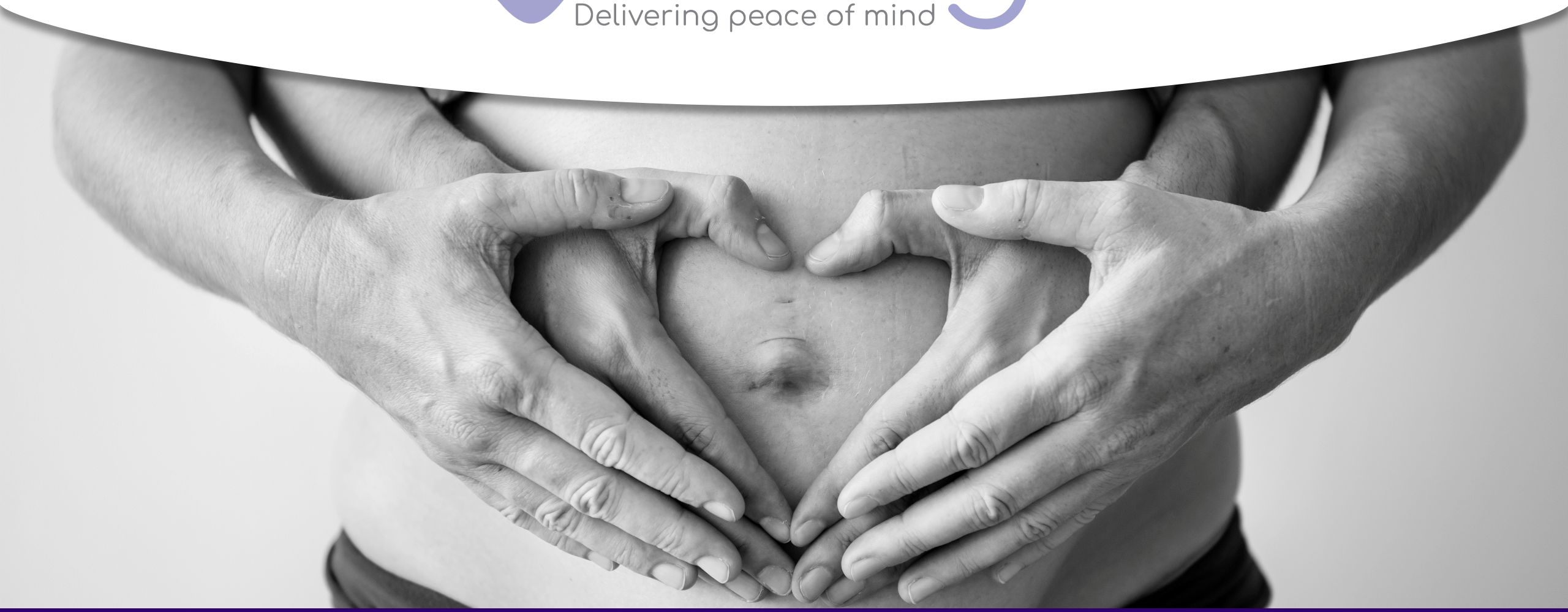
Vantage®

Delivering peace of mind



Enhancing existing prenatal screening pathways with faster, more accurate & reliable results

Obtaining a Vantage® View Safely & Peacefully

An easy, non-invasive blood test delivering faster and accurate results, reducing the need for invasive tests and the associated stress and anxiety.

- ✓ **SAFE:** with no risk of miscarriage
- ✓ **FAST:** results deliverable within four to six working days
- ✓ **ACCURATE:** >99% detection rate for trisomy conditions*
- ✓ **SIMPLE:** uses only a single tube of blood
- ✓ **QUALITY:** CE-IVD workflow; a regulated test

*For Trisomy 21 (Down's Syndrome), 18 (Edwards' Syndrome) and 13 (Patau's Syndrome)

The Technology Behind the Vantage® Test

Powered by IONA® Nx NIPT Workflow*

Employing advanced DNA technology and instrumentation with an **enhanced methodology for the enrichment of foetal fraction** and genomic-wide coverage through Next Generation Sequencing (NGS) with high accuracy and sensitivity.

