Krankenkasse bzw. Kostenträger

Name, Vorname und Adresse des Versicherten

geb. am

Kassen-Nr. | Versicherten-Nr. | Status

Betriebsstätten-Nr. | Arzt-Nr. | Datum

harmony PRENATAL TEST

cenata
Cenata GmbH
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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: __.__.__ 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

Harmony® Test variants

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

Additional options

selectable only together with a Harmony® Test variant

☐ + Determination of fetal sex	+ 19 €
☐ + Analysis of sex chromosomal aneuploidies [1]	+ 69 €

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

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 physician 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 (GenDG). 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. Following the GenDG 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 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 passed to me solely by the responsible physician.

Place, date

X

Patient's signature

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

☐ ja ☐ nein

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.

Information about payment
see back

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harmony
PRENATAL TEST

Preferred form of payment (please only choose one option)

SEPA direct debit permission / credit card

☐ 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 [4]
- ☐ Mastercard
- ☐ VISA
- ☐ American Express

Card number ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

Exp. date: ☐☐/☐☐

check digit (3 to 4 digits) ☐☐☐☐

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. Once the payment is processed you will receive an invoice via post.

Alternate invoice address

_____

X _____
Signature of the account / card holder

[4] *Exclusively for the purpose of invoicing and accounting*

OR

Joint invoice according to GOÄ

If this billing option is selected, the services of Cenata GmbH and the treating doctors office will be billed subsequently by a billing service.

☐ joint settlement according to GOÄ

Services in the doctor's office

Please check at least one service

Number	Digit		Cost € (Factor)*	Date	diff. Factor**
1	☐	Initial consultation, simple	10,72 € (2,3)		
3	☐	Consultation more than 10 min.	20,11 € (2,3)		
1	☐	2. consultation, simple	10,72 € (2,3)		
3	☐	2. consultation more than 10 min.	20,11 € (2,3)		
21	☐	Human genetic counseling	48,26 € (2,3)		
34	☐	Detailed report discussion	40,22 € (2,3)		
250	☐	Blood collection	4,20 € (1,8)		
415	☐	Ultrasound pregnancy	40,22 € (2,3)		
403	☐	US transcavitary surcharge	15,74 € (1,8)		
1006	☐	Malformation ultrasound	110,75 € (1,0)		
___	☐	Other services			

* The stated costs correspond to the stated increase factor.

** If the increase factor differs, please note this.

The indication of the treatment date for the various services is mandatory. According to the GOÄ, the consultation numbers 1, 3, 21 and 34 require different treatment dates.

I agree to the forwarding of the laboratory samples and the passing on of personal data required for the purpose of diagnostic laboratory medicine by my consultant physician to Cenata GmbH - hereinafter referred to as laboratory.
Furthermore, I agree to the passing on of information and especially of information taken from the patients files (name, date of birth, address, diagnosis, examination and treatment data) for the purpose of accounting and joint invoicing from medical and laboratory services as well as to the assignment of claims for purpose of accounting and invoicing to the Privatärztliche Verrechnungsstelle Baden-Württemberg eG (short: PVS BW), Bruno- Jacoby-Weg 11, 70597 Stuttgart.
I agree that PVS BW will invoice services of my chosen consultant physician in own name and will collect these to own account. Should there exist differing opinions about validity of claims I also agree to passing on of additionally required data taken from the patients' files for the purpose of justification of claims.
I discharge my physician and the employees of the laboratory from their legal duty of confidentiality, insofar as this is necessary for joint invoicing and assertion of the claim by PVS BW eG. This declaration also applies for claims resulting of future treatment(s). The declaration of agreement towards the physicians or the PVS BW may be revoked at any time, in written form.

_____
Place, date

X _____
Signature of the patient

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Dr. med. Kai Lüthgens

Medical Directors
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