Zentrum für Humangenetik
Tübingen

harmony
PRENATAL TEST

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

For expectant parents

Test variants

The Harmony® Test is available in two test variants with two additional options.

Variants

Trisomy 21	169,00 EUR
Trisomy 21, 18, 13 *	199,00 EUR

Additional options

X/Y-chromosomal disorders **	69,00 EUR
Fetal sex determination	17,49 EUR

Billing is according to GOÄ. For privately insured patients, the 1.15-fold increase rate applies. The prices are only valid for Germany and may vary in other countries. 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.

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

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.

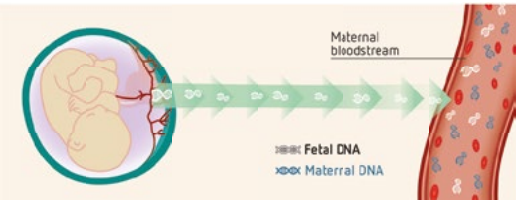
In chromosomally healthy fetuses, the genetic information is stored in **23 pairs of chromosomes**. A trisomy is a chromosomal disorder in which a certain chromosome occurs three times instead of twice.

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%.



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

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 has 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

of doctors and scientists

Zentrum für Humangenetik Tübingen brings together a team of qualified specialists and scientists for the interpretation of findings and medical advice.

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. In case of more than two fetuses or a vanishing twin, the Harmony® Test can not be performed.

	One fetus	Twins	3 or more fetuses	Vanishing twin
Trisomy 21	✓	✓	✗	✗
Trisomy 21, 18, 13	✓	✓	✗	✗
X/Y-chromosomal disorders*	✓	✗	✗	✗
Fetal sex determination	✓	✓	✗	✗

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

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 micro-arrays or next generation sequencing (NGS) is consistent across multiple controlled clinical studies. Prenat Diagn. 2015 Sep 1.

[2] Norton ME, Jacobsson B, Swamy GK, Laurent LC, Ranzini AC, Brar H, Tomlinson MW, Pereira L Spitz JL, Hollemon D, Cuckle H, Musci TJ and Wapner RJ (Next-Study): Cell-free DNA Analysis for Noninvasive Examination of Trisomy. N Engl J Med. 2015, Apr 1.

[3] Bianchi DW, Rava RP, Sehnert AJ: DNA sequencing versus standard prenatal aneuploidy screening.N Engl J Med. 2014 Aug 7;371(6):578. doi: 10.1056/NEJMc1405486.

About us

Since 2010 we are supporting patients and doctors in clarifying genetic issues. Our interdisciplinary team, which now has more than 150 colleagues, is specialized in the diagnosis of genetic diseases.

„Zentrum für Humangenetik Tübingen“ (Center for Human Genetics Tuebingen) offers all relevant prenatal genetic tests. Depending on the issue, the most modern sequencing technologies as well as microarrays or MLPA examinations are used. Our competent team of consultants will support you in all situations concerning genetic diagnostics. We are looking forward to your inquiry.

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