Efficient Multicore BI Analysis

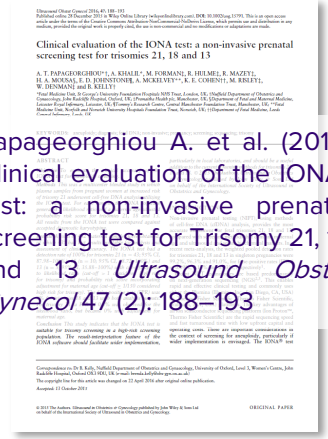
Proprietary, highly efficient multicore bioinformatics analysis software incorporates the background (prior) risk, using maternal age, of an affected pregnancy into its algorithms to give the most accurate result.

Online Secure Delivery Portal

Results and final reports are viewable and accessible through our **highly secured LIMS portal** under strict HIPAA security.

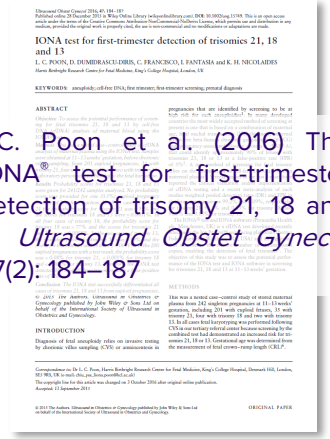
*A CE-IVD diagnostic test developed by Yourgene Health PLC, a molecular diagnostic company from Manchester, UK. IONA® is a registered trademark of Yourgene Health PLC. Vantage® is a registered trademark of LifeStrands Genomics Pte. Ltd.

Clinical Validity of the Core Technology


Clinical evaluation of the IONA test: a non-invasive prenatal screening test for trisomies 21, 18 and 13

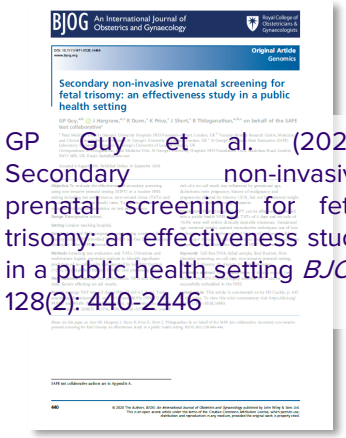
Papageorghiou A. et al. (2015) Clinical evaluation of the IONA® test: a non-invasive prenatal screening test for Trisomy 21, 18 and 13 *Ultrasound Obstet Gynecol* 47 (2): 188–193

https://doi.org/10.1002/uog.15791


IONA test for first-trimester detection of trisomies 21, 18 and 13

L.C. Poon et al. (2016) The IONA® test for first-trimester detection of trisomy 21, 18 and 13 *Ultrasound Obstet Gynecol* 47(2): 184–187

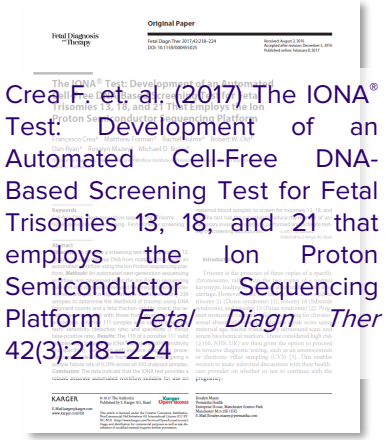
https://doi.org/10.1002/uog.15749


BJOG An International Journal of Obstetrics and Gynaecology

Secondary non-invasive prenatal screening for fetal trisomy: an effectiveness study in a public health setting

