ANTENATAL SCREENING REQUEST FORM

AUSTRALIAN Clinicalabs

ACC STAMP

harmony™ PRENATAL TEST performed in Australia & FIRST TRIMESTER SCREEN

PATIENT INFORMATION

Patient Surname

Patient Given Name

Date of Birth (DOB) / /

Address

City

State Post Code

Phone

Mobile

Medicare IRN Ref

CLINIC INFORMATION

Referring Clinician Name

Address

City

State Post Code

Phone Provider No.

Copy To (please include ultrasound clinic details)

Clinic Name

Address

Phone

CLINICAL INFORMATION

Gestational Age, **choose A *OR* B**:

A. _____ weeks ____ days Measured on: _____/_____/_____

B. ☐ LMP ☐ EDD ☐ IVF Date: _____/_____/_____

Clinical Due Date: _____/_____/_____

Number of Fetuses: ☐ 1 ☐ 2

Weight _____ (kg) Height _____ (cm)

Conception Information:

☐ Natural ☐ IVF (Patient Egg) | Age at egg retrieval: _____Years

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

DOB of egg donor: _____/_____/_____

Date of egg transfer: _____/_____/_____

Is this a redraw? ☐ Yes ☐ No

History suggestive of high risk chromosomal abnormalities? ☐ Yes ☐ No

Previous history of ☐ T21 (Down) ☐ T18 (Edwards) ☐ T13 (Patau)

Family history of ☐ T21 (Down) ☐ T18 (Edwards)

FIRST TRIMESTER SCREENING (FTS) 9 - 13.6 WEEKS

☐ Maternal Serum Screen (PAPPA + BhCG)

☐ Placental Growth Factor (PlGF) (Pre-Eclampsia Predictor)

Current History:

Smoker ☐ Yes ☐ No

Diabetes (NIDDM only) ☐ Yes ☐ No

Ethnic Group:

☐ Caucasian ☐ Aboriginal ☐ Afro-Caribbean

☐ Asian ☐ Other

HARMONY NON-INVASIVE PRENATAL TEST (NIPT) 10 WEEKS + x2

☐ Harmony Prenatal Test (T21, T18, T13)

harmony™ PRENATAL TEST

Please mark any additional test options requested (no additional cost):

☐ Fetal Sex

☐ Monosomy X (Singletons Only)[1]

☐ Sex Chromosome Aneuploidy Panel (Singletons Only)[1]

[1] Fetal Sex not reported

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

BILLING INFORMATION

Please tick one:

☐ Cheque ☐ VISA ☐ Mastercard ☐ Money Order

☐ Commercial Client (Biller Code _____)

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

Please bill my credit card for $

Card Number

Expiry Date

Cardholder Name (please print)

Cardholder Signature ✕

PATIENT 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 Antenatal 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 counseling before signing this consent.

Patient Signature ✕

Date

COLLECTION INFORMATION

Person collecting specimen to complete:

Date of Collection: ____/____/____ Time of Collection: _____

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.

Collector Signature ✕

Collector Name (please print)

ANTENATAL SCREENING REQUEST FORM

Patient Informed Consent

The Harmony Prenatal Test and the available test options are laboratory-developed screening tests that analyse 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 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

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. 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 Monosomy 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 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 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.

HARMONY PRENATAL TEST COLLECTION CENTRES

Please note, the collection centres at which samples may be collected for the Harmony Prenatal Test may change over time. For a list of collection centres, please visit **www.clinicallabs.com.au/location**

Please call and book an appointment, as bookings are essential at collection centres across South Australia and Northern Territory.

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harmony™ PRENATAL TEST
performed in Australia

FIRST TRIMESTER SCREEN

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ClinicalLabs.com.au

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