia

AUSTRALIAN Clinicalabs

Dr. M SAAD
LABORATORY 3427-3420, 1868 DANDENONG RD CLAYTON VIC - 3168 PH: 03 9538 6777

PATIENT:	REQUEST DETAILS:	
MS RASHID QLD TEST	LAB REF: 18-9902261-HPT-0	TESTING SYSTEMS DEPARTMENT
52 QUEENS ST	REFERRED: 01/02/18	1868 DANDENONG ROAD
SOUTHPORT QLD 4215	COLLECTED: 26/02/18 10:00	1868 DANDENONG ROAD
PH:	REPORTED: 11/10/18 12:57	CLAYTON VIC 3168
DOB: 06/01/1976 SEX: FEMALE	TESTED: 26/02/18	
UR#: REF:	BATCH: 0 0	

Gestational Age	12 weeks 3 days
Number of Fetuses	1

Test Results — **Fetal cfDNA Percentage : 13.6 %**

CHROMOSOME	RESULT	PROBABILITY	RECOMMENDATION
Trisomy 21 (T21)	Low Probability	Less than 1/10,000 (0.01%)	Review results with patient
Trisomy 18 (T18)	Low Probability	Less than 1/10,000 (0.01%)	Review results with patient
Trisomy 13 (T13)	Low Probability	Less than 1/10,000 (0.01%)	Review results with patient

Fetal Sex #	Female	> 99% accuracy for male or female sex (95% CI: 99.2-100%)
Sex Chromosome Aneuploidy (SCA)Panel ##	Low Probability	
22q11.2 ###	No Evidence of a Deletion Observed	

TEST DESCRIPTION

NIPT is a screening test with high detection rate and accuracy. Negative result does not ensure unaffected pregnancy (false negative <0.5%). Clinical correlation and follow up are suggested.

The Harmony Prenatal Test measures the relative proportion of chromosomes to aid in the probability assessment of fetal trisomies 21, 18, and 13. Harmony performs a direct analysis of cell-free DNA (cfDNA) in maternal blood and incorporate the fetal fraction of cfDNA in test results. Test results also incorporate maternal age (or egg donor age) and gestational age related probability based on information provided on the test requisition form. Tests have been validated in singleton and twin pregnancies of at least 10 weeks gestational age. Tests are neither intended nor validated for diagnosis or for use in pregnancies with more than two fetuses, mosaicism, partial chromosome aneuploidy, translocations, or maternal aneuploidy. Harmony does not detect neural tube defects. Twin results reflect the probability that the pregnancy involves at least one affected fetus. Analysis of cfDNA does not always correlate with fetal genotype. Not all aneuploid fetuses will be classified as high probability and some euploid fetuses will have a high probability result. The Harmony Prenatal Test is not diagnostic and results should be considered with other clinical criteria and communicated in a setting that includes appropriate counselling.
CLINICAL DATA

Trisomy	Detection Rate	False Positive Rate
T21	>99pc (95pc CI: 97.9-99.8pc)	<0.1pc (95pc CI: 0.02-0.08pc)
T18	>97.4pc (95pc CI: 93.4-99.0pc)	<0.1pc (95pc CI: 0.01-0.05pc)
T13	>93.8pc (95pc CI: 79.9-98.3pc)	<0.1pc (95pc CI: 0.01-0.06pc)

Detection and false positive (discordant result) rates based on probability cut-off of 1/100 (1pc) and on singleton, non-egg donor pregnancy. Because these conditions are rare, limited numbers of aneuploidy twin egg donor pregnancies have been evaluated. The negative predictive value for Trisomy 21, 18, and 13 is greater than 99pc. Positive predictive value (PVV) varies by prevalence. The probability result reported is not equivalent to the PPV.