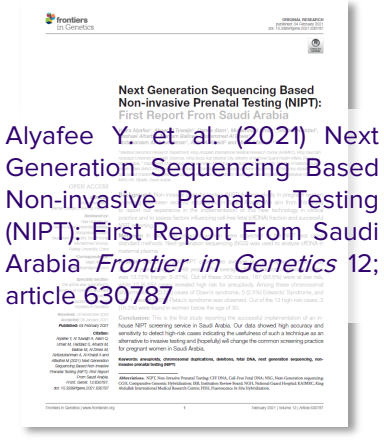
GP Guy et al. (2020) Secondary non-invasive prenatal screening for fetal trisomy: an effectiveness study in a public health setting *BJOG* 128(2): 440-2446

https://doi.org/10.1111/1471-0528.16464


Original Paper

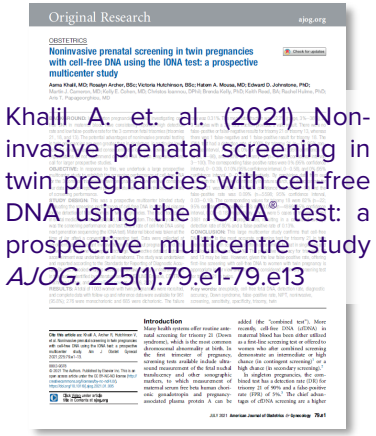
Crea F. et al. (2017) The IONA® Test: Development of an Automated Cell-Free DNA-Based Screening Test for Fetal Trisomies 13, 18, and 21 that employs the Ion Proton Semiconductor Sequencing Platform *Fetal Diagn Ther* 42(3):218–224

https://doi.org/10.1159/000455025


Next Generation Sequencing Based Non-invasive Prenatal Testing (NIPT): First Report From Saudi Arabia

Alyafee Y. et al. (2021) Next Generation Sequencing Based Non-invasive Prenatal Testing (NIPT): First Report From Saudi Arabia *Frontier in Genetics* 12; article 630787

https://doi.org/10.3389/fgene.2021.630787


Original Research

Noninvasive prenatal screening in twin pregnancies with cell-free DNA using the IONA test: a prospective multicenter study

Khalil A. et. al. (2021) Non-invasive prenatal screening in twin pregnancies with cell-free DNA using the IONA® test: a prospective multicentre study *AJOG*. 225(1):79.e1-79.e13

https://doi.org/10.1016/j.ajog.2021.01.005

Assurance of Clinical Accuracy

Core NIPT workflow technology performance behind the Vantage® Test* was validated and extensively evaluated on >9,200 singletons and >1,200 twins pregnancies samples by NHS UK and various experts in the field of prenatal medicine.

	Condition	Sensitivity (95% CI)	Specificity (95% CI)
Singleton Pregnancies	Trisomy 21	>99.99% (90.1 – 100%)	>99.99% (98.1 – 100%)
	Trisomy 18	>99.99% (51.0 – 100%)	
	Trisomy 13	>99.99% (34.2 – 100%)	
Twin Pregnancies	Trisomy 21	100% (75.0 100%)	100% (99.6 – 100%)
	Trisomy 18	0 (0-97%)	99.9% (99.4 – 100%)
	Trisomy 13	100% (3-100%)	100% (99.6 – 100%)

*Data based on IONA® NIPT workflow. The Vantage test utilises the IONA® Nx NIPT workflow. IONA® and IONA® Nx tests are powered by the same core capabilities, including the CE-IVD IONA® Analysis Software, and only differ by the NGS sequencing instruments used (IONA® uses Thermo Ion-Proton sequencing platform while IONA® Nx uses Illumina NextSeq 550dx sequencing platform).

The Vantage® Test Overall Performance

Post-market surveillance data conducted on ≥10,000 pregnancies

Condition	Sensitivity (95% CI)	Specificity (95% CI)	PPV	NPV
Trisomy 21[a]	>99.99% (92.3 - 100%)	>99.99% (99.1 – 100%)	99.50%*	>99.99%*
Trisomy 18[a]	>99.99% (83.2 – 100%)	>99.99% (99.2 – 100%)	96.72%*	99.99%*
Trisomy 13[a]	>99.99% (69.2 – 100%)	>99.99% (99.2 – 100%)	>99.99%*	>99.99%*
Sex Chromosomal Aneuploidies[b]	>99.99% (59.04 – 100.00%)	>99.99% (97.72 – 100.00%)	>99.99%	>99.99%
Extended Autosomal Aneuploidies[b]	>99.99% (29.2 – 100.00%)	>99.3% (97.8 – 99.9%)	>99.99%	>99.99%
Microdeletions[c]	66.67% (29.93% – 92.51%)	>99.99% (98.56% – 100%)	>99.99%	98.84%

