

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<sup>®</sup> Test



### **Powered by IONA<sup>®</sup> Nx NIPT Workflow<sup>\*</sup>**

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**

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Clinic: screen	al evaluation of the IONA test: a non-invasive prenatal ing test for trisomies 21, 18 and 13
H.A. MO	(GEORGHIOU*†, A. KHALIL*, M. FORMAN;, R. HULME;, R. MAZEY;, (SA5, E. D. JOHNSTONE], A. MCKELVEY**, K. E. COHEN††, M. RISLEY;, AN; and B. KELLY†
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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

Conclusion: This study indicator that the IONA text is antable for focusey accessing in a high-rate accessing population. The result-interpretation feature of the IONA software should facilitate under implementation,	Thermo Tuber Scientific are the rapid sequencing upon and fast mensional draw while low uploces capital an operating costs. These are impostant considerations is the context of screening for areceptioidy, particularly is wider implementation is envisaged. The IONA® ter-
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	Original Paper		
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DNA using the IONA<sup>®</sup> test: a prospective multicentre study AJOG. 225(1):79.e1-79.e13

	Introduction Mary health systems offer routine ante-	added (the "combined test"). More recently, cell-free DNA (cfDNA) is
On this article are X-old A, Archer R, Hotchinson V, et al. Summarise percellationeering in bein programmer with could-new DNA miles the IDRA best a prospective multicarear dealy. Am J Obstat Opmaal 2021;229:7181-10.	natal screening for trisonry 21 (Down syndrome), which is the most common deconcosmal abasematicy at birth. In the first trimester of pregnance, screening tests available include ultra-	maternial blood has been sitter utilized as a first-line screening tost or offered to women who after combined screening demonstrate an intermediate or high datase (in consingut screening) <sup>1</sup> or a high chance (in scondary screening) <sup>1</sup> . In singleton preparation, the com- blood text has a detection rate (DR) for interver 31 or 1997s and a fibe prairing
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#### 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% Cl)	Specificity (95% Cl)
	Trisomy 21	>99.99% (90.1 – 100%)	_
Singleton Pregnancies	Trisomy 18	>99.99% (51.0 – 100%)	>99.99% (98.1 – 100%)
	Trisomy 13	>99.99% (34.2 – 100%)	
	Trisomy 21	100% (75.0 100%)	100% (99.6 – 100%)
Twin Pregnancies	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 NextSeg 550dx sequencing platform).

https://doi.org/10.1159/000455025

### The Vantage<sup>®</sup> Test Overall Performance

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

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



<sup>a</sup> Validation performance was demonstrated by evaluating 472 clinical samples from singletons and monochorionic/dichorionic twin pregnancies and comparing them to a reference result.

<sup>b</sup> 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. <sup>c</sup> Based on collective interim validation data performed on 264 samples from Yourgene Health PLC Manchester, UK and LifeStands Genomics Singapore.

<sup>d</sup> 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: <u>https://www.yourgene-health.com/nipt/iona-nx/clinical-performance</u>

## 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<sup>®</sup> 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<sup>#</sup>)
- ✓ 5p (Cri-du-Chat Syndrome)
- ✓ 4p16.3 (Wolf-Hirschhorn Syndrome)

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

### **Clear and Easy to Read Test Results**



Results available for  $\geq$  2.5% foetal fraction<sup>\*</sup> with the incorporation of prior risk (maternal age) in its algorithm to obtain the most accurate results.

1	TEST RESULTS SUMMARY				
	Overall Ris HIGH RI Genetic cou				
	ESTIMATED FOETAL FR	4%			
	CHROMOSOME	CHROMOSOME BACKGROUND RISK <sup>1</sup> Vantage <sup>®</sup> Test RISK SCORE <sup>2</sup>			
	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	

\* >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:

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

# **Ordering the Vantage<sup>®</sup> 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<sup>®</sup> Test is powered by the IONA<sup>®</sup> NIPT platform, a CE-IVD diagnostic test developed by Yourgene Health PLC, a molecular diagnostic company from Manchester, UK. IONA<sup>®</sup> is a registered trademark of Yourgene Health PLC. Vantage<sup>®</sup> 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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