GENETIC SCREENING TEST CONSENT FORM

SECTION 1. CUSTOMER INFORMATION

Full name:

Gender: ☐ Male ☐ Female NRIC/ID No:

Date of birth: DD / MM / YY

Ethnicity/Race:

DOCTOR INFORMATION

Requesting doctor:

MCR/MMC number:

Doctor's email:

Clinic/Hospital Name:

Clinic/Hospital Tel:

SECTION 2. TEST BEING ORDERED: SPOT-MAS

SPOT-MAS 10 is an early screening test for the 5 most common cancers (Breast, Lung, Liver-Biliary tract, Colorectum, Stomach) and 5 uncommon cancer types without standard of care screening (Ovary, Pancreas, Esophagus, Endometrium, Head & Neck[#]). It detects the presence of tumor DNA fragments (ctDNA) released into the blood.
1 tube of blood (10 mL) will be collected for this test.

SPECIMEN INFORMATION

Sample collection date and time:

[#]Head & Neck cancer DOES NOT include brain tumors, orbital tumors, thyroid cancer, or skin cancer of the head and neck.

SECTION 3. PERSONAL INFORMATION (accurate information is required to support analysis of results)

A. PERSONAL CANCER HISTORY. Persons with cancer within the last 5 years are NOT eligible for this test.

Previously diagnosed with cancer: ☐ No ☐ Yes Type of cancer: _____ Diagnosis date (MM/YY): _____

B. BENIGN TUMORS SUPPORTED BY SPECIAL ANALYSIS

Some benign tumors can cause fluctuations in the ctDNA signals and need in-depth analysis support

• Uterine fibroids:	□ No □ Yes □ Treated	
• Breast lesion:	□ No □ Yes □ Treated	BI-RADS:
• Thyroid lesion:	□ No □ Yes □ Treated	TI-RADS:
• Lung lesion:	□ No □ Yes □ Treated	LUNG-RADS:
• Liver lesion:	□ No □ Yes □ Treated	LI-RADS:
• Polyp:	□ No □ Yes □ Treated	Organ:
• Other benign tumors:	□ No □ Yes □ Treated	Organ:

** For each "Yes" option, please provide the corresponding diagnostic imaging ± pathology results*

C. RISK FACTORS

• Smoke cigarettes:	□ No □ Yes
• Hepatitis B or C:	□ No □ Yes
• Drink alcohol:	□ No □ Yes
• Carry inherited cancer genes:	□ No □ Yes □ Unknown
• Family member has cancer:	□ No □ Yes □ Unknown
◦ Relationship with patient:	
◦ Cancer type:	

SECTION 4. INFORMED CONSENT AGREEMENT

Full name of patient / guardian:

_____

Signature _____

Date: DD / MM / YY

- I have reviewed and fully understood the information presented in this Consent form.
- I agree with all the terms and conditions in this Consent form. I understand that this is a supportive test for screening and is NOT a substitute for recommended cancer screening and diagnosis tests.
- I understand that the turnaround time given for the Test is an indicative guide only. As the performance of the Test may require the input of third parties and involve factors that are not within Gene Solutions' control, I understand that Gene Solutions is unable to guarantee the turnaround time. However, Gene Solutions shall keep my physician informed in the event of unusual delays in providing the Test results and my physician shall have the duty to communicate such information to me.
- I agree to provide all personal details to perform the type of test mentioned in this Consent form and to sequence the gene on the sample at the Gene Solutions laboratory. I agree to allow Gene Solutions to perform data processing activities from genetic sequencing, including but not limited to collection, recording, analysis, validation, storage, modify, disclose, combine, access, retrieve, revoke, encrypt, decrypt, copy, share, transmit, provide, transfer, delete, destroy personal data or other relevant action.

Consent for research studies:

☐ **YES**

☐ **NO**

Gene Solutions may de-identify my genetic information and results and use or disclose such de-identified genetic information/results for future research. I agree that Gene Solutions may retain this de-identified information for future research purposes. I understand that this information will be de-identified in a manner that meets de-identification standards under the United States Health Information Portability and Accountability Act of 1996, the Singapore Personal Data Protection Act 2012, the Hong Kong Personal Data (Privacy) Ordinance (Cap 486) and local data protection laws, as applicable.