MOLECULAR GEN

Patient Demographics

Fetal cfDNA Fraction %

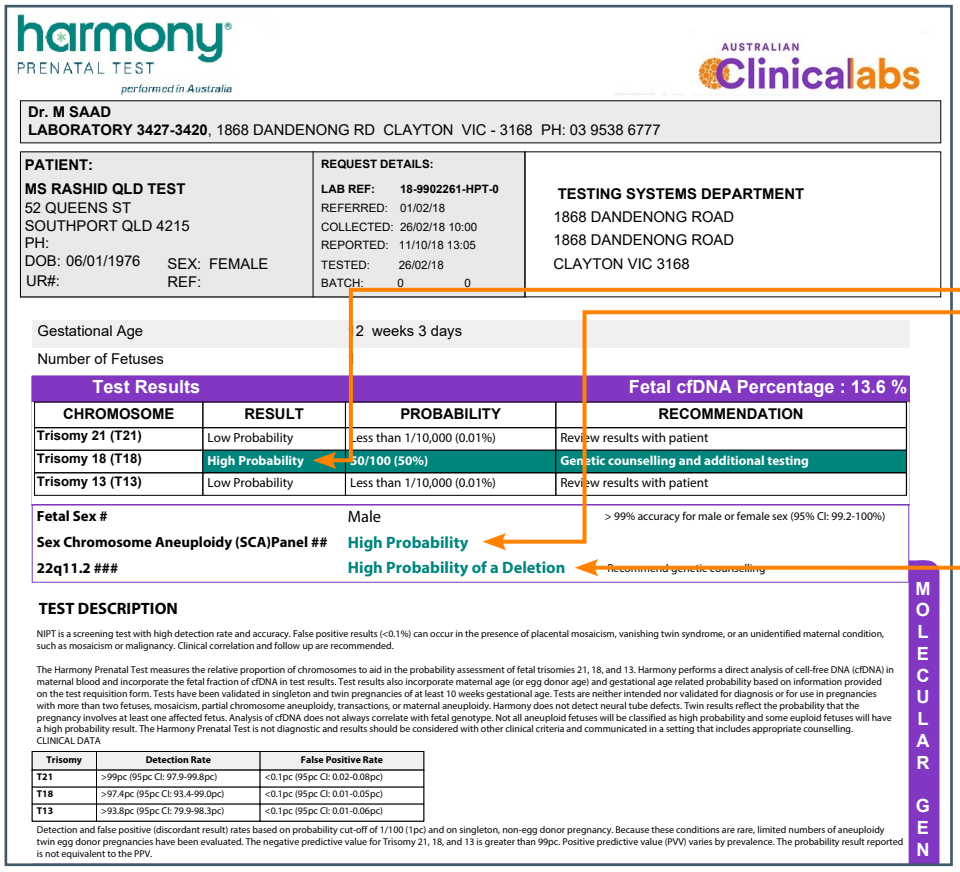
Low Probability

Highly likely that the result is correct but doesn't exclude the condition. Interpret in the clinical context.

No Evidence of Deletion Observed

It is likely that the result is correct but doesn't exclude the condition. Interpret in the clinical context.

High probability result



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PH:	REPORTED: 11/10/18 13:05	CLAYTON VIC 3168
DOB: 06/01/1976 SEX: FEMALE	TESTED: 26/02/18	
UR#: REF:	BATCH: 0 0	

Gestational Age	2 weeks 3 days
Number of Fetuses	

Test Results — **Fetal cfDNA Percentage : 13.6 %**

CHROMOSOME	RESULT	PROBABILITY	RECOMMENDATION
Trisomy 21 (T21)	Low Probability	Less than 1/10,000 (0.01%)	Review results with patient
Trisomy 18 (T18)	**High Probability**	**50/100 (50%)**	**Genetic counselling and additional testing**
Trisomy 13 (T13)	Low Probability	Less than 1/10,000 (0.01%)	Review results with patient

Fetal Sex #	Male	> 99% accuracy for male or female sex (95% CI: 99.2-100%)
Sex Chromosome Aneuploidy (SCA)Panel ##	**High Probability**	
22q11.2 ###	**High Probability of a Deletion**	Recommend genetic counselling

TEST DESCRIPTION

NIPT is a screening test with high detection rate and accuracy. False positive results (<0.1%) can occur in the presence of placental mosaicism, vanishing twin syndrome, or an unidentified maternal condition, such as mosaicism or malignancy. Clinical correlation and follow up are recommended.

