The Harmony® Test compared to other prenatal testing methods

The Harmony® Test allows the detection of the most common chromosomal disorders in the unborn child by taking a sample of the mother's blood. Unlike invasive methods, the Harmony® Test carries no risk of miscarriage. Especially for a fetal trisomy 21, the informative value of the Harmony® Test is far higher than other methods such as First Trimester Screening.

	Type of test	Risk of miscarriage	Detection rate trisomy 21
Non-invasive	harmony PRENATAL TEST Analysis of fetal DNA in the maternal blood	0%	99.5%
	First Trimester Screening	0%	85 - 90%
Invasive	Chorionic villus sampling, amniocentesis	0.1%	Close to 100%

Test variants

Trisomy 21, 18, 13	1
Trisomy 21, 18, 13 and X/Y analysis*	2

Additional options

- ⊕ DiGeorge syndrome (Microdeletion 22q11.2)
- ⊕ Fetal sex determination

* Monosomy X, Klinefelter syndrome, Triple X syndrome, XYY and XXYY syndrome.

Invoices are issued according to the German Scale of Medical Fees (GOÄ).A number of public health insurance plans do not currently cover the cost of the Harmony® Test, or only with prior authorization. Private health insurance plans often cover the costs of the Harmony® Test; however, we recommend that you do inquire about reimbursement prior to ordering the test. All of the necessary forms can be downloaded from our website (www.cenata.de/en). In addition to the costs for the Harmony® Test itself, your physician will provide services associated with the Harmony® Test (counseling, blood draw, examination). Please enquire at your physician beforehand about the costs of these services.

Results
on average in
3 working days*

*after the sample is received by the laboratory

harmony
PRENATAL TEST

cenata
safe method. secure result.

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harmony
PRENATAL TEST

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Highly sensitive, non-invasive test for the detection of fetal chromosomal abnormalies

For expectant parents

What is the Harmony® Test?

The Harmony® Test is a non-invasive method for the detection of fetal trisomies in the unborn child, based on the analysis of the genetic material (fetal DNA) that circulates in the mother's blood. The Harmony® Test is an early and reliable prenatal screening test for the most common chromosomal disorders. It can be performed using the mother's blood after completion of the 10th week of gestation.

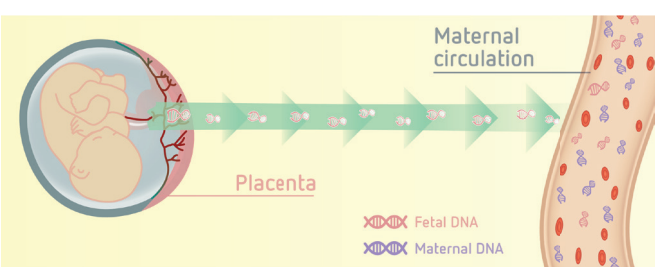
In chromosomally healthy fetuses, the genetic information is stored in 23 pairs of chromosomes. A trisomy is a chromosomal disorder in which a certain chromosome occurs three times instead of twice.

Trisomy 21 is the most common form of a chromosomal disorder at birth. It occurs in approximately one out of every 830 newborns. The probability of its occurrence depends to a large extent on the age of the mother. A trisomy 21 leads to "Down syndrome", which can cause mild to moderate mental disability as well as other illnesses such as congenital heart diseases. The average life expectancy of affected persons today is around 60 years.

Trisomy 18 causes "Edwards syndrome". This trisomy appears in approximately one out of every 5,000 newborns. Trisomy 13 ("Patau syndrome") affects approximately one out of every 16,000 newborns. Both trisomies are associated with a high rate of miscarriage. Affected children suffer from several disorders simultaneously, including serious heart diseases. The mean life expectancy of babies affected by a trisomy 18 or 13 is only a few months and they rarely survive their first year of life. The risk for both trisomies also depends on the age of the mother.

What is cell-free fetal DNA?

DNA (genetic material) passes from the placenta to the mother's blood and can be analysed for chromosomal disorders using the Harmony® Test. Although highly accurate, the Harmony® Test still must be regarded as a screening test in which false positive and false negative cases can occur.



Performance appraisal of the Harmony® Test

The Harmony® Test is a non-invasive test to detect fetal trisomies 21, 18, 13, and sex chromosomal disorders. The test can be performed after the 10th week of pregnancy and has no risk of a procedure-related miscarriage.

High detection rate

99.5% detection rate for trisomy 21 in published studies

No other NIPT method has been investigated as intensely in clinical studies as the Harmony® Test. If one summarises all studies published on singleton pregnancies, the Harmony® Test has a detection rate of 99.5% for trisomy 21.

Low false positive rate

only 0.06% for trisomy 21

In one of the largest studies on NIPT (NEXT study) performed to date, exact data on the false positive rate of the Harmony® Test was determined. Of 18,955 pregnancies with a normal risk, the false positive rate (positive results that were not confirmed by invasive testing or after birth) of the Harmony® Test was only 0.06% for a trisomy 21. For trisomies 18 and 13 it was even lower (0.02% and 0.01% respectively). Please note that the Harmony® Test's false positive rate for sex chromosomal disorders is slightly higher.

High success rate

only 1.6% of unanalysable samples, after repetition only 0.6%

The Harmony® Test is characterised by a high success rate. According to our own data, 98.4% of the tests are successful at the first attempt. These findings have been confirmed and published by an independent investigation of Prof. Nicolaides (London).

Highly qualified team of physicians

specialists in human genetics, laboratory medicine, and obstetrics

Cenata comprises a team of qualified doctors, including specialists in human genetics, laboratory medicine, and obstetrics and gynaecology, for diagnosis and counseling.

Examination procedure

1. Patient requests the Harmony® Test
2. Genetic counseling by obstetrician / human geneticist
3. Blood sample taken
4. Doctor & patient complete the request form
5. Sending of the sample
6. Harmony® Test is performed
7. Data analysis and report creation by medical doctors
8. Result is sent to the requesting physician
9. Costs billed to patient's account (only for a successful test) and payment receipt is sent to the patient
10. Doctor reports findings to patient including genetic counseling

Applications of the Harmony® Test

The Harmony® Test can be applied for all singleton or twin pregnancies, irrespective of the manner of conception or origin of the ovum. Cenata must be informed about an egg donation when the test is requested. If an egg donation is kept secret, the Harmony® Test is not able to deliver a result. In case of more than 2 fetuses or a vanishing twin, the Harmony® Test can not be performed.

	Singleton pregnancy	Twin pregnancy	More than two fetuses	Vanishing twin
Trisomy 21, 18, 13	✓	✓	X	X
X/Y chromosomal disorders	✓	X	X	X
DiGeorge-syndrome (Microdeletion 22q11.2)	✓	X	X	X
Fetal sex determination	✓	✓	X	X