

Patient and Provider Information

Patient ID/Patient Name	Clinic/Hospital Name		Referring Clinician
	Prom-Test LLC		
Date of Birth	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: 18.77% (≥3.5%)

Test Name	Result	Reference Interval	Probability	Note
Trisomy 21	Low risk	Low risk	1/766883	Please review with physician
Trisomy 18	Low risk	Low risk	1/23276174	Please review with physician
Trisomy 13	Low risk	Low risk	1/416655342	Please review with physician

Test Description: The NIFTY® test is a screening test and is not diagnostic. It works by isolating the cfDNA (including both maternal and fetal DNA) from a maternal blood sample and performing low coverage whole genome sequencing using Next Generation Sequencing technology. The unique reads of each chromosome are calculated and compared to an optimal reference control sample. Data is analyzed using BGI's proprietary bioinformatics algorithms' and an assessment is produced for 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 the sole basis for diagnosis or other pregnancy management decision.

Disclaimer: The NIFTY® test is NOT a diagnostic test, the results are for informational use and therefore false positive and false negative results cannot be excluded. Potential sources of an inaccurate test result may include but 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 surrogates. 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	Reference
T21	99.17%	99.95%	UltrasoundObstet Gynecol. 2015 May;45(5):530-8. doi: 10.1002/uog.14792.
T18	98.24%	99.95%	
T13	>99.9%	99.96%	

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. Further information regarding the conditions tested for and support groups can be found at www.niftytest.com.

Approved by:.....

YUEN Ka Yiu MLT (HK) Registration Number: MT103521

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

Y Chromosome	Not detected
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Test Description: The NIFTY® 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® 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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