The Harmony Prenatal Test measures the relative proportion of chromosomes to aid in the probability assessment of fetal trisomies 21, 18, and 13. Harmony performs a direct analysis of cell-free DNA (cfDNA) in maternal blood and incorporate the fetal fraction of cfDNA in test results. Test results also incorporate maternal age (or egg donor age) and gestational age related probability based on information provided on the test requisition form. Tests have been validated in singleton and twin pregnancies of at least 10 weeks gestational age. Tests are neither intended nor validated for diagnosis or for use in pregnancies with more than two fetuses, mosaicism, partial chromosome aneuploidy, transactions, or maternal aneuploidy. Harmony does not detect neural tube defects. Twin results reflect the probability that the pregnancy involves at least one affected fetus. Analysis of cfDNA does not always correlate with fetal genotype. Not all aneuploid fetuses will be classified as high probability and some euploid fetuses will have a high probability result. The Harmony Prenatal Test is not diagnostic and results should be considered with other clinical criteria and communicated in a setting that includes appropriate counselling.
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MOLECULAR GEN

High Probability

It is likely but not definite that the result is correct. Confirmation is advised.

High Probability

It is likely but not definite that the result is correct. Confirmation is advised.

High Probability of a Deletion

It is likely but not definite that the result is correct. Confirmation by amniocentesis or CVS with FISH (fluorescent in-situ hybridisation) or microarray analysis should be considered.

How to order Harmony

Step 1
If your patient is at least 10 weeks pregnant, fill out the Harmony request form, ensuring the referring clinician details are correct. The Harmony request form can be downloaded from antenatal.clinicallabs.com.au/doctor/harmony

Step 2
Please ensure that both you and the patient have signed the request form and read the detailed information on the front and back of the form.

Step 3
Payment is required before collection. Please advise your patient to scan the QR code on their request form or visit pay.clinicallabs.com.au/harmony to pay for their test online.

Step 4
Direct your patient to take their signed Harmony request form and payment receipt to their nearest Clinical Labs collection centre (clinicallabs.com.au/location).

Step 5
You will receive the patient's results within 5-10 business days of sample receipt at our labs.


harmony
Harmony NIPT Request Form
Australian Clinicallabs
antenatal.clinicallabs.com.au
Patient Information
Referring Clinician
Patient Signature for Informed Consent
Clinician Signature
Copy Doctor
Test Menu Options MANDATORY
Clinical Information MANDATORY
Payment Information MANDATORY
pay.clinicallabs.com.au/harmony
Important Collector Instructions

NOW AVAILABLE!
The Clinical Labs Harmony Request form template is now available in Genie, MedicalDirector and Best Practice.

Australian Clinical Labs - your Harmony provider

Australian Clinical Labs is NATA-accredited for the Harmony Non-Invasive Prenatal Testing/Screening (NIPT/NIPS), which allows for high accuracy and quick result turn-around times. Clinical Labs offers expert pathologist advice and a counselling service for patients who display a high probability result to a genetic defect.

To find out more about Harmony NIPT testing at Clinical Labs, please visit antenatal.clinicallabs.com.au/doctor.

