Order form Harmony® Prenatal Test

GENERAL PATIENT INFORMATION

First and last name of patient

Home address | Post-code /City

Date of birth | Social security number

telephone number

Please keep this field free for internal purposes.

harmony® *Performed in Austria*

Roche

MEDSANA

medilab

SENDER INFORMATION

Name of the doctor in block capitals (first and last name)

Stamp of medical practice

I confirm that my patient has been fully informed about the capabilities, limitations and possible risks of the Harmony® Prenatal Test. The patient has given her consent to the selected laboratory test(s).

Place, date | Signature of the doctor in charge

REQUESTED TEST OPTION(S)

- ☐ Trisomy 21, 18, 13
- ☐ Trisomy 21, 18, 13 and monosomy X[2]
- ☐ Trisomy 21, 18, 13 and sex chromosomal disorders[1,2]

1 Monosomy X, Klinefelter's, Triple X, XYY and YY syndrome; 2 only in singleton pregnancies.

Possible add-on options:

- ☐ + Foetal Sex Discernment
- ☐ + 22q11.2

Repeat examination? ☐ Yes ☐ No

INFORMATION ON PREGNANCY AT THE TIME OF BLOOD SAMPLING

Date of blood sampling | Time

____ + ____ (at least pregnancy week 10+0 at blood sampling, if possible after ultrasound)

Gestational age (pregnancy week + day p.m.)

☐ Singleton pregnancy[3] ☐ Twin pregnancy

3 In case of "Vanishing Twin" phenomenon, the Harmony® Prenatal Test cannot be performed.

IVF/ICSI, if yes:

☐ Own egg cell(s) ☐ Egg donation (Donor egg(s))

☐ Age of the egg donor/mother (own egg) at retrieval: _____ years

Body weight: _____

Height: _____

Ultrasound date: _____

Pregnancy complications:

Declaration of consent for the performance of the Harmony® Prenatal Test

By signing this form, I confirm that I have read the consent form. I have been fully informed by my specialist doctor about the nature, scope and significance as well as the consequences of the genetic test. I have had the opportunity to ask questions and have been informed about the capabilities, limitations and possible risks of the test procedure(s). I understand the declaration of consent and I agree to the examination of the selected laboratory test(s) by medilab with my own free consent. I can stop the examination at any time and change or revoke the decisions made in the current declaration by notifying medilab in writing without giving reasons.

I hereby give my express consent and permission for my personal data contained in this test request form (including, without limitation, my name, address, details of my pregnancy and other information contained in this form) as well as my blood sample to be be sent to and kept and stored by medilab (Medizinisches Diagnostisches Laboratorium Dr. Holzer GmbH, located at Strubergasse, nr. 20, 5020 Salzburg, Austria) for the purpose of performing the Harmony® Prenatal Test(s) in accordance with legal requirements. All legal requirements of data protection and the Austrian Genetic Engineering Act will be complied with. The results will be summarised in a report and sent to the referring specialist.

Place, date | Patient signature

Consent for handling samples for quality assurance, study or research use

☐ I give / ☐ I do NOT give

my consent and permission for medilab to use unused sample material for laboratory validation, process development, quality control studies and/or other research purposes after completion of the examination. I understand that if I give my consent and allow medilab to use my sample, all information will be removed from the sample to exclude attribution to any individual.

☐ I agree / ☐ I do NOT agree to the anonymised further use of my samples.

Place, date | Patient signature

medilab - medizinisch-chemisches Labor Dr. Mustafa, Dr. Richter OG | Strubergasse 20 | A-5020 Salzburg | Tel. 0662/2205 - 260 | Fax 0662 / 2205 - 421

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Informed consent of the patient

The Harmony® Prenatal Test is a laboratory-developed screening test that analyses the cell-free DNA (cfDNA) in the mother's blood. The test is used to assess the probability, not diagnose, of foetal chromosomal or genetic disorders, and to determine foetal sex. The results of the Harmony® Prenatal Test should be considered in the light of other clinical criteria.

In some cases, subsequent confirmatory tests based on the Harmony® Prenatal test results for trisomy 21, 18, 13, aneuploidy of the sex chromosomes or 22q11.2 could detect chromosomal or genetic conditions in the mother. As part of the results communication of the Harmony® Prenatal Test, there should be an opportunity for you to receive appropriate genetic counselling from your healthcare provider.
For a full description of the Harmony® Prenatal Test and available testing options, please visit: www.medilab.at

Who is the Harmony® Prenatal Test suitable for?

The Harmony® Prenatal Test is suitable for women from 10+0 weeks of pregnancy. Patients with a twin pregnancy cannot be tested for aneuploidy of the sex chromosomes or anomalies of 22q11.2. The Harmony® Prenatal Test is not suitable for patients with:

> previous or current malignant disease
> a pregnancy with stillbirth
> a pregnancy with more than two foetuses
> previous bone marrow or organ transplants

What are the limitations of the Harmony® Prenatal Test for trisomy 21,18,13, aneuploidy of the sex chromosomes and determination of the foetal sex?

The Harmony® Prenatal Test has not been validated for use in pregnancies with more than two foetuses, stillbirth, mosaicism, partial chromosomal aneuploidy, translocations, maternal aneuploidy, transplantation, malignancy or in women under 18 years of age. The Harmony® Prenatal Test cannot detect neural tube defects. Certain rare biological conditions may also affect the accuracy of the test. Test results for pregnancies with twins indicate a HIGH PROBABILITY that the pregnancy will include at least one affected foetus. A "male" pregnancy outcome refers to one or both foetuses and a "female" pregnancy outcome refers to both foetuses.

Due to the limitations of the test, inaccurate results are possible. A LOW PROBABILITY result is not a guarantee that a foetus is not affected by a chromosomal or genetic condition. Some non-aneuploid foetuses may have a HIGH PROBABILITY result. In the case of HIGH PROBABILITY results and/or other clinical indications of chromosomal disease, tests are required to confirm the diagnosis.

How does medilab use my blood sample and my personal data?

medilab takes and processes the blood samples and personal data for the Harmony® Prenatal Test in the laboratory in Salzburg. Without personal data, medilab is not able to perform your test. No clinical tests will be performed on your blood sample other than those approved by your healthcare provider. Your test results will only be shared with the healthcare provider (or their representative) named on this form unless otherwise authorised by you or required by law, regulation or court order.

Your blood samples will be stored by medilab for 60 days. This is the time required to perform the test and additional tests as instructed by your healthcare provider. Your blood samples will be destroyed after this time unless you have given your consent for your sample to be used for validation and research purposes. medilab is a laboratory located in Salzburg, Austria and must comply with certain state and federal laws and regulations that apply in the United States regarding its procedures. These laws and regulations require medilab to maintain files on patient test results for a period of several years for quality and compliance purposes. During this time, medilab will maintain patient records in its secure and HIPAA-compliant IT systems and they will only be used or disclosed for purposes required or permitted by law.

You have certain rights regarding the processing of your data. You can find more information about these rights, as well as information about medilab's patient data protection policies and procedures, in our privacy policy at: www.medilab.at.