cenata
Cenata GmbH
Paul-Ehrlich-Str. 23
D-72076 Tübingen
Tel. +49 7071 - 565 44 430
Fax +49 7071 - 565 44 444
E-Mail info@cenata.de

harmony PRENATAL TEST

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

Patient's name (name, first name)

Patient's date of birth

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 [1]

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

☐ 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:

Desired type of Harmony® Test

☐ Trisomy 21, 18, 13

☐ Trisomy 21, 18, 13 + analysis of sex chromosome aneuploidies [2]

Additional options

☐ + Determination of fetal sex

[2] *Monosomy X, Klinefelter-, Triple-X-, XYY- and XXYY-syndrome and only for singleton pregnancies*

Please place the included barcode here:

☐ redraw / repeat test

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

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.

Requesting physician

Stamp

Name of the doctor in plain text:

Place, date

X

Signature of the requesting physician

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. 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 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. The test results will passed to me solely by the responsible doctor.

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

Patient phone number or email address

Information concerning the Harmony® Prenatal 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. In rare cases the Harmony® Test or single test options (analysis of X/Y chromosomal aneuploidy, determination of fetal sex) are not evaluable.

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

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