NON-INVASIVE PRENATAL SCREENING REPORT

PATIENT INFORMATION

Patient's Name:	Jane Doe
Date of Birth:	DD-MM-YYYY
ID Number:	SXXXXXXA
Maternal Age:	32 years
Maternal Weight:	77.1 kg
Gestational Age:	17 weeks 4 days
No. of Foetus:	Singleton
Pregnancy Status:	Natural
LSG Lab Accession ID:	S2022XXXXX
Ref Lab Accession ID:	22-XXXXXXX

PHYSICIAN INFORMATION

Ordering Physician:	Dr. John
Clinic/Hospital:	ABX ObGyn
Address:	123 Hack Street
	Green Building Unit 01-23
	Singapore 330123
Referring Laboratory:	SGIQRefLab
Sample Type:	Whole Blood
Collection Date:	DD-MM-YYYY
Reception Date:	DD-MM-YYYY
Report Date:	DD-MM-YYYY

TEST RESULTS SUMMARY

Overall Risk:
HIGH RISK FOR TRISOMY 21
Genetic counselling & further testing recommended

Foetal Sex:
MALE

ESTIMATED FOETAL FRACTION 4%

Aneuploidies Results Details

CHROMOSOME	BACKGROUND RISK[1]	Vantage® Test RISK SCORE[2]	RISK RESULT
TRISOMY 21 (Down's Syndrome)	1 : 496	Greater than 95%	High Risk
TRISOMY 18 (Edwards' Syndrome)	1 : 1680	Less than 1:1,000,000 (<0.0001%)	Low Risk
TRISOMY 13 (Patau's Syndrome)	1 : 4963	Less than 1:1,000,000 (<0.0001%)	Low Risk
SEX CHROMOSOMAL ANEUPLOIDIES (SCAs)			Low Risk
EXTENDED AUTOSOMAL ANEUPLOIDIES (EAAs)			Low Risk

Microdeletion Results Details

22q11.2 DELETION (DiGeorge Syndrome)	Low Risk
1p36 DELETION (1p36 Deletion Syndrome)	Low Risk
15q11.2 DELETION (Prader-Willi/Angelman Syndrome)[3]	Low Risk
5p DELETION (Cri-du-Chat Syndrome)	Low Risk
4p16.3 DELETION (Wolf-Hirschhorn Syndrome)	Low Risk

[1]Based on maternal age.
[2]Refer to the second page of this report for more details.
[3]Prader-Willi and Angelman syndromes are two distinct clinical disorders associated within the same microdeletion location.

IONA® software version: **TOA**: 2.0.3.1934, **DAA**: 2.0.3.1806

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Medical Director: Dr. Tan Hong Wui | Laboratory Director: Priscillia D. Siswara

The Vantage® Test is a screening test, and the results should be discussed with a healthcare provider in the context of all available clinical findings, including advising for the need for genetic counselling or additional confirmation diagnostic testing (e.g., amniocentesis).

Description of the Test

During pregnancy, the placenta releases cell-free foetal DNA, which circulates in the maternal bloodstream. As a result, a maternal blood sample contains a mixture of placental and maternal circulating DNA. Vantage® directly measures the amount of this cell-free DNA using whole genome shotgun next-generation sequencing (NGS) and can detect small changes in the DNA ratio when a genetic abnormality is present. The Test aids in screening for selected chromosome disorders and determining the sex of the foetus.

The Vantage® Risk Score for Trisomy 13, 18 and 21
The final Vantage® adjusted risk combines the prior (background) risk of a trisomy with a likelihood ratio to generate a final risk score. The likelihood ratio is derived from the relative amounts of chromosomes 21, 18 and 13 in cell-free DNA from a blood sample of a pregnant woman. A risk score greater than or equal to 1:150 (~0.67%) is considered high risk. This risk score is capped based on an estimated prevalence of biological factors such as placental mosaicism. 95% is the maximum risk score estimate displayed on the report.

