Krankenkasse bzw. Kostenträger

Name, Vorname des Versicherten

geb. am

Kassen-Nr. | Versicherten-Nr. | Status

Betriebsstätten-Nr. | Arzt-Nr. | Datum

harmony PRENATAL TEST

cenata

Non-invasive screening test for trisomies 21, 18, 13 and X/Y-chromosomal aneuploidy

Information about pregnancy at the time of blood collection

Date of blood collection: D D . M M . Y Y Time: :

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

☐ singleton pregnancy [1] ☐ twin pregnancy

☐ IVF / ICSI

☐ 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: D D . M M . Y Y

[1] In case of a Vanishing Twin the Harmony® Test cannot be performed

Please place the included barcode here:

Beleg/Req.Form XXXXXX

Name

Geb.-Dat./DOB T T M M J J J J

☐ redraw / repeat test

Desired type of Harmony® Test

☐ Trisomy 21	249 €
☐ Trisomy 21, 18, 13	269 €
☐ Trisomy 21, 18, 13 + analysis of sex chromosome aneuploidies [2,3]	299 €

Additional options

☐ + Microdeletion 22q11.2 [3]	35 €
☐ + Determination of fetal sex	0 €

[2] Monosomy X, Klinefelter-, Triple-X-, XYY- and XXYY-Syndrom | [3] only for singleton pregnancies

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

I hereby confirm that I have consulted the patient in accordance with §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.

Requesting physician

Stamp

Place, date

X

Signature of the requesting physician

Written consent for the performance of the Harmony® Test according to the German Genetic 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. 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 German Genetic Diagnostics Act [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 hereby agree that the Harmony® Prenatal Test is also processed by Medirex Servis, s.r.o., member of MEDIREX GROUP, Galvaniho 17 / C, 820 16 Bratislava, Slovak republic, EUROPE. Medirex Servis is a laboratory licensed by Roche Diagnostics for the performance of the Harmony® Prenatal Test. Cenata is validating the results and ensures the transmission of the report to the physician according to German law. 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 Cenata GmbH.

I agree to the storage and use of my anonymized plasma for purposes of quality assurance and research ☐ yes ☐ no

Place, date

X

Patient's signature

Method of Payment

☐ **SEPA direct debit permission**

I / we hereby authorize Cenata GmbH 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 (Cenata GmbH Creditor ID: DE75ZZZ00001576615). 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 _____

☐ **Credit Card**

☐ Mastercard

☐ VISA

☐ American Express

Exp. date: /

Card number

Name of card holder

Charges will be deducted earliest 4 days after the submission date. The mandate reference number is the number of the barcode.

Alternate invoice address

X

Signature of the card holder

Patient phone number or email address

Information concerning the Harmony® Test

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. The Harmony® Test may not be part of statutory health care and might have to be paid by the patient.

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