Vantage®
Delivering peace of mind

For Laboratory Use Only (barcode space)

Non-Invasive Prenatal Screening*
TEST REQUISITION & INFORMED CONSENT FORM

Please write legibly. All fields need to be completed in English.
Any missing information may cause a delay in test turnaround time.
Include the completed form with your sample.

Patient Information

Full Name

Race/Ethnicity

☐ Chinese ☐ Malay ☐ Indian ☐ Others, please specify: _____

Date of Birth (DD/MM/YYYY) | Patient ID (NRIC/Passport No.)

Address

Postal Code | Country

Clinical information

Maternal Age (years) | Weight (kg) | Height (cm)

Gestational Age
_____ weeks _____ days

Pregnancy Status
☐ Single
☐ Twins (mono/dichorionic/unknown)

Conception Information
☐ Natural ☐ IVF | Egg donor age at retrieval _____ years

Date of Sample Collection (DD/MM/YYYY) | **Time (HH/MM)**

Sample Type ☐ **Whole Blood** ☐ **Plasma**
Is this a ☐ **RE-COLLECTION?** Previous lab accession no.: _____

Remarks (e.g., notes on pregnancy, history, heparin use, etc.)

Patient Consent

- I have read or have read to me the informed consent information about this test (on reverse).
- I understand that my Physician has ordered the Test on my behalf and have had the opportunity to ask my Physician about this test, including the reliability and limitations of the Test, risks, and alternatives prior to giving my informed consent.
- I consent to the administration of the Test based on the terms and conditions as set out in this form.
- I also consent to my Personal Information being collected, used, and disclosed for the purposes of administering the Test. I further consent to my Personal Information being stored in secure databases within and outside of Singapore on the basis set out in this form.
- I confirm that I have received an adequate explanation from my Physician or his/her designee on the contents of this form in a language that I understand, and I have fully understood the contents of this form, including but not limited to the benefits and risks of the Test.
- I agree and accept the terms of the consent form.

Patient's Signature (required)

Date (DD/MM/YYYY):

Physician Information

Full Name

Clinic/Hospital

Prefer e-Report? ☐ Yes

Email Required: _____

Address

Postal Code | Country

Telephone

I attest that:
1. Informed consent has been obtained from the patient.
2. Appropriate pre-test counselling has been provided to the patient and post-test counselling will be provided once the test results are released.

Physician's Signature (required)

Date (DD/MM/YYYY):

Note: Sample and/or test will not be processed without complete information together with patient's consent and physician's attestation.

Test Selection (tick where appropriate)

	☐ **Vantage® Basic** (Trisomy 21, 18 & 13)	☐ **Vantage® Plus** (Trisomy 21, 18 & 13 + 5 microdeletions)
Panel		
Add-on Options (NO extra charge)	☐ Sex Chromosomal Aneuploidies (SCAs) ☐ Extended Autosomal Aneuploidies (EAAs) ☐ Foetal Sex Determination#	☐ Sex Chromosomal Aneuploidies (SCAs) ☐ Extended Autosomal Aneuploidies (EAAs) ☐ Foetal Sex Determination#

Microdeletions – screens for 22q11.2, 1p36, 15q11.2, 5p, 4p16.3
SCAs – screens for XO, XXX, XXY, XYY | EAAs – screens through chromosomes 1 - 22 for other trisomy or monosomy conditions
#Foetal sex determination is not available for diachronic (non-identical) twin pregnancies

LifeStrands
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Vantage® Prenatal Screening Test* | Informed Consent

This informed consent form must be fully completed and signed by the Patient undergoing the Vantage® Test ("the Test") or a person authorised to grant consent on the Patient's behalf if the Patient is unable to give consent.

General information about the Test

Purpose of the Test: The Vantage® Test is a non-invasive advanced prenatal screening test (NIPS/NIPT) that is carried out on a maternal blood sample that measures the likelihood that a pregnant woman is carrying a foetus with Trisomy 21, 18 or 13 as well as optionally determine the foetal sex, screen for foetal sex chromosome aneuploidy, all other foetal autosomal aneuploidies, and a selection of clinically relevant foetal microdeletions.