More than 99% accuracy with less than 1% false positive rate for Trisomy 21, 18 & 13

Observed Sensitivity for Foetal Sex Determination
99.3%[d]

[a] Validation performance was demonstrated by evaluating 472 clinical samples from singletons and monochorionic/dichorionic twin pregnancies and comparing them to a reference result.
[b] Validation performance was demonstrated by evaluating 443 clinical samples from singletons and comparing them to a reference result. Reference results include an amniocentesis or chorionic villus sample (CVS) or a birth outcome. [c] Based on collective interim validation data performed on 264 samples from Yourgene Health PLC Manchester, UK and LifeStands Genomics Singapore.
[d] Validation performance has been demonstrated by evaluating 400 clinical samples from known foetal sex singleton and monochorionic twin pregnancies, compared to an ultrasound sex phenotype or a birth outcome. An investigation concluded that two out of the three cfDNA foetal sex discordant results, compared to the birth phenotype, were most likely due to an incorrect reference.
*Observed Post Market Surveillance performances based on over 9,575 singleton and monochorionic twin pregnancies from a population of women who are predominantly at a higher risk of having a foetus with Down's syndrome.

IONA® Nx workflow performances are dependent on laboratories fully reporting discordant results to Yourgene Health Plc. Data held on file by Yourgene Health and LifeStrands Genomics. Updated as of March 2022.
For more updated and information on the clinical performances of IONA® Nx NIPT workflow, please visit: https://www.yourgene-health.com/nipt/iona-nx/clinical-performance

A Comprehensive & Flexible Test Menu

Available as a clinical service at LifeStrands Genomics, a dual-accredited laboratory based in Singapore as a CE-IVD prenatal screening test which offers the following test panels to all pregnant women:

Vantage® Basic
Common Trisomies

Vantage® Plus
Common Trisomies + 5 Microdeletions

Optional add-on Test (at no extra charge)

- **Sex Chromosome Aneuploidies (SCAs)**
- **Extended Chromosome Aneuploidies (EAAs)**
- **Fetal Sex Determination***

*Not available for dichorionic (fraternal) twin pregnancies

Most Common Trisomies
- ✓ **Trisomy 21** (Down's Syndrome)
- ✓ **Trisomy 18** (Edwards' Syndrome)
- ✓ **Trisomy 13** (Patau's Syndrome)

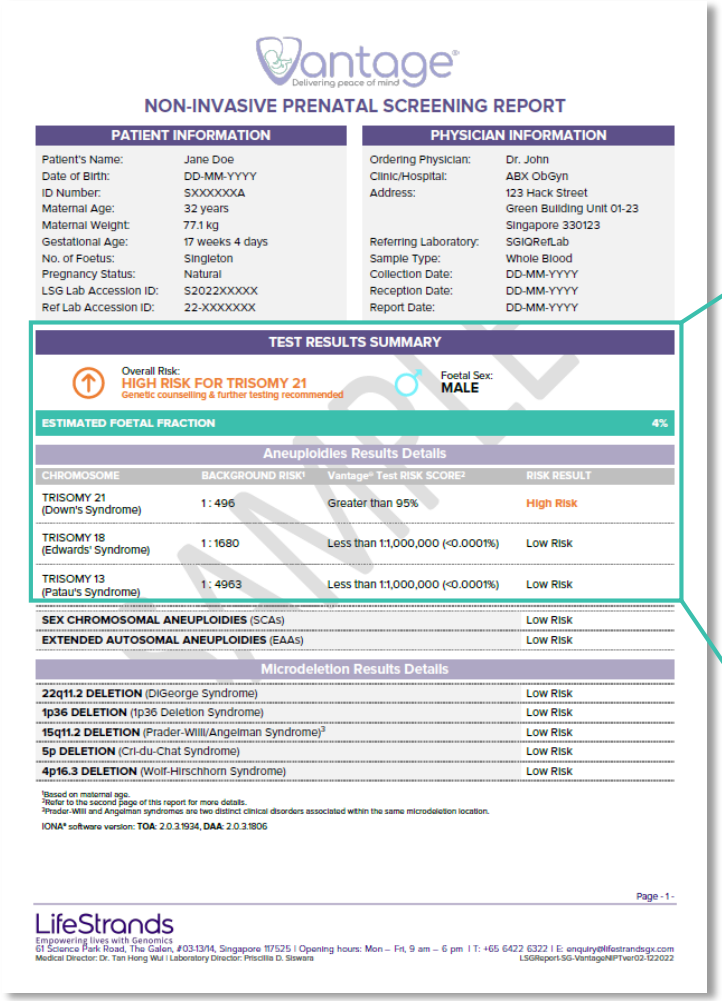
Extended Autosomal Aneuploidies
- ✓ **Additional 19 chromosomal aneuploidies analysis for monosomy or trisomy**

