Examination procedure

- Patient requests the Harmony® Test
- Genetic counseling by obstetrician/human geneticist
- Blood sample is taken
- Physician & patient complete the request form
- Transport of the sample to the lab
- Harmony® Test is performed
- Data analysis and report creation
- Result is sent to the requesting physician
- Costs billed to patient's account (only for a successful test) and payment receipt is sent to the patient
- Physician reports findings to patient including genetic counseling

References

[1] Stokowski R, Wang E, White K, Batey A, Jacobsson B, Brar H, Balanarasimha M, Hollemon D, Sparks A, Nicolaides K, Musci TJ.: Clinical performance of non-invasive prenatal testing (NIPT) using targeted cell-free DNA analysis in maternal plasma with microarrays or next generation sequencing (NGS) is consistent across multiple controlled clinical studies. Prenat Diagn. 2015 Sep 1.

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harmony
PRENATAL TEST

DAkkS
Deutsche Akkreditierungsstelle
D-ML-21205-01-00

Accredited according to DIN EN ISO 15189

cenata
safe method. secure result.

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Vm05-V12-20251112

harmony
PRENATAL TEST

For expectant parents

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

False positive rate of 0.04% for trisomy 21

cenata

Test variant and additional options

The Harmony® Test is available with three additional options.

- ✓ Trisomy 21, 18, 13

Additional options

- ⊕ Fetal sex determination
- ⊕ X/Y analysis*
- ⊕ Microdeletion 22q11.2 (DiGeorge syndrome)

Please note that your physician can demand fees associated with the Harmony® Test (e.g. advice, taking a blood sample). You can inquire about the costs incurred for this in advance. According to the German Genetic Diagnostics Act, the fetal sex will be communicated from week 14+0 (p.m.). Under certain conditions reimbursement by statutory health insurance companies.

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

What is the Harmony® Test?

The Harmony® Test is a non-invasive method for detecting certain chromosomal disorders in the unborn child. During pregnancy, fragments of DNA from the placenta are released into the mother's blood. The Harmony® Test examines these free fragments of DNA to determine the risk that the child has trisomy 21, trisomy 18, trisomy 13, or a sex chromosomal (X/Y) disorder. It is an early and reliable prenatal test (NIPT, non-invasive prenatal test), which can be carried out from the 10+0 week of pregnancy using the mother's blood.

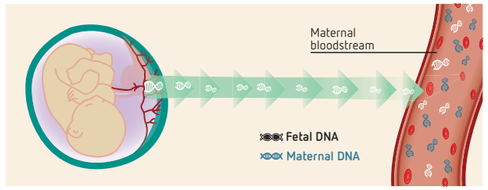
In chromosomally healthy fetuses, the genetic information is stored in 23 pairs of chromosomes. A trisomy is a chromosomal disorder in which a certain chromosome occurs three times instead of twice.

Trisomy 21 is the most common trisomy. It occurs in about 1 in 830 newborns. A trisomy 21 leads to the so-called „Down syndrome", which can cause both mild to moderate mental disability and other diseases, such as congenital heart defects. The average life expectancy of an affected person today is about 60 years. The probability of occurrence depends strongly on the age of the mother.

Another relatively common trisomy is trisomy 18. It causes the so-called "Edwards syndrome". This trisomy occurs in about 1 in 5,000 newborns. Trisomy 13 ("Patau syndrome") affects about one in 16,000 newborns. Both trisomies are associated with a high miscarriage rate. Affected children almost always have several diseases at the same time, including mostly serious heart defects. Their life expectancy is only a few months, and they rarely survive past the first year of life. The risk for both trisomies is also strongly dependent on the age of the mother.

What is cell-free fetal DNA?

DNA from the unborn child passes from the placenta into the mother's blood and can be examined for chromosomal disorders using the Harmony® Test. The proportion of cell-free fetal DNA in the amount of free DNA in the mother's blood is on average approximately 10%.



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The Harmony® Test compared to other prenatal testing methods

Unlike invasive methods, the Harmony® Test does not lead to any risk of miscarriage. Its informative value, especially for trisomy 21, is many times higher than e.g. in the first trimester screening (ultrasound + hormone analysis). However, it cannot replace a detailed ultrasound examination in which structural changes in the unborn child are detected.

	Type of examination	Risk of miscarriage		Detection rate
Non-invasive	harmony PRENATAL TEST Analysis of fetal DNA in the maternal blood	0%	T21	99.3%
			T18	97.4%
			T13	93.8%
	+ First trimester screening	0%	T21	85–90%
			T18	approx. 95%
			T13	approx. 95%
Invasive	Amniocentesis Chorionic villus sampling	0.1%	T21	Close to 100%
			T18	Close to 100%
			T13	Close to 100%

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

99.3% detection rate for trisomy 21 in published studies[1]

The Harmony® Test is one of the clinically most intensly investigated NIPT methods[1,2]. If one summarises the most important studies published, the Harmony® Test has a detection rate of 99.3% for trisomy 21 (trisomy 18: 97.4%, trisomy 13: 93.8%)[1].

Low false positive rate

only 0.04 % for trisomy 21[1]

In a large interdisciplinary analysis[1] exact data on the false positive rate of the Harmony® Test could be determined in an unselected patient collective. The false positive rate for more than 23,155 pregnant women for trisomy 21 is 0.04% (trisomy 13 and trisomy 18: 0.02% each) and thus about 125 times lower than in the first trimester screening which had a false positive rate of about 5%.

Fast results

on average 3 working days

Due to its unique technology, the Harmony® Test is characterized by a short analysis time. After the blood sample arrives at our lab, the result is usually available in 2-4 working days.

HIghly qualified team

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.

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 egg. In the case of egg donation, the information provided on the request form is a prerequisite for obtaining a test result. The Harmony® Test can not be performed if there are more than 2 fetuses. In the case of a vanishing twin, we recommend performing the Harmony® test no earlier than the 15th week of pregnancy, or at least eight weeks after the death of the second fetus[4]. This is because the placenta of the deceased twin often persists for several weeks, continuing to release cell-free DNA.

	Singleton pregnancy	Twin pregnancy	More than 2 fetuses
Trisomy 21, 18, 13	√	√	X
Fetal sex determination	√	√	X
X/Y analysis*	√	X	X
Microdeletion 22q11.2	√	X	X

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

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