

Krankenkasse bzw. Kostenträger		
Name, Vorname und Adresse des Versicherten		
geb. am		
Kassen-Nr.	Versicherten-Nr.	Status
Betriebsstätten-Nr.	Arzt-Nr.	Datum



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PRENATAL TEST

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

Coverage provider: IGeL Private health insurance

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 will 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: []

Required material: 2 x 8 mL blood, cfDNA tubes	IGeL ¹	private health ¹ insurance
<input type="checkbox"/> Trisomy 21	169,00 €	194,39 €
<input type="checkbox"/> Trisomy 21, 18, 13	199,00 €	224,55 €
<input type="checkbox"/> + Determination of fetal sex ²	17,49 €	20,11 €
<input type="checkbox"/> + Analysis of sex chromosomal aneuploidies ³	69,00 €	77,08 €

¹ Invoicing is based on the German fee schedule for physicians (GOÄ) according to the insurance status.

² Only in combination with Trisomy 21, 18, and 13

³ Monosomy X, Klinefelter, Triple-X, XYY, and XYY syndrome (only for singleton pregnancies and in combination with Trisomy 21, 18, and 13)

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 physician in plain text: []



Signature of the requesting physician

Place, date

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 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



Signature of the patient

Phone number or email address of the patient

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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Preferred form of payment (please select only 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 mail.

Alternate invoice address

X

Signature of the patient / account / card holder

⁴ Exclusively for the purpose of invoicing and accounting

OR

Joint invoice according to German fee schedule for physicians (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	<input type="checkbox"/> Initial consultation, simple	10,72 € (2,3)	_____	_____
3	<input type="checkbox"/> Consultation more than 10 min.	20,11 € (2,3)	_____	_____
1	<input type="checkbox"/> 2. consultation, simple	10,72 € (2,3)	_____	_____
3	<input type="checkbox"/> 2. consultation more than 10 min.	20,11 € (2,3)	_____	_____
21	<input type="checkbox"/> Human genetic counseling	48,26 € (2,3)	_____	_____
34	<input type="checkbox"/> Detailed report discussion	40,22 € (2,3)	_____	_____
250	<input type="checkbox"/> Blood collection	4,20 € (1,8)	_____	_____
415	<input type="checkbox"/> Ultrasound pregnancy	40,22 € (2,3)	_____	_____
403	<input type="checkbox"/> US transcavitary surcharge	15,74 € (1,8)	_____	_____
1006	<input type="checkbox"/> Malformation ultrasound	110,75 € (1,0)	_____	_____
_____	<input type="checkbox"/> 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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