Sex Chromosome Results (SCAs)
The analysis measures the proportions of the X and Y chromosomes present in cfDNA to infer on sex chromosome aneuploidies (SCAs). A valid result would be either reported as "female" or "male". In the presence of a sex chromosome aneuploidy, results are reported as X0, XXY, XYY, XXX (XYY result indicates two or more foetal Y chromosomes). In the absence of aneuploidy, the results are reported as XX or XY. Sex determination and sex chromosome aneuploidy testing have been validated in singleton and monochorionic twin pregnancies. This analysis is separate from the trisomy analysis and does not reflect on the quality of any other result generated by the Vantage® test.

Extended Autosomal Aneuploidy (EAAs)
The EAAs analysis detects full trisomy and monosomy in the additional 19 human autosomal chromosomes. If Trisomy/Monosomy is detected, the result is displayed as 'High Risk' and the chromosome listed. 'Low Risk' is reported when no Trisomy/Monosomy is detected. This analysis is separate from the trisomy analysis and does not reflect on the quality of the result generated by the Vantage® Test. EAAs have been validated in singleton and monochorionic twin pregnancies.

Microdeletions
The analysis can screen for five clinically relevant microdeletions, or a smaller subset as required, associated with the following six conditions:

- DiGeorge syndrome
- 1p36 deletion syndrome
- Prader-Willi syndrome
- Angelman syndrome
- Cri-du-Chat syndrome*
- Wolf-Hirschhorn syndrome*

If a microdeletion is detected and has been included for analysis, the result is displayed as 'High Risk'. 'Low Risk' is reported when no microdeletion is detected. A 'Low Risk' result does not indicate that the foetus will be free from a genetic microdeletion or associated condition. Foetal fraction must be above 5% to produce a valid result for microdeletion screening. If the foetal fraction is too low, an 'Invalid' result is reported. This analysis is separate from the aneuploidies analysis and does not reflect on the quality of the result generated by the Vantage® test. Microdeletions have been validated in singleton pregnancies and monochorionic twins. Items marked * are not under the SAC Scope of Accreditation.

Foetal Sex Determination
The test uses cfDNA from the Y chromosome to infer on foetal sex with an accuracy of 99%. A "female" result indicates the absence of a Y chromosome, and a "male" result indicates the presence of a Y chromosome. It does not exclude sex chromosome aneuploidy. This is separate from the trisomy analysis and does not reflect on the quality of any other result generated by the Vantage® test. foetal sex determination has been validated in singleton pregnancies and monochorionic twins.

Test Limitations

The Vantage® Test should be considered a **screening** test only. In rare cases, analysis of cfDNA derived from the fetoplacental unit may not correlate with the foetal genotype. The test may be affected by any chromosomal change which affects the genomic ratio. Inaccurate test results or a failure to obtain test results may occur in rare circumstances, which include, but are not limited to, biological factors affecting the mother, including those arising during pregnancy; conditions affecting the pregnancy; improper collection, handling, storage and transportation of the blood samples; and/or pre-existing conditions and medical interventions. This list is inclusive but not exhaustive.

The test does not screen for or rule out the possibility of other genetic conditions, balanced or unbalanced chromosomal abnormalities or mosaic anomalies being present other than those expressly identified in this document. This test is not intended to identify pregnancies at risk for open neural tube defects and is not a replacement for routine pregnancy monitoring. A high-risk result (i.e., a high chance of Down, Edward or Patau syndrome is likely to present) should be considered along with other clinical screening results and may be followed up with an invasive diagnostic procedure (i.e., Amniocentesis or CVS). It is recommended to discuss the results with the relevant healthcare provider.

About this Test

The Vantage® Test is powered by IONA® Nx CE-IVD NIPT Workflow, and its performance is validated by LifeStrands Genomics. This test is performed in a MOH-certified, SAC ISO 15189:2012 and CAP (No. 9084781) accredited laboratory and is intended for clinical purposes. The results reported herein have been performed in accordance with the terms of accreditation under the Singapore Accreditation Council. The IONA® prenatal screening test was developed, and its performance characteristics were determined by Yourgene Health in Manchester, UK. IONA® is a registered trademark of Yourgene Health PLC. Vantage® is a registered trademark of LifeStrands Genomics Pte. Ltd.

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