Doctor's Signature:

I have fully explained the test, including the benefits, risks, and alternatives available to this individual.
I have addressed the limitations outlined in Section 6 (overleaf), and I have answered this person's questions.

SECTION 5. EXCLUSION CRITERIA

The test **SHOULD NOT** be performed on the following individuals:

- **Individuals who have been diagnosed with cancer in the last 5 years.**
- **Individuals who have highly suspected signs of cancer**
  - Have breast/lung/liver lesions with BI-RADS/LUNG-RADS/LI-RADS ≥ 4.
  - Have polyps ≥ 1cm or warts/ulcers suspected of malignancy through digestive endoscopy.
- Individuals who are pregnant
- Individuals with a history of bone marrow transplant or whole blood transfusion (within 3 months)

**** Patients with signs and symptoms of cancer should NOT perform this screening test.***
Consult with your doctor to perform an appropriate cancer diagnostic test.

SECTION 6. LIMITATIONS OF THE TEST

This screening test was developed by, and its performance characteristics determined by Gene Solutions Genomics Pte Ltd, a company registered in Singapore. Gene Solutions Genomics is licensed by the Ministry of Health (Singapore) as a Clinical Laboratory (License no. L/24I1577/CLB/001/242) under the Healthcare Services Act 2020.

The method of analyzing ctDNA released from cancer cells into the peripheral blood will have the following limitations:

- A negative result (no ctDNA detected) does NOT COMPLETELY rule out the presence of a tumor. This may occur if the tumor falls outside of the 10 cancer types, resides in a difficult location for ctDNA release or the secondary cancer has a radically different omics profile compared to the primary cancer.
- The overall sensitivity of the test is 78.1% (including pre-cancerous lesions of digestive tract) or 70.8% (cancerous lesions only)[1]. This means that for every 100 cancer cases, about 22 cases will be missed. The sensitivity of the test varies depending on the organ within the scope of investigation[2,3]. This test is a supporting screening test, and is NOT a substitute for recommended routine cancer screening tests.
- A positive result (ctDNA detected) does NOT COMPLETELY confirm that a test participant has cancer, as specific physiological or pathological conditions may lead to a "pseudo" ctDNA signal.
- The specificity of the test is 99.7%[1], which means that for every 1000 cancer-free cases there will be about 3 cases with positive ctDNA signal.
- The positive predictive value of the test is 58.1% (including pre-cancerous lesions of digestive tract) or 39.5% (cancerous lesions only)[1]. This means that for every 100 positive cases, 58 cases will have cancerous or precancerous lesions. A positive result should be evaluated by an oncologist and confirmed by diagnostic imaging tests.
- The negative predictive value of the test is 99.9%[1], which means that for every 1000 negative cases, about 999 cases actually do not have cancer.
- The tumor's origin was predicted using DNASphere.AI algorithm analyzing the distinct features of ctDNA from the potential tissue origins in the scope of this test, achieving a prediction accuracy of 68% (including pre-cancerous lesions of digestive tract) or 52% (cancerous lesions only)[1]. However, these features of the ctDNA may overlap, resulting in the INCOMPLETE determination of the tumor's origin.

1. Nguyen et. al. (2025) Prospective validation study: a non-invasive circulating tumor DNA-based assay for simultaneous early detection of multiple cancers in asymptomatic adults. *BMC Med* 23, 90. https://doi.org/10.1186/s12916-025-03929-y
2. Nguyen, et. al. (2023) Multimodal analysis of methylomics and fragmentomics in plasma cell-free DNA for multi-cancer early detection and localization. *eLife* 12:RP89083. https://doi.org/10.7554/eLife.89083.3
3. Nguyen et. al. (2024) Evaluation of a multimodal ctDNA-based assay for detection of aggressive cancers lacking standard screening tests. *Future Oncology*:1-11. https://doi.org/10.1080/14796694.2024.2413266.

SECTION 7. DISCLAIMER OF LIABILITY

Gene Solutions Genomics Pte. Ltd. disclaims support for the following cases:

- Performing the test without signing the consent and/or without the Doctor's order in Section 4 of this Consent Form.
- Declare untruthful, incomplete or inaccurate health information in Section 3 above.
- Exclusions criteria mentioned in Section 4 above.

Gene Solutions complies with all relevant data protection and privacy laws; refer to genesolutions.com for details of the privacy policy