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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

☐ 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:

Harmony® Test variant *Required material: 2 x 8 mL blood, cfDNA tubes*

☐ Trisomy 21, 18, 13

Additional options *selectable only together with a Harmony® Test variant*

☐ + Determination of fetal sex

☐ + Analysis of sex chromosomal aneuploidies [1, 2]

☐ + Microdeletion 22q11.2 (DiGeorge syndrome) [1]

[1] *only for singleton pregnancies*

[2] *Monosomy X, Klinefelter, Triple-X, XYY and XXYY syndrome*

Please place the included barcode here:

☐ redraw / repeat test

Declaration of the requesting physician according to the Genetic Diagnostics Act

I hereby confirm that I have genetically consulted the patient in accordance with local laws. The patient was informed about the purposes and limitations of the Harmony® Test. I hereby request this prenatal genetic analysis.

Requesting physician

Stamp

Name of the physician in plain text:

Place, date

X

Signature of the requesting physician

Written consent for the performance of the Harmony® Test according to the 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. I have had the opportunity to ask questions and discuss the test with my physician or someone my physician 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. I am aware that I may revoke my consent at any time in written form to my physician. 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 be provided to me only by the responsible physician.

I hereby agree that pseudonymised sample material may be used for in-house quality assurance (if the box is not ticked, it will be treated as 'no'). ☐ yes ☐ no

I hereby agree that results from follow-up tests may be sent to the laboratory in writing and may be stored and processed by the laboratory (if the box is not ticked, it will be treated as 'no'). ☐ yes ☐ no

Place, date

X

Signature of the patient

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.

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