

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 test(s) 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.

Patient Signature

Date YYYY/MM/DD

## Opt-In for Sample Retention for Study or Research Use

Opt-In

With your consent, the unused portions of your sample may be used by Ariosa and its affiliates for laboratory validation, process development, quality control studies, and/or other research purposes. If you choose to opt in and allow Ariosa to use your unused sample in this manner, the sample will be stripped of the information that can identify you (anonymized) while some of the non-identifiable clinical data we received from you (e.g., gestational age, number of fetuses) will be retained for use in these activities.

If you do not opt in, your unused sample will not be used for these purposes and will be destroyed in accordance with Ariosa's policies and procedures. In all cases, your sample and personal data, including your test results, will be stored, used, and destroyed in compliance with applicable laws, rules, and regulations.

## Clinic Information

Account Number

Roche Customer ID

Account Name

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)<sup>1</sup>

Sex Chromosome Aneuploidy Panel (Singletons only)<sup>1</sup>

<sup>1</sup>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.



**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 assessment 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](http://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, with history of or active malignancy, or demised twin are ineligible 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 validated for use in pregnancies with more than two fetuses, demised twin, mosaicism, partial chromosome aneuploidy, translocations, maternal aneuploidy, transplant, malignancy, or in women under the age of 18. Harmony does not detect neural tube defects. 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 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/](http://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.



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