Sex Chromosome Aneuploidies
- ✓ **45, X** (Turner Syndrome)
- ✓ **47, XXX** (Trisomy X)
- ✓ **47, XXY** (Klinefelter's Syndrome)
- ✓ **47, XYY** (Jacob's Syndrome)

Microdeletions
- ✓ **22q11.2** (DiGeorge Syndrome)
- ✓ **1p36** (1p36 Deletion Syndrome)
- ✓ **15q11.2** (Prader-Willi/Angelman Syndrome#)
- ✓ **5p** (Cri-du-Chat Syndrome)
- ✓ **4p16.3** (Wolf-Hirschhorn Syndrome)

#Prader-Willi and Angelman syndrome are two specific conditions affected by the same microdeletion.

Clear and Easy to Read Test Results



Vantage
Delivering peace of mind

NON-INVASIVE PRENATAL SCREENING REPORT

PATIENT INFORMATION		PHYSICIAN INFORMATION	
Patient's Name:	Jane Doe	Ordering Physician:	Dr. John
Date of Birth:	DD-MM-YYYY	Clinic/Hospital:	ABX ObGyn
ID Number:	SXXXXXXA	Address:	123 Hack Street Green Building Unit 01-23 Singapore 330123
Maternal Age:	32 years		
Maternal Weight:	77.1 kg	Referring Laboratory:	SGIQRefLab
Gestational Age:	17 weeks 4 days	Sample Type:	Whole Blood
No. of Foetus:	Singleton	Collection Date:	DD-MM-YYYY
Pregnancy Status:	Natural	Reception Date:	DD-MM-YYYY
LSG Lab Accession ID:	S2022XXXXX	Report Date:	DD-MM-YYYY
Ref Lab Accession ID:	22-XXXXXXX		

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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LifeStrands
Empowering lives with Genomics
61 Science Park Road, The Galen, #03-13/14, Singapore 117525 | Opening hours: Mon – Fri, 9 am – 6 pm | T: +65 6422 6322 | E: enquiry@lifestrandsgx.com
Medical Director: Dr. Tan Hong Wui | Laboratory Director: Priscilla D. Siswara
LSGReport-SG-VantageNIPTver02-122022

Results available for ≥2.5% foetal fraction* with the incorporation of prior risk (maternal age) in its algorithm to obtain the most accurate results.

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
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TRISOMY 13 (Patau's Syndrome)	1 : 4963	Less than 1:1,000,000 (<0.0001%)	Low Risk

* >5% foetal fraction is required for microdeletion screening.
For every 100 women opting for NIPT screening, less than five will have a high-risk result. A high-risk result does not mean the baby is affected by a genetic condition. An invasive procedure will be required to confirm the screening results further.

Who can have The Vantage® Test?

