K-TRACK™ : CONSENT FORM

SECTION 1: PATIENT INFORMATION

K-TRACK™ ID: _____

Full name: _____ Date of birth: *(dd/mm/yy)* _____ Gender: ☐ Male ☐ Female

Phone: _____ Place of treatment: _____

Referring physician: _____ Referring physician's email: _____

K-TRACK™

- ☐ Blood sample (after radical surgery) — Date of collection: _____
- ☐ Blood sample (before radical surgery) — Date of collection: _____
- ☐ Tissue sample — Date of surgery/biopsy: _____
- ☐ K-Track N (Follow UP) — Date of collection: _____

K-TRACK™ MET

- ☐ Blood sample (metastasis stages) — Date of collection: _____
- ☐ Tissue sample — Date of surgery/biopsy: _____
- ☐ K-Track N (Follow UP) — Date of collection: _____

A. HISTORY AND TREATMENT PROCESS

Cancer type*:

☐ Lung ☐ Prostate ☐ Liver ☐ Breast, receptor status::

☐ Esophageal ☐ Colorectal ☐ Gastric

☐ Endometrial ☐ Ovarian ☐ Pancreatic

☐ Others: _____

	ER	PR	HER
Negative	☐	☐	☐
Positive	☐	☐	☐

Cancer stage at diagnosis:

☐ I ☐ II ☐ III ☐ IV

Metastatic organs: _____

Regimen (radiotherapy/chemotherapy/immunotherapy/hormones, if any):

_____

B. PATHOLOGY *(please ignore if this is a follow-up test and collect only blood sample)*

Pathology code: _____ Date of tumor collection: _____ Place of collection: _____

SECTION 2: TEST AGREEMENT

I acknowledge that I have been fully provided with information and carefully went through all sections of this Consent form. I hereby acknowledge that I understand and agree that.

- I agree with all the terms and conditions in this Consent form.
- I agree to provide all details to perform the type of test mentioned in this Consent form and to sequence the gene on the sample at the Gene Solutions Lab Co. laboratory. I agree to allow Gene Solutions Lab Co. to perform data processing activities from genetic sequencing, including but not limited to collection, recording, analysis, validation, storage store, modify, disclose, combine, access, retrieve, revoke, encrypt, decrypt, copy, share, transmit, provide, transfer, delete, destroy personal data or other relevant action.
- I consent to the processing of my personal data, including my health data, and residual material by Gene Solutions Lab Co. for research and scientific purposes as specified in this Consent form
- Providers may use customer residuals and de-identified information for scientific studies. These studies can be published in scientific journals or used to develop products and services. Customers will not be notified or paid for these research activities.

I ☐ allow ☐ / do not allow my personal information and my genetic test result to be part of the research of Gene Solutions

Patient/ Family member supervisor's signature

Full name:.....

Date:.....

I have fully explained the test, including the benefits, risks, and alternatives to clients based on the legal basis, and answered all of their questions.

Physician's signature

Full name:.....

Date:.....

SECTION 3: SCOPE OF THE TEST

	Actionable Mutation	MRD	MSI	Germline
Lung Cancer				
Liver Cancer				
Esophageal – Gastric Cancer				
Pancreatic Cancer				
Colorectal Cancer				
Breast Cancer				
Ovarian Cancer				
Endometrial Cancer				
Prostate Cancer				

Panel 155 genes:

ACVR2A	*ASXL2*	*CASP8*	*CTNNB1*	*EPHA5*	*FBXW7*	*GNAS*	*KEAP1*	*MAP2K4*	*MSH6*	*NRG1*	*PDPK1*	*PRKD1*	*RASA1*	*SMAD4*	*TSC1*
AFF3	*ATM*	*CDH1*	*DICER1*	*EPHA7*	*FGFR2*	*GRIN2A*	*KIT*	*MAP3K1*	*MTOR*	*NSD1*	*PIK3C2G*	*PTCH1*	*RB1*	*SMARCA4*	*TSC2*
AKT1	*ATR*	*CDK12*	*DNMT3B*	*ERBB2*	*FGFR3*	*HRAS*	*KMT2A*	*MAX*	*MUTYH*	*NTRK1*	*PIK3CA*	*PTEN*	*RBM10*	*SOX9*	*VHL*
ALK	*AXIN1*	*CDKN2A*	*DOT1L*	*ERBB3*	*FH*	*IDH1*	*KMT2B*	*MDM2*	*NCOR1*	*NTRK2*	*PIK3CD*	*PTPN13*	*RET*	*STAT5A*	*ZFHX3*
AMER1	*BCOR*	*CHD4*	*EGFR*	*ERBB4*	*FHIT*	*IDH2*	*KMT2C*	*MED12*	*NCOR2*	*NTRK3*	*PIK3R1*	*PTPRB*	*RHOA*	*STK11*	*ZNF521*
APC	*BRAF*	*CHEK2*	*EIF1AX*	*ERCC3*	*FLT1*	*IGF2*	*KMT2D*	*MEN1*	*NF1*	*PALB2*	*PMS2*	*PTPRD*	*RNF213*	*TBX3*	
AR	*BRCA1*	*CIC*	*ELF3*	*ERCC4*	*FOXA1*	*IKZF1*	*KNSTRN*	*MET*	*NFE2L2*	*PARP1*	*POLD1*	*PTPRS*	*RNF43*	*TCF7L2*	
ARID1A	*BRCA2*	*CREBBP*	*EP300*	*ESR1*	*FOXP1*	*INPP4B*	*KRAS*	*MGA*	*NOTCH1*	*PBRM1*	*POLE*	*PTPRT*	*ROS1*	*TERT promoter*	
ARID1B	*BRIP1*	*CSDE1*	*EPCAM*	*FAT1*	*GATA3*	*KDM6A*	*LRP1B*	*MLH1*	*NOTCH2*	*PDE4DIP*	*PRDM14*	*RAB35*	*SETD2*	*TP53*	
ARID2	*CAMTA1*	*CTCF*	*EPHA3*	*FAT4*	*GNA11*	*KDR*	*MAP2K1*	*MSH2*	*NRAS*	*PDGFRA*	*PREX2*	*RARA*	*SF3B1*	*TRRAP*	

A. PURPOSES AND BENEFITS OF TESTING

1. The test examines the genes related to targeted therapy and drug resistance .

- Lung Cancer: *EGFR, KRAS, BRAF, NRAS, MET amplification/mutations, HER2 amplification/mutations,ALK fusion/mutations, ROS1 fusion, NTRK fusion, PIK3CA, RET fusion/mutations, TP53, SKT11, KEAP1*
- Colorectal Cancer: *KRAS, NRAS, BRAF, HER2 amplification/mutations, PIK3CA, NTRK fusion, RET fusion*
- Breast Cancer: *AKT1, PTEN, BRCA1, BRCA2, PALB2, PIK3CA, ESR1, HER2 amplification/mutations, NTRK fusion, RET fusion*
- Esophageal – Gastric Cancer: *HER2 amplification/mutation, PIK3CA, NTRK fusion, BRAF, RET fusion*
- Ovarian Cancer: *BRCA1, BRCA2, BRAF, NTRK fusion, RET fusion*
- Prostate Cancer: *BRCA1, BRCA2, PALB2, AR, NTRK fusion, RET fusion*
- Pancreatic Cancer: *BRCA1, BRCA2, PALB2, KRAS, NRAS, BRAF, RET fusion, NTRK fusion*
- Endometrial Cancer: *POLE, POLD1, AKT1, BRAF, NTRK fusion, RET fusion/mutations*
- Liver Cancer: *BRAF, NTRK fusion*

2. Microsatellite instability (MSI): is a marker that is associated with the ability to respond to adjuvant therapy or immunotherapy. For MSI, the percentage of microsatellite instability (MSI) regions is calculated using the MSIsensor-pro tool, comparing these regions between the tumor tissue samples and the corresponding leukocyte samples, and the threshold value for MSI-High classification is 20%.

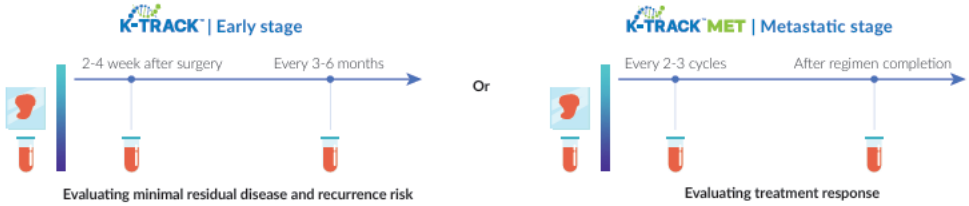
3. Germline mutations associated with hereditary cancer: are identified from leukocyte samples, and the pathogenicity of these variants is classified according to the American College of Medical Genetics and Genomics (ACMG) criteria.