If further information regarding testing is required, please contact:

Assoc. Prof. Mirette Saad

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Associate Professor Mirette Saad is a Consultant Chemical Pathologist and the National Director of Molecular Genetics at Australian Clinical Labs. She has a Fellowship with honours in Chemical and Molecular Pathology, with a sub-specialty in Microbiology, from Suez Canal University, Egypt. A/P Saad received her NHMRC sponsored PhD degree in Cancer Genetics from Melbourne University and Peter MacCallum Cancer Institute. Along with her teaching and research roles, A/P Saad is a registered medical practitioner with AHPRA and a Chemical Pathology Fellow (FRCPA) at the Royal College of Pathologists of Australasia. She is also a member of the Australasian Association of Clinical Biochemists (MAACB). A/P Saad chairs the RCPA Chemical Pathology Advisory Committee, serves as a member of the RCPA Genetic Advisory Committee and AACB, and is the Chair of the Precision Medicine Services at Australian Clinical Labs. At Clinical Labs, A/Prof Mirette Saad leads the Molecular Genetic testing for non-invasive prenatal testing (NIPT), antenatal screening, personalised drug therapy, and cancer.

Why recommend Harmony to your patients?

RANZCOG and the Human Genetics Society of Australasia (HGSA) recommend that NIPT antenatal screening should be discussed with all pregnant women (and their partners) so that they can make an informed decision whether to proceed with testing.[7] Invasive testing is always recommended to confirm a positive result.

- Exceptional accuracy for any age or risk*[5]. Demonstrated in studies involving >268,000 women in >72 peer reviewed publications[1]. Less than 0.1% false-positive rate for trisomies 21, 18, and 13.[5]
- Trusted by clinicians worldwide. Over 1.8 million pregnancies screened and available in over 100 countries[6]
- Can be performed as early as 10 weeks gestation
- May minimise invasive procedures caused by false-positive results

*Any risk refers to the average risk population (age < 35) and high risk population (age > 35). The Harmony test has been studied in women aged 18 - 48. Pregnancies with more than two foetuses, a history of vanishing twin, maternal organ transplant or maternal aneuploidy are not eligible for the Harmony test.

Australian Clinical Labs specialise in FTS and Harmony testing. Below is a comparison tool for clarification purposes.

FIRST TRIMESTER SCREEN	harmony®
Partial Medicare rebate	No Medicare rebate
Detection rate 85-90%	Detection rate >99%
False positive rate 3-5%	False positive <0.1%
Pre-eclampsia risk assessment (additional fee)	Not performed
Not performed	Gender of the baby
Not performed	Sex chromosomal aneuploidy
Ultrasound essential for risk analysis	Ultrasound recommended
Cannot be validated if number of foetuses >2	Cannot be validated if number of foetuses >2

harmony®

Roche

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References:

1. Demonstrated by 72 peer-reviewed published studies using the Harmony prenatal test as of Jan 2021
2. Norton et al. N Engl J Med. 2015 Apr 23; 372 (17): 1589-97
3. Sparks et al. Prenat Diagn. 2012 Jan; 32(1): 3-9
4. Juneau et al. Fetal Diagn Ther. 2014. 36(4): 282-6
5. Stokowski et al. Prenat Diagn. 2015 Dec; 35(12): 1243-1246
6. Data on file
7. RANZCOG Guideline (C-Obs59) July 2018
8. Grati et al. Prenat Diagn 2015; 35: 801-809
9. Wapner et al. N Engl J Med 2012; 367: 2175-2184
10. McDonald-McGinn et al. Genet Couns. 1999; 10(1): 11-24
11. de Wergifosse et al. The Journal of Maternal-Fetal & Neonatal Medicine 2019. DOI: 10.1080/14767058.2019.1686478

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The Harmony non-invasive prenatal test is based on cell-free DNA analysis and is considered a prenatal screening test, not a diagnostic test. Harmony does not screen for potential chromosomal or genetic conditions other than those expressly identified in this document. All women should discuss their results with their healthcare provider who can recommend confirmatory, diagnostic testing where appropriate. The Harmony prenatal test is validated for use in women ≥ 18 years. The Harmony prenatal test was developed by Ariosa Diagnostics. The Harmony prenatal test is performed in Australia.