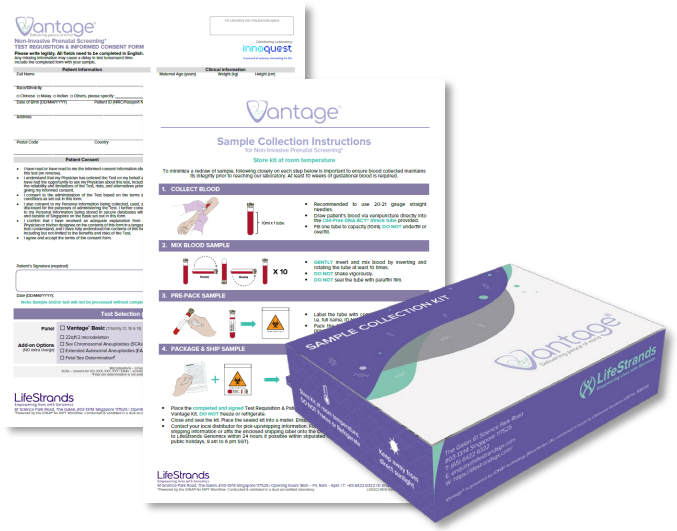
Suitable for pregnant women:

- ✓ From 10 weeks gestation
- ✓ Singleton or twin pregnancies
- ✓ IVF or surrogate pregnancies

Not suitable for those who are:

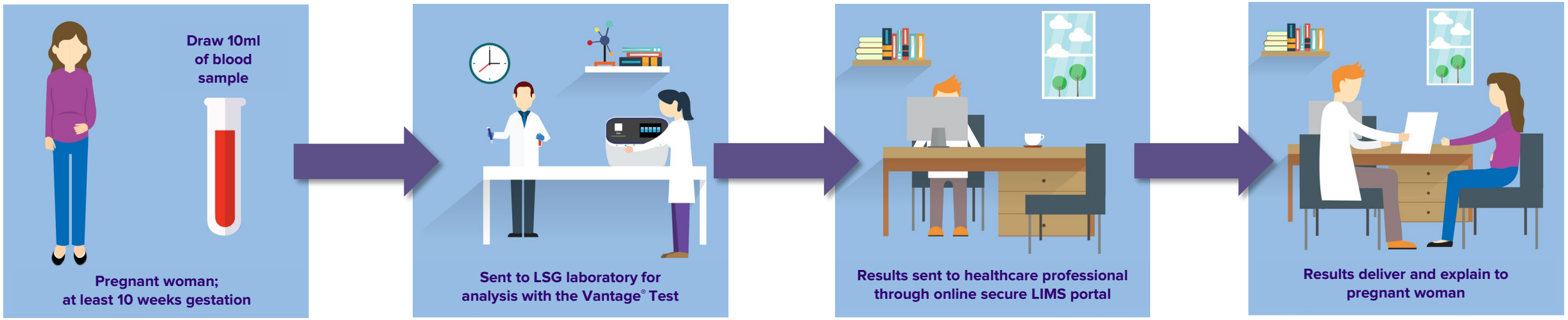
- ✗ Organ transplant recipients
- ✗ Cancer patients or have recently undergone immunotherapy
- ✗ Carriers of a chromosomal imbalance
- ✗ Recipients of heterologous cells transfusion in the past 12 months
- ✗ Complete or partial monosomy X (i.e. Turner Syndrome)

Ordering the Vantage® Test



- Complete sample collection kit with clear patient preparation instructions. Screening test conducted locally in Singapore with results deliverable within four to six working days*.
- Post-test genetic counselling and confirmatory diagnostic testing are available upon request for “high-risk” screening results.

*Upon sample receipt at LifeStrands Genomics (LSG) laboratory and subject to sample acceptance and QA/QC criteria; applicable for e-reporting ONLY.



Contact our representative or your local distributing laboratory for more information about The Vantage® Test* and how to order the test.

*The Vantage® Test is powered by the IONA® NIPT platform, a CE-IVD diagnostic test developed by Yourgene Health PLC, a molecular diagnostic company from Manchester, UK.
IONA® is a registered trademark of Yourgene Health PLC. Vantage® is a registered trademark of LifeStrands Genomics Pte. Ltd.

LifeStrands

Our mission is to empower lives through genomics; revolutionise personalised healthcare towards a patient-centric approach by providing more accurate and clinically relevant testing with better accessibility.

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