Principle of the Test: This test utilises technologies for the preparation of DNA libraries, coupled with next-generation sequencing (NGS) technology, to determine the likelihood that a foetal aneuploidy is present. Cell-free DNA (cfDNA), which consists of maternal and foetal genetic material, is extracted from the maternal plasma and the relative amount of genetic material that aligns to each chromosome is analysed. In an instance of foetal aneuploidy, a higher or lower-than-expected amount of genetic material for the relevant chromosome is expected. The sensitivity of the next-generation sequencing technology allows the detection of this change, which is dependent on the presence of sufficient cell-free foetal DNA in the DNA extract (the foetal fraction). The results of this test, interpreted in the appropriate clinical context, can aid the physician in making informed management decisions.

Pre- and Post-Test Counselling: The Physician is responsible for ensuring the provision of appropriate pre-test and post-test counselling by qualified personnel. LifeStrands Genomics Pte. Ltd. ("LifeStrands Genomics") shall be responsible for performing the Test only.

Risks and limitations of the Test: The Vantage® Test should be considered a screening test only. It is recommended that you discuss the results with your healthcare provider and that a high-risk result (i.e., a high chance of Down's, Edwards' or Patau's syndrome being present) is considered along with other clinical screening results and may be followed up with an invasive diagnostic procedure (i.e., Amniocentesis or CVS). 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; improper collection, handling, storage, and transportation of the blood samples; and/or pre-existing conditions and medical interventions.

The test is not suitable for pregnant women who:

a. Have vanishing twin syndrome;
b. Have cancer or aneuploidy;
c. Who are pregnant for less than 10 weeks;
d. With multiple pregnancies, except for monochorionic twin pregnancies;
e. Have had treatment involving the transfusion of heterologous cells in the last 12 months (e.g. a white cell blood transfusion or stem cell therapy)
f. Have had transplant surgery (organ, bone marrow).

This test was validated and its performance characteristics were determined by LifeStrands Genomics' laboratory. This test is performed in a MOH-certified, SAC ISO 15189:2012 and CAP (No. 9084781) accredited laboratory and is intended for clinical purposes.

Management of Personal Information and Disclosure of Test Results

1. The personal information collected for the purposes of administering the Test includes the patient's name, date of birth, gender, ethnicity, NRIC, FIN or passport number, medical history, test results of genetic analysis, and any other health records (collectively, "Personal Information").
2. The patient's test results are confidential. The results and patient's personal information, as set out above, will be accessible only by the relevant hospital/clinic, LifeStrands Genomics, and will be shared with other health care providers ONLY to comply with applicable laws and regulations and for clinical decisions.
3. The patient's personal information, Test results and clinical data are retained in secure servers located in the USA under strict regulatory (e.g., HIPAA) security. LifeStrands Genomics ensures that it abides by the proper protection of all information within its possession, doing so at least in accordance with the requirements under the Singapore Personal Data Protection Regulations 2021.

Storage and Use of Patient Samples

LifeStrands Genomics may collect, use, store, disclose, transfer, and/or process anonymized patient samples for the following purposes:

1. Laboratory accreditation, including monitoring the provision of its services; compliance with regulatory obligations, accounting, audit and record keeping, quality control, staff training, product testing and development; and
2. Use for test validation, process development, and quality assurance purposes to continually improve the quality of services provided.

Disclaimers

Neither the Patient nor any third party shall hold LifeStrands Genomics liable for any damages, expenses, costs, liabilities or losses which he/she may suffer or incur in connection with the Test and the Test results, including but not limited to any delays in the delivery of the Test results. For the avoidance of doubt, to the fullest extent permitted by law, in no event shall LifeStrands Genomics have any liability to the Patient or to a third party for any indirect, special, incidental, consequential damages, loss of profits, or pure economic loss.

General Provisions

1. If any term, condition or provision of this consent form is held to be a violation of any applicable law, statute, or regulation, the same shall be deemed to be deleted from this consent form as if such term, condition, or provision had not originally been contained in this consent form. Where such term, condition or provision is only partially unlawful, any remaining portion of said term, condition, or provision that is lawful shall remain in force and have full effect, and this consent form shall remain in full force and effect as if such partially lawful term condition or provision had originally been contained in this consent form.
2. The validity and interpretation of this consent form and the legal relations of the parties to it shall be governed by the laws of Singapore, and parties shall submit to the exclusive jurisdiction of the courts of Singapore without regard to conflicts of laws principles.
3. Unless otherwise expressly specified, this consent form embodies the entire understanding between the parties in respect of the Test, and any prior or contemporaneous representations, either oral or written, are hereby superseded. No amendments or changes to this consent form shall be effective unless made in writing and signed by the parties.