## Patient and Provider Information

| | Clinic/Hospital Name | | Referring Clinician |
|---|---|---|---|
| | Prom-Test LLC | | |
| | Gestational Age | EDC | Insurance ID (if relevant) |
| | | | |
| | | Sample Type | |
| | | Blood | |

NIFTY® is a screening test. Genetic counselling and diagnostic testing should be offered to further evaluate these findings.

## Results

**Fetal Fraction:** 22.70% **(≥3.5%)**

| Test Name | Result | Reference Interval | Probability | Note |
|---|---|---|---|---|
| Trisomy 21 | Low risk | Low risk | 1/1131227681 | Please review with physician |
| Trisomy 18 | Low risk | Low risk | 1/7918119550 | Please review with physician |
| Trisomy 13 | Low risk | Low risk | 1/1226096878 | Please review with physician |

## Other Findings

| Rare Autosomal Aneuploidies | Result | Note |
|---|---|---|
| Trisomy 9 | Low risk | Please review with physician |
| Trisomy 16 | Low risk | Please review with physician |
| Trisomy 22 | Low risk | Please review with physician |
| **Sex Chromosomal Aneuploidies** | **Result** | **Note** |
| Monosomy X (XO) | Not detected | Please review with physician |
| XXY | Not detected | Please review with physician |
| XXX | Not detected | Please review with physician |
| XYY | Not detected | Please review with physician |
| **Microdeletions/duplications (84 types)** | Not detected | |
| **Incidental Findings** | Not detected | |

**Test Description:** The NIFTY Pro™ test is a screening test and is not diagnostic. It works by isolating the cfDNA (including both maternal and fetal DNA) from a materna blood sample and performing low coverage whole genome sequencing using Next Generation Sequencing technology. The unique reads of each chromo-some ar calculated and compared to an optimal reference control sample. Data is analyzed using BGI's proprietary bioinformatics algorithms and an assessment is produced fo the conditions tested only. Tests should always be ordered by a qualified healthcare professional and results reviewed with the patient. The test must not be used as th sole basis for diagnosis or other pregnancy management decision.

**Disclaimer:** The NIFTY Pro™ test is NOT a diagnostic test, the results are for informational use and therefore a false positive and false negative results cannot be excluded. The performance of "Other Findings" has not been fully validated, but the data in the table below can be used for reference. 84 types of del/dup syndromes are detected in this test. Some of the diseases on the list of del/dup syndromes can also be caused by other genetic factors, NIFTY Pro™ only detects an analyzes the specific fragment according to authorized databases. Potential sources of an inaccurate test result may include but are not limited to: maternal, fetal and/o placental mosaicism, low fetal fraction, blood transfusion, transplant surgery, stem cell therapy, heparin therapy and the abnormal karyotype of biological parents o surrogate. Test results are specific to the tested sample and should always be interpreted by a qualified professional in the context of clinical and familial data.

| Condition | Sensitivity | Specificity | PPV | Reference |
|---|---|---|---|---|
| T21 | 99.17% | 99.95% | 92.19% | UltrasoundObstet Gynecol. 2015 May;45(5):530-8. doi: 10.1002/uog.14792. |
| T18 | 98.24% | 99.95% | 76.61% | |
| T13 | >99.9% | 99.96% | 32.84% | |
| CNV | >90% | N/A | N/A | From in-house data. Internal analysis shows a sensitivity of over 90% (cfDNA≥9.5%) in selected del/dup syndromes with abnormal size over 3 Mb. |
| **Condition** | **Detection Rate** | **PPV** | **NPV** | |
| XYY | >99.9% | 50.00% | >99.9% | BMC Med Genomics. 2012 Dec 1;5:57. doi: 10.1186/1755-8794-5-57. UltrasoundObstet Gynecol. 2014 Jul;44(1):17-24. doi: 10.1002/uog.13361. |
| XXY | >99.9% | 42.86% | >99.9% | |
| XXX | >99.9% | 70.00% | >99.9% | |
| XO | >99.9% | 40.00% | >99.9% | |

Note: The data in the table is based on historical literature and internal data, and only reflects past detection, not the actual condition of the tested sample nor the promised value.

Approved by:_____

YUEN Ka Yiu MLT (HK) Registration Number: MT103521

Date:_____

## Patient and Provider Information

| | Clinic/Hospital Name | |
|---|---|---|
| | Prom-Test LLC | |
| Gestational Age | EDC | |
| | | |
| | Sample Type | |
| | Blood | |

NIFTY® is a screening test. Genetic counselling and diagnostic testing should be offered to further evaluate these findings.

| | |
|---|---|
| Y Chromosome | Detected |

**Test Description:** The NIFTY Pro™ test is a screening test and is not diagnostic. Gender identification works by isolating cell free DNA (including both maternal and fetal DNA) from a maternal blood sample, followed by molecular genetic testing to determine the relative quantities of the Y chromosome.

**Disclaimer:** The NIFTY Pro™ test is NOT a diagnostic test, the results are for informational use only. Although the methodology is highly accurate, the test does not provide a result with 100% accuracy. The Y chromosome detection provided in this report cannot be used for diagnosis of fetal sex or gender-related diseases, and is only used as additional information for reference analysis. Potential sources of an inaccurate test result may include but are not limited to: maternal, fetal and/or placental mosaicism, low fetal fraction, blood transfusion, transplant surgery, stem cell therapy, heparin therapy and the abnormal karyotype of biological parents or surrogate. Test result is specific to the tested sample and should always be interpreted by a qualified professional in the context of clinical and familial data.

| Condition | Sensitivity | Specificity | PPV | Reference |
|---|---|---|---|---|
| Fetal Sex | 99.53% | 99.20% | N/A | J MaternFetal Neonatal Med. 2014 Dec;27(18):1829-33. doi: 10.3109/14767058.2014.885942. |

Note: The data in the table is based on historical literature and internal data, and only reflects past detection, not the actual condition of the tested sample nor the promised value.

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