Examination procedure

- Patient requests the Harmony® Test
- Genetic counseling by obstetrician / human geneticist
- Blood sample taken
- Doctor & patient complete the request form
- Sending of the sample
- Harmony® Test is performed
- Data analysis and report creation by medical doctors
- 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
- Doctor 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.

[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.

harmony
PRENATAL TEST

cenata
safe method. secure result.

Cenata GmbH
Paul-Ehrlich-Str. 23
D-72076 Tübingen
Tel.: 0049 7071 565 44 430
Fax: 0049 7071 565 44 444
www.cenata.de/en
info@cenata.de

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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 variants

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

- Trisomy 21, 18, 13
- Trisomy 21, 18, 13 and X/Y analysis*

Additional option

- ⊕ Fetal sex determination

A number of public health insurances do not currently cover the cost of the Harmony® Test, or only with prior authorization. Private health insurances often cover the costs of the Harmony® Test; however, we recommend that you do inquire about reimbursement prior to ordering the test. 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.

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

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.

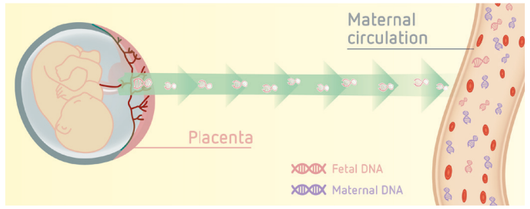
The Harmony® Test compared to other prenatal testing methods

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 (ultrasound + hormone analysis).

	Type of test	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 ca. 95 % T13 ca. 95 %
Invasive	Chorionic villus sampling, amniocentesis	0.1 %	T21 Close to 100 % T18 Close to 100 % T13 Close to 100 %

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

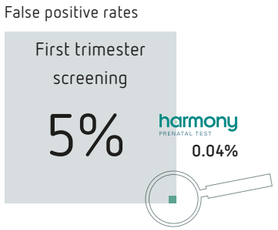
99.3% detection rate for trisomy 21 in published studies [1]

No other NIPT method has been investigated as intensely in clinical studies as the Harmony® Test [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%.



Highly qualified teams 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.

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 two fetuses or a vanishing twin, the Harmony® Test can not be performed.

	Singleton pregnancy	Twin pregnancy	> 2 fetuses	Vanishing Twin
Trisomy 21, 18, 13	√	√	X	X
Trisomy 21, 18, 13 and X/Y analysis*	√	X	X	X
Fetal sex determination	√	√	X	X

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