Cenata GmbH, Paul-Ehrlich-Str. 23, 72076 Tübingen

ALFA Diagnostica SRL
N.TESTEMITANU STREET 29/5
MD2025 CHISINAU
Moldawien

Cenata GmbH
Paul-Ehrlich-Str. 23
72076 Tübingen
Tel: +49 (0)7071 565 44 430
Fax: +49 (0)7071 565 44 444
info@cenata.de
www.cenata.de

Date of medical report Feb 25, 2026

Medical report - Harmony® Prenatal Test

PATIENT NAME:		**DATE OF BIRTH:**	
LAB No.:		**YOUR NUMBER:**	
COLLECTION DATE:		**PATIENT AGE:**	
DATE OF SAMPLE ENTRY:		**BODY WEIGHT:**	
GESTATIONAL AGE:			
# OF FETUSES:			
IVF STATUS:		**PRIMARY SAMPLE:**	cfDNA blood collection tube

Test Results

Harmony® Test: Unsuspicious

		Results	Normal Range
	Fetal cfDNA Percentage	11.0%	≥4%
1	Probability for trisomy 21	low risk (<0.01%)	<1%
2	Probability for trisomy 18	low risk (<0.01%)	<1%
3	Probability for trisomy 13	low risk (<0.01%)	<1%
4	Probability of sex chromosome aneuploidies	low risk (<0.01%)	<1%
	Sex chromosome analysis	XY	
5	Fetal Sex	male	

Interpretation

The Harmony® Test is a highly accurate screening test for fetal chromosomal abnormalities. The test is not validated as a diagnostic procedure. False-positive and false-negative results can, though relatively rarely, occur. The Harmony® Test is not validated for use in pregnancies with more than two fetuses, vanishing twin syndrome, chromosomal mosaicism, partial chromosomal aneuploidy, translocations, maternal aneuploidy, post-transplant state, or active cancer. The test was performed by Cenata GmbH, Tübingen, Germany.

1. **Unsuspicious finding with low risk for the presence of a trisomy 21.** The detection rate of the Harmony® Test for a fetal trisomy 21 is > 99% at a false-positive rate of 0.04% (n = 23,155) (Stokowski et al., Prenat. Diagn. 2015;35:1243–1246).
2. **Unsuspicious finding with low risk for the presence of a trisomy 18.** The detection rate of the Harmony® Test in singleton pregnancies for a fetal trisomy 18 is 97.4% at a false-positive rate of 0.02% (n = 22,399) (Stokowski et al., Prenat. Diagn. 2015; 35: 1243–1246). For twin pregnancies, the detection rate of the Harmony® test for trisomy 18 is 92.8% at a false positive rate of 0.01% (n = 6,840) (Judah et al., Ultrasound Obstet Gynecol. 2021; 58:178–189).

Cenata GmbH, Paul-Ehrlich-Str. 23, 72076 Tübingen

ALFA Diagnostica SRL
N.TESTEMITANU STREET 29/5
MD2025 CHISINAU
Moldawien

Cenata GmbH
Paul-Ehrlich-Str. 23
72076 Tübingen
Tel: +49 (0)7071 565 44 430
Fax: +49 (0)7071 565 44 444
info@cenata.de
www.cenata.de

Date of medical report Feb 25, 2026

Medical report - Harmony® Prenatal Test

PATIENT NAME:	**DATE OF BIRTH:**
LAB No.:	**YOUR NUMBER:**
COLLECTION DATE:	**PATIENT AGE:**

3 **Unsuspicious finding with low risk for the presence of a trisomy 13.** The detection rate of the Harmony® Test for a fetal trisomy 13 in singleton pregnancies is about 93.8% at a false-positive rate of 0.02% (n = 14,243) (Stokowski et al., Prenat. Diagn. 2015;35:1243–1246). For twin pregnancies, the detection rate of the Harmony® test for trisomy 13 is 94.7% at a false positive rate of 0.10% (n = 6,290) (Judah et al., Ultrasound Obstet Gynecol. 2021; 58:178–189).

4 **Unsuspicious finding. No increased risk for the presence of an X/Y-chromosomal disorder.** The detection rate of the Harmony® test for X /Y-chromosomal aneuploidies is approximately 94% for singleton pregnancies (Hooks et al, Prenat. Diagn. 2014; 34:496-499; Nicolaides et al, Fetal Diagn. Ther. 2014; 35: 1-6.) at a false-positive rate of 0.14% (n=61606) (Lüthgens et al., Prenat. Diagn. 2021; 41: 1258- 1263).

5 The fetal sex analysis determines the presence of Y-chromosomal cell-free DNA sequences. A “female” result indicates the absence of a Y chromosome and a “male” result indicates the presence of a Y chromosome. In the present test Y-chromosomal sequences could be detected in the maternal blood, which indicates that the fetus is male. The accuracy of the fetal sex determination is > 99% (95%-CI: 99.2 - 100%). The fetal sex test does not exclude sex chromosome aneuploidy.

For any inquiries please contact us per email (info@cenata.de) or phone under the number +49 (0)7071 565 44 430.

Validated by

Dr. med. Erkan Koparir

M. Sc. Wenying Tao