Panel genes: *ALK, APC, ATM, BRCA1, BRCA2, BRIP1, CDH1, CDKN2A, CHEK2, DICER1, EGFR, EPCAM, ERCC3, ERCC4, FH, HRAS, KIT, MAX, MEN1, MET, MLH1, MSH2, MSH6, MUTYH, NF1, NF2, PALB2, PDGFRA, PMS2, POLD1, POLE, PTCH1, PTEN, RET, RNF43, SMAD4, SMARCA4, STK11, TP53, TSC1, TSC2, VHL*

4. Minimal residual disease (MRD) testing: based on LIQUID BIOPSY technology, designed for each patient, and utilizes Next-generation Sequencing technology with deep coverage (10,000X). Therefore, it helps detect ctDNA at low levels (LOD: 0.05%) facilitating early detection of recurrence and evaluation of treatment effectiveness. In addition to personalized mutations for each patient, the K-TRACKTM MET also examines an additional panel of 300-500 hotspot mutations specifically designed for metastatic stage.

Panel genes (the entire gene length is not examined, but only some hotspot mutations. The location and quantity of mutations examined depends on each different type of cancer): *ACVR2A, AKT1, ALK, AMER1, APC, ARID1A, AXIN1, BRAF, BRCA1, BRCA2, CDH1, CTNNB1, EGFR, ERBB2, ESR1, FBXW7, GATA3, GNAS, HRAS, IDH1, IDH2, KEAP1, KRAS, LRP1B, MET, NRAS, PIK3CA, POLE, PPP2R1A, PTEN, RB1, SMAD4, STK11, TCF7L2, TERT, TP53, ZFHX3.*

PROCEDURE FOR CONDUCTING K-TRACK™ TEST TO MONITOR ctDNA



B. METHODS FOR RETURNING RESULTS

The K-TRACK™ test package includes 2 result tables:

1. The K-TRACK™ result for Actionable mutations + Microsatellite Instability (MSI).
2. The K-TRACK™ result for detection of Minimal residual disease (MRD)/ctDNA dynamics + Germline mutations

The K-TRACK™ result for detection of Minimal residual disease (MRD)/ctDNA dynamics will manifest in 2 forms: POSITIVE or NEGATIVE, indicating the presence of ctDNA in the blood. This outcome will provide physicians with additional information and aid in determining the suitable treatment regimen for each individual.

- NEGATIVE: indicates that ctDNA is not detected in the blood. For patients diagnosed with early-stage cancer, this signifies the absence of residual disease or the presence of very low, undetectable levels within the body. In the case of metastatic (late-stage) cancer, a negative result suggests the effectiveness of the treatment. Recommendation: It is advisable to maintain ongoing ctDNA monitoring.
- POSITIVE: indicates the presence of ctDNA in the blood. This signifies an elevated risk of cancer recurrence or inadequate response to treatment. Your physician may recommend a repeated test to assess your tumor's response to treatment. Recommendation: Please consider undergoing imaging (PET/MRI) for further evaluation

C. LIMITATION

- The test results are TIME-DEPENDENT. Therefore, a K-TRACK™ analysis result indicating a negative residual tumor does not provide an absolute assurance against future cancer detection or progression. Consequently, it is of utmost importance to undergo repeated analyses as directed by your physician in order to facilitate early detection of recurrence and ensure ongoing monitoring of treatment effectiveness.
- The K-TRACK™ test CANNOT be performed on patients who meet any of the following criteria:
  - Pregnancy
  - History of bone marrow transplant
  - History of whole blood transfusion within the past three months.
- The examined mutations encompass point mutations, deletions and short insertions (less than 20 nucleotides) in the coding region and in the vicinity of intron (-20/+10 nucleotides from exon) of the genes under examination.
- Additional mutations include variants outside the coding region, large deletions and insertions (greater than 100 nucleotides), short continuous repeats (nucleotide repeats), CG-rich region, high homologous regions (pseudogenes) and mosaicism. Detecting these mutations may not be reliable enough to be detected in this test.
- The test does not encompass the comprehensive examination of all genes implicated in cancer. Consequently, a negative result (indicating no detected mutations) does not definitively exclude the possibility that the participant may carry a mutation in another gene that is not included in this test.
- This test serves as a valuable adjunct to existing methodologies for monitoring recurrence and evaluating treatment efficacy, offering additional insights and assisting in the informed decision-making process for effective treatment strategies.
- The test may not yield results in the following scenarios:
  - No cancer-specific mutations were identified or
  - The tumor demonstrates challenges in releasing ctDNA, often attributable to factors such as tumor location and type or
  - The quality of the tissue sample (FFPE) does not meet the requirements for next-generation gene sequencing.

D. SUPPORT

Patients with a positive ctDNA result will receive free counseling on the test results as well as referrals to the best cancer specialists to optimize treatment and disease monitoring..

(*) We always comply with HIPAA law and Privacy Policy to protect customer's medical information, please check our website to learn more about privacy policy