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 17, 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: Suspicious

		Results	Normal Range
	Fetal cfDNA Percentage	14.2%	≥4%
1	**Probability for trisomy 21**	**high risk (>99%)**	<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	XX	
5	Fetal Sex	female	

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 **The result indicates a high risk for a fetal trisomy 21.** The probability result reported is not equivalent to the PPV (positive predictive value) for the presence of the aneuploidy. Based on the performance values of the Harmony® Test (sensitivity 99.3%, specificity 99.96%), the age-adjusted PPV is 97%. The PPV indicates the probability that a trisomy 21 is present in the fetus. Please note that the PPV is conditional on prior risk factors. If an ultrasound examination indicated an increased risk for trisomy 21 or if other reasons for an increased trisomy 21 probability exist (such as trisomy 21 in a previous pregnancy), the PPV is significantly increased. Further investigation by means of an invasive procedure (CVS/amniocentesis) and subsequent chromosome analysis is recommended. We recommend the communication of the findings in the context of detailed genetic counseling.

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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).

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 no Y-chromosomal sequences could be detected in the maternal blood, which indicates that the fetus is female. 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

Christian Kempf
resident physician