Krankenkasse bzw. Kostenträger

Name, Vorname und Adresse des Versicherten

geb. am

Kassen-Nr. | Versicherten-Nr. | Status

Betriebsstätten-Nr. | Arzt-Nr. | Datum

Zentrum für Humangenetik Tübingen

# harmony PRENATAL TEST

**Non-invasive screening test for a fetal trisomy 21, 18, 13 and X/Y-chromosomal aneuploidy**

## Information about pregnancy at the time of blood collection

Date of blood collection: __.__.__ Time: __:__

Gestational age (weeks + days): __ + __ (min. 10 + 0, preferably according to ultrasound)

☐ singleton pregnancy ☐ twin pregnancy

*A Vanishing Twin can lead to incorrect results or test failures in the Harmony® test. The Harmony® test should therefore not be performed in this situation.*

☐ IVF / ICSI, if so:

☐ self egg donor ☐ non-self egg donor

Age of patient (own egg cell)/donor at the time of egg donation: __ years

Patient weight: ___,__ kg Patient height: ___ cm

Date of ultrasound: __.__.__

Abnormalities in pregnancy: _____

## Please place the included barcode here:

☐ redraw / repeat test

## Declaration of the requesting physician according to the German Genetic Diagnostics Act

Requesting physician

Stamp

I hereby confirm that I have consulted the patient in accordance with the §10 of the German Genetic Diagnostics Act (GenDG). The patient was informed about the purposes and limitations of the Harmony® Test. According to my specific qualification (§7 GenDG) I request this prenatal genetic analysis.

Place, date

Name of the doctor in plain text

X

Signature of the requesting physician

*needed material: 2 x 8 ml blood, cfDNA-tubes*

**Covered by health insurance:** *Please include "Überweisungsschein Muster 10"*

☐ Trisomy 21, 18, 13

**Self-payer service:** [1]

| | |
|---|---|
| ☐ Trisomy 21 | 169 € |
| ☐ Trisomy 21, 18, 13 | 199 € |

**Additional options:** *Only in combination with an other test option*

| | |
|---|---|
| ☐ + Determination of fetal sex | + 19 € |
| ☐ + analysis of sex chromosome aneuploidies [2] | + 69 € |

[1] *Charging to the patient according to the valid statutory scale of fees for physicians (GOÄ). There might be additional costs for the blood draw and consultation.*

[2] *Monosomy X, Klinefelter-, Triple-X-, XYY- and XXYY-syndrome and only for singleton pregnancies and in combination with Trisony 21, 18, and 13*

## Written consent for the performance of the Harmony® Test according to the German Diagnostics Act

With my signature on this form I give my consent to have the Harmony® Test performed from my blood sample. I confirm that I have received counseling and explanations from my responsible physician in accordance with the German Genetic Diagnostics Act (Gen DG). I have had the opportunity to ask questions and discuss the test with my physician or someone my doctor has designated. I was informed about the purposes and limitations of the Harmony® Test. I am aware that I may obtain professional genetic counseling if desired before signing this consent. I was informed that the Harmony® Test is a screening test and not intended or validated for diagnosis. Clinical studies demonstrate high accuracy for fetal trisomy detection, but not all trisomic fetuses will be identified by the Harmony® Test. Following the Gen DG the information about the fetal gender will only be reported after completion of the 14th week of gestation. I am aware that I may revoke my consent at any time in written form to my doctor. In addition, in the event of revocation I am obligated to pay for the services rendered so far. I was informed that I have the right not to be informed about the result. I hereby consent to the processing, use, storage and transmission (e.g. by fax) of my personal data by the Zentrum für Humangenetik Tübingen. The test results will passed to me solely by the responsible doctor.

I agree to the storage and usage of sample material for quality assurance purposes ( a non-selection is treated like "no")

☐ yes ☐ no

Place, date

X

Patient's signature

## Preferred form of payment (only fill out for self-payer service)

☐ SEPA direct debit permission

I/we hereby authorize the Zentrum für Humangenetik Tübingen or its partners to collect the amount to be paid by me/us according to the test option selected above. Furthermore I instruct my bank irrevocably to honor direct debits (Zentrum für Humangenetik Creditor ID: DE39ZZZ00002420581). I am aware that I have the right to demand a chargeback within 8 weeks, according to pre-agreed terms and conditions of the bank. An invoice/payment receipt will be sent to me automatically after receipt of payment.

Name (account holder)_____

IBAN

BIC

Name of bank_____

Charges will be deducted earliest 4 days after the submission date. The mandate reference number is the number of the barcode (top right corner).

X

Signature of the account holder

☐ via invoice

Alternate invoice adress:

Patient phone number or email address

The Harmony® Test is a laboratory-based screening test that is intended to aid in the risk determination of fetal trisomy 21, trisomy 18, and trisomy 13 in women of at least 10 weeks of gestation. As a primary sample maternal blood is taken in cfDNA blood collection tubes. The Harmony® Test is a screening test and not intended or validated for diagnosis. Clinical Studies demonstrate a high accuracy for fetal trisomy detection, but not all trisomic fetuses will be detected. Some fetuses with a trisomy may have "LOW RISK" results. Some euploid (not trisomic) fetuses may have "HIGH RISK" results. Results should be considered in the context of other clinical criteria. It is recommended that results are communicated in a setting that ensures appropriate counseling. In rare cases the Harmony® Test or single test options (analysis of X/Y chromosomal aneuploidy, determination of fetal sex) are not evaluable.

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