PLEASE SEND THIS TOP COPY WITH THE SAMPLES

harmony®

performed in the UK

For Laboratory use only

Place the FORM barcode label here

TAP2122J/23-04-19/27

Patient Information

Patient Name (First)

Patient Name (Last)

Date of Birth (DD/MM/YYYY)

Address

City/State or Province

Country/Postcode

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 and agree to the informed consent and give permission for the laboratory tests selected to be performed in accordance with the informed consent. 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 counselling before signing this consent.

☐ Tick to opt-in to anonymised laboratory development and validation studies.

If I tick the opt-in box, I agree and consent to allow TDL Genetics Limited or its subcontractor to use the unused portions of my sample for laboratory validation, process development, quality control studies and/or other research purposes as described in the informed consent. I understand that if I choose to opt in and allow TDL Genetics Limited or its subcontractor to use my unused sample in this manner, my sample will be anonymised, 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 TDL Genetics Limited or its subcontractor received from me (e.g., gestational age, number of fetuses), which will be retained for use in these activities. The unused samples and non-identifiable clinical data may be stored for longer than 60 days.

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 TDL Genetics Limited's or its subcontractor's policies and procedures. In all cases, patient samples and personal data, including results will be stored, used, and destroyed in compliance with applicable laws, rules, and regulations.

Patient signature

Date (DD/MM/YYYY)

Clinician signature

I confirm that my patient has been fully informed about capabilities, limitations, and possible risks of the test(s). The patient has given full consent for this test.

Clinician signature

Date (DD/MM/YYYY)

Clinic Information

Account Name

Ordering Clinician

Address

City/State or Province

Country/Postcode

Phone

Email

Referring Clinician

Test menu options

☑ Harmony Prenatal Test (T21, T18, T13)

Please mark any additional test options requested:

Fetal sex to be reported (now available for twins)

☐ Yes ☐ No

☐ Harmony with Monosomy X only[1]

☐ Harmony with sex chromosome aneuploidy panel (X and Y)[1]

☐ 22q11.2 deletion[1] *additional charge applies

Note: [1] Available for singleton pregnancies only.

Fetal sex will be apparent if a high risk sex chromosome aneuploidy is indicated even when fetal sex has not been reported. For twin pregnancies, male results apply to one or both fetuses, female results apply to both fetuses.

Essential clinical information*

Gestational Age* weeks days measured on (DD/MM/YYYY)

Number of Fetuses* ● 1 ○ 2

IVF Pregnancy?* ● No ○ Yes → Egg used in IVF: ○ Patient ○ Donor

Patient/donor age at egg retrieval: Years

U/S findings or biochemical risk

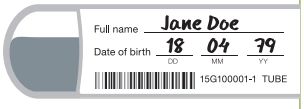
Is this a redraw?* ○ Yes

IMPORTANT BLOOD DRAW INFORMATION

Complete A & B:

A. Blood collected on: (DD/MM/YYYY) by:

B. Write the patient's full name and date of birth on tube barcodes. Name, barcode, and date of birth must match the Request Form. Place labels lengthwise on the cfD tubes as shown in the example.



Billing Information

○ Bill Patient ○ Bill Doctor

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Patient Informed Consent

The Harmony Prenatal Test is a CE marked screening test that analyses 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?

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:

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, triploidy, 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.

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. Your test results will be disclosed only to the healthcare provider(s) listed on the front of this form (or to his or her agent) or to its permitted subcontractors unless otherwise authorised by you or as required by laws, regulations, or judicial order.

Personal data

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

The Harmony Prenatal Test will usually be performed in the UK by TDL Genetics Limited. Under certain circumstances TDL Genetics Limited may subcontract with other laboratories approved to perform the Harmony Prenatal Test and may need to transfer your information to overseas for this purpose, including to countries outside the European Economic Area (EEA) which may not offer the same rights in respect of your personal data as countries within the EEA. When this is necessary any transfer will be made in full compliance with all aspects of applicable data protection legislation. By signing the consent form overleaf, you give permission for your personal data included in this form, as well as your blood sample, to be shipped and transmitted to any of such other approved laboratories to perform the Harmony Prenatal Test (including to Ariosa, the provider of Harmony testing in the United States) and to have your test results transmitted to TDL Genetics Limited and your ordering healthcare provider. You consent to the treatment, handling, and retention of your patient data and samples by the laboratory subcontracted by TDL Genetics Limited in accordance with applicable regulations and laws. For information on the TDL group privacy policy please visit: https://tdlpathology.com/about-tdl/tdl-group-privacy-notice/.

In the event your test is performed by Ariosa, certain U.S. and state-based laws and regulations apply. 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. For information on your rights regarding the processing of your information, as well as detailed information regarding Ariosa's patient privacy policies and procedures in our privacy notice, please visit www.ariosadx.com/privacy-policy/.

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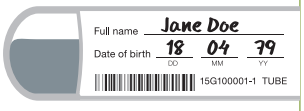

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