harmony™
PRENATAL TEST

Ordering Lab Specimen ID
Optional

Place the -PAT barcode label here

Patient Information

Patient Name (Last, First)

Date of Birth YYYY/MM/DD

Address

City/State or Province

Country/Postal Code

Phone Medical Record Number

Gender ☐ Female ☐ Male

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 Ariosa to perform the laboratory 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 know that if I wish, I may obtain professional genetic counseling before signing this consent.

I expressly agree and give permission for my personal data included in this test requisition form (including, without limitation, my name, address, information about my pregnancy, and other relevant information), as well as my blood sample, to be shipped and transmitted to Ariosa in the United States for the purpose of performing the Harmony test(s). In the event I withdraw my consent or request not to receive the results of the Harmony test(s), Ariosa will use commercially reasonable efforts to promptly destroy my blood sample in compliance with applicable US laws and regulations, and Ariosa's standard protocols for sample destruction. I agree that in the event Ariosa performs the Harmony test(s) selected on this form, Ariosa may store my personal data (including my test results) and remaining sample (if any) for the applicable legally required time period.

☐ Opt-In ☐ Opt-Out

Check to indicate whether you consent to anonymized laboratory development and validation studies. If you check the opt-in box, you acknowledge and agree that after the completion of your selected test(s), your personal data (including, without limitation, information included on the test requisition form and test results) and the remaining unused portion of your sample, which may be stored for longer than 60 days, will be anonymized and may be used in laboratory validation, process development, and/or quality control studies at Ariosa, its affiliates, or a third party. If you do not check the opt-in box, your personal data and the remaining unused portion of your sample will not be used in laboratory development or validation studies. In all cases, patient samples and personal data, including results will be stored, used, and destroyed in compliance with applicable US, Federal, and state laws, rules, and regulations.

Patient Signature

Date YYYY/MM/DD

Billing Information

○ Credit Card
○ Client/Provider

Clinic Information

Account Number 15393:1 Account Name Healthscope NZ

Ordering Clinician

Address

City/State or Province

Country/Postal Code

Phone

Referring Clinician

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 YYYY/MM/DD

Test Menu Options and Clinical Information

☑ Harmony Prenatal Test (T21, T18, T13)
Please mark any additional test options requested:
☐ Fetal Sex
☐ Monosomy X (Singletons only)[1]
☐ Sex Chromosome Aneuploidy Panel (Singletons only)[1]

[1]Fetal sex not reported

Gestational Age, choose A or B:

A. weeks days measured on YYYY/MM/DD

B. ○ LMP ○ EDD ○ IVF Date YYYY/MM/DD

Number of Fetuses ○ 1 ○ 2

IVF Pregnancy? ○ No ○ Yes → Egg used in IVF: ○ Patient ○ Donor
Patient/donor age at egg retrieval: Years

Important Blood Draw Information

Complete A & B:

A. Collection Date YYYY/MM/DD

B. 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.

harmony™
PRENATAL TEST

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 confirmatory 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 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 counseling.

What is done with my sample after testing is complete?

No additional clinical testing will be performed on your blood sample other than those authorized by your healthcare provider. Ariosa Diagnostics 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 authorized by you or as required by laws, regulations, or judicial order.

Details on Ariosa's policies and procedures governing patient privacy and health information, including patient rights regarding such information, can be found at www.ariosadx.com/privacy-policy/.

It is standard of care for physicians to obtain informed consent for genetic testing. This form is designed to address the requirements of New York State Civil Rights Law Section 79-L and Massachusetts General Law Chapter 111, Section 70G.

Ariosa®
DIAGNOSTICS

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