Warde Medical Laboratory

# LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

**EXAMPLE, REPORT W**
WX0000003826 F 12/05/1988 34 Y

## Non-invasive Prenatal Testing (NIPT)

Collected: 09/11/2023 13:32 Received: 09/11/2023 13:32

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| **Panorama Prenatal Screen** | | | | | |
| Is the patient pregnant? | Yes | | | | NTRA |
| Expected Due Date (MM/DD/YYYY) | 01/01/2024 | | | | NTRA |
| Is this an in-vitro fertilized pregnancy? | No | | | | NTRA |
| Is this a twin pregnancy? | Twin Pregnancy, Dichorionic | | | | NTRA |
| I want gender results included in this report. | Yes | | | | NTRA |
| Maternal Weight (in pounds) | 150 | | | | NTRA |
| What type of billing? | Bill Insurance | | | | NTRA |
| **Final Results Summary** | | | | | |
| Report Summary | SEE BELOW | | | | NTRA |

```
Natera Case Number:

Report Summary: LOW RISK

LOW RISK

Report Note: See Notes

Trisomy 13 Age-Based Risk: <1/10,000 (<0.01%)

Trisomy 13 Risk Score: <1/10,000 (<0.01%)

Trisomy 13 Result: Low Risk

Trisomy 18 Age-Based Risk: 1/6,548 (0.02%)

Trisomy 18 Risk Score: <1/10,000 (<0.01%)

Trisomy 18 Result: Low Risk

Trisomy 21 Age-Based Risk: 1/2,815 (0.04%)

Trisomy 21 Risk Score: <1/10,000 (<0.01%)

Trisomy 21 Result: Low Risk

Monosomy X Age-Based Risk: 1/759 (0.13%)

Monosomy X Risk Score: <1/10,000 (<0.01%)

Monosomy X Result: Low Risk
```

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

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Zygosity: Monozygotic

Sex of Fetus: Male

Gender of Second Fetus: Male

Fetal Fraction: 7.6%

Footnotes: See Notes
Testing Methodology
DNA isolated from the maternal blood, which contains placental DNA, is amplified at specific loci using a targeted PCR assay and is sequenced using a high-throughput sequencer. Fetal fraction is determined using a proprietary algorithm incorporating data from single nucleotide polymorphism-based (SNP-based) next-generation sequencing [Pergament E et al. Obstet Gynecol. 2014 Aug;124(2 Pt 1):210-8]. If the estimated fetal fraction is 2.8%, sequencing data is analyzed using a proprietary SNP-based algorithm to determine the fetal copy number for chromosomes 13, 18, 21, X and Y [Ryan A et al. Am J Obstet Gynecol. 2014 Nov;211(5):527.e1-527.e17]. If ordered, specific microdeletions will be evaluated using similar methodology [Wapner RJ et al. Am J Obstet Gynecol. 2015 Mar;212(3):332.e1-9]. If a sample fails to meet the quality threshold, or the fetal fraction is insufficient, an additional algorithm is utilized to determine whether there is an increased risk for triploidy, trisomy 18 and trisomy 13 [McKanna et al. The European Human Genetics Conference. Copenhagen, Denmark. May 27-30, 2017]. However, some samples will not produce a result due to failure to meet the necessary quality thresholds.
This test has been validated on women with a singleton, twin or egg donor pregnancy of at least nine weeks gestation. A result will not be available for higher order multiples and multiple gestation pregnancies with an egg donor or surrogate, or bone marrow transplant recipients. Complete test panel is not available for twin gestations and pregnancies achieved with an egg donor or surrogate. For twin pregnancies with a fetal fraction value below the threshold for analysis, a sum of the fetal fractions for both twins will be reported. Findings of unknown significance will not be reported. As this assay is a screening test and not diagnostic, false positives and false negatives can occur. High risk test results need diagnostic confirmation by alternative testing methods. Low risk results do not fully exclude the diagnosis of any of

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the syndromes nor do they exclude the possibility of other chromosomal abnormalities or birth defects, which are not a part of this test. Potential sources of inaccurate results include, but are not limited to, mosaicism, low fetal fraction, limitations of current diagnostic techniques, or misidentification of samples. This test will not identify all deletions associated with each microdeletion syndrome. This test has been validated on full region deletions only and may be unable to detect smaller deletions.
Microdeletion risk score is dependent upon fetal fraction, as deletions on the maternally inherited copy are difficult to identify at lower fetal fractions. Test results should always be interpreted by a clinician in the context of clinical and familial data with the availability of genetic counseling when appropriate.
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Disclaimers
The extraction, library preparation, and sequencing of this test were performed by NSTX, Inc., 13011 McCallen Pass Building A Suite 100, Austin, TX 78753 (CLIA ID 45D2093704). The data analysis and reporting of this test were performed by Natera, Inc., 201 Industrial Rd. Suite 410, San Carlos, CA 94070 (CLIA ID 05D1082992). The performance characteristics of this test were developed by NSTX, Inc.(CLIA ID 45D2093704). This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). These laboratories are regulated under CLIA as qualified to perform high-complexity testing.

Please refer to the attached PDF report
Reviewed By: Wenbo Xu, M.D., Ph.D., FACMG, Senior Laboratory Director
CLIA Lab Director: J. Dianne Keen-Kim, Ph.D., FACMG
IF THE ORDERING PROVIDER HAS QUESTIONS OR WISHES TO DISCUSS THE RESULTS, PLEASE CONTACT US AT 650-249-9090 #3. Ask for the NIPT genetic counselor on call.

**Reported Date:** 2023.09.11 13:32 PAN