harmony®
PRENATAL TEST
performed in Sweden

Ordering Lab Specimen ID
Optional

Place the -PAT barcode label here

Patient Information

Patient Name (Last, First)

Date of Birth YYYY/MM/DD

Medical Record Number

Weight (kg) Height (m)

Patient Signature for Informed Consent

By signing this consent document, I hereby certify that I have read, or have had read for me, the information of consent. I understand the information and allow Life genomics AB ("Life Genomics") to perform my chosen laboratory tests. I have had the opportunity to ask questions and discuss the possibilities, limitations and possible risks of the test with my doctor or midwife. I am aware that, upon request, I may receive professional genetic counselling before signing this consent.

By signing this document, I agree that Life Genomics processes my personal data covered by this referral (including my name, address, pregnancy information and other relevant information) for the purpose of performing Harmony tests and in accordance with the Privacy Policy. I hereby certify that I have taken part of the Privacy Policy (http://www.lifegenomics.se/om-oss/personuppgiftspolicy), which applies to the personal data processing provided by LG's services. I am aware that my personal data may be transferred to third parties in accordance with the Privacy Policy. I agree that my blood sample will be delivered to Life Genomics in Sweden for the purpose of performing Harmony tests.

I am aware that, at any time, I can revoke my consent. If I choose to revoke my consent or request not to receive the results of the Harmony test, Life Genomics will, through commercially reasonable efforts to destroy my blood sample in accordance with applicable laws and regulations. Withdrawal of my consent can be done by writing to Life Genomics at: Life Genomics AB, Odinsgatan 28, 411 03 Gothenburg, Sweden.

I am aware that when Life Genomics performs the Harmony tests based on referral, Life Genomics can store my personal data (including my test results) and any remaining sample in accordance with applicable statutory time period.

☐ Opt-In ☐ Opt-Out

Check to indicate whether you consent to 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 longer than 60 days will be used in laboratory validation or Quality control at Life Genomics. If you check-the opt-out box the remaining unused portion of your sample will be discarded. If no box is ticked, opt-in will be assumed. In all cases, patient samples and personal data, including results will be stored, used and destroyed in compliance with law, rules and regulations.

Patient Signature

Date YYYY/MM/DD

Clinic Information

Account Number 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.

Terms and conditions apply for ordering analysis, available at: http://www.nipt.se/resources/

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

☐ Microdeletion 22q11.2 (Singletons only)[1]

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

[1]Fetal sex not reported

Gestational Age, choose A or B:

A. weeks days at blood draw

B. ○LMP ○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
Name, barcode, and date of birth must match the TRF.

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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.lifegenomics.se.

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 22q11.2
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.

LIFE GENOMICS

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