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 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

I agree and consent to allow Ariosa and its affiliates to use the unused portions of my sample for laboratory validation, process development, quality control studies and/or other research purposes. I understand that if I choose to opt in and allow Ariosa to use my unused sample in this manner, my sample will be anonymized, meaning that information that can identify me will be removed. I understand that my unused sample will be stored with some of the non-identifiable clinical data Ariosa or its affiliates received from me (e.g., gestational age, number of fetuses), which will be retained for use in these activities).

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

Clinic Information

Account Number 18430

Roche Customer ID

Account Name Life Genomics

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 the capabilities, limitations, and possible risks 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[1,2]
- ☐ Sex Chromosome Aneuploidy Panel[1,2]
- ☐ 22q11.2[1]

[1]Singletons only [2]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 is a laboratory-developed screening test that analyzes cell-free DNA (cfDNA) in maternal blood. The test provides a probability assessment, not a diagnosis, of fetal chromosomal or genetic conditions, and fetal sex determination. Consider Harmony results in the context of other clinical criteria. Follow up confirmatory testing based on Harmony results for Trisomy 21, 18, 13, sex chromosome aneuploidy, or 22q11.2 could reveal maternal chromosomal or genetic conditions in some cases. Results from the Harmony Prenatal Test should be communicated in a setting designated by your healthcare provider that includes the availability of appropriate genetic counseling.

For a full test description of the Harmony Prenatal Test and available report options, please visit: www.harmonytest.com.

Who is eligible for the Harmony Prenatal Test?

Women who are at least ten weeks pregnant are eligible for the Harmony Prenatal Test offerings. Patients with a twin pregnancy are not eligible for sex chromosome aneuploidy or 22q11.2 options. The Harmony Prenatal Test is not for patients with:

- a history of or active malignancy;
- a pregnancy with fetal demise;
- a pregnancy with more than two fetuses;
- a history of bone marrow or organ transplants.

What are the limitations of the Harmony Prenatal Test for Trisomies 21, 18, and 13, sex chromosome aneuploidy, and fetal sex determination?

The Harmony Prenatal Test is not validated for use in pregnancies with more than two fetuses, fetal demise, 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. For twin pregnancies, HIGH PROBABILITY test results apply to at least one fetus; male test results apply to one or both fetuses; female test results apply to both fetuses.

Due to the limitations of the test, inaccurate results are possible. A LOW PROBABILITY result does not guarantee that a fetus is unaffected by a chromosomal or genetic condition. Some non-aneuploid fetuses may have HIGH PROBABILITY results. In cases of HIGH PROBABILITY results and/or other clinical indications of a chromosomal condition, confirmatory testing is necessary for diagnosis.

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 fetuses. Due to the limitations of the test, a NO EVIDENCE OF A DELETION OBSERVED result does not guarantee result 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.

How is my blood sample and personal data used by Ariosa Diagnostics?

Ariosa Diagnostics, Inc. (Ariosa) collects and processes the blood samples and personal data provided by you to perform the Harmony Prenatal Test at our California-based laboratory. Without your personal data, we will be unable to perform your test. No additional clinical testing will be performed on your blood sample other than those authorized by your healthcare provider. Your test results will be disclosed only to the healthcare provider listed on this form (or to his or her agent), unless otherwise authorized by you or as required by laws, regulations, or judicial order.

Your blood samples will be retained by Ariosa for 60 days, which is the amount of time needed to perform the test and to perform additional testing as directed by your healthcare provider. Your blood samples will be destroyed after this time unless you have consented to allow your sample to be used for validation and research purposes. Ariosa is a U.S.-based laboratory and is required to comply with certain U.S. and state-based laws and regulations regarding its operations. Those laws and regulations require Ariosa to maintain records of patient test results for a period of years for quality and compliance purposes. During this time, Ariosa maintains patient records in its secure and HIPAA-compliant IT systems and is not used or disclosed for purposes outside of what is required or permitted by law.

You have certain rights with regards to the processing of your information. You can get more information on these rights, as well as detailed information regarding Ariosa's patient privacy policies and procedures in our privacy notice at: www.ariosadx.com/privacy-policy/.

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