Advantages of the Harmony® technology

- Exact determination of the proportion of fetal DNA by **SNP analysis**.
- DANSR™ technology specifically examines fragments of the chromosomes that are of interest. This enables a **targeted, in-depth chromosome analysis** - for clear results.
- Even with a **low fetal fraction**, the FORTE™ algorithm **accurately** distinguishes between high and low risk results.
- Consideration of maternal risk factors leads to an **individual risk calculation** for each patient.

harmony
PRENATAL TEST

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D-ML-21205-01-00

Accredited according to DIN EN ISO 15189

cenata
safe method. secure result.

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Medical information

Non invasive test for the prenatal detection of the most common chromosomal disorders

False positive rate of 0.04% for trisomy 21

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)

Applications of the Harmony® Test

	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.

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

The Harmony® Test compared to other prenatal testing methods

	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

The Harmony® Test is a non-invasive prenatal screening test (NIPT) to detect fetal chromosomal disorders from maternal blood. The chromosomal disorders trisomy 21, 18, and 13, sex chromosomal disorders, and fetal sex can be determined with the test. The Harmony® Test can be performed after the 10th week of pregnancy and unlike invasive methods there is no risk of a procedure-related miscarriage.

Excellent detection rate

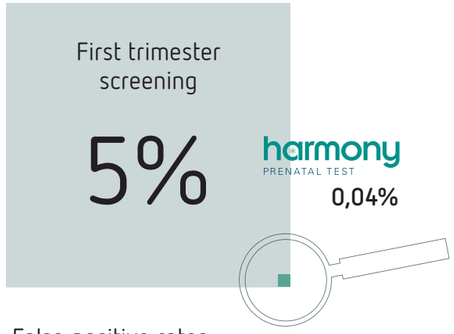
99.3% detection rate for trisomy 21 in published studies[1]

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%.



False positive rates

Highly qualified team

of physicians and scientists

Cenata is comprised of a team of qualified physicians, including specialists in human genetics, laboratory medicine, and obstetrics and gynaecology. Our team is at your disposal for all questions related to prenatal diagnosis, NIPT, and the interpretation of the Harmony® Test results.

Fast reporting of results

on average 3 working days

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

Limitations of the Harmony® Test

Vanishing twin, malformations, genetic mosaics, translocations

Most of the serious diseases in unborn children are not caused by chromosomal abnormalities[9]. **Therefore, a NIPT cannot replace an ultrasound examination of the fetus.** The detection rate of the Harmony® test is limited in cases of chromosomal mosaicism and translocations. The Harmony® test has not been validated for use in pregnant women with active tumour disease, following allogeneic stem cell transplantation or in the presence of maternal chromosomal abnormalities, and cannot be performed in these cases.
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[10]. This is because the placenta of the deceased twin often persists for several weeks, continuing to release cell-free DNA.

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