HEREDITARY CANCER GENETIC REQUISITION FORM-NY

SureTox Laboratory
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CLIA: 31D2063148

Practice information:

1. Patient information:

Last Name	First Name	Street Address	
City	State	Zip Code	Date of Birth (MM/DD/YY)_____/_____/_____
Patient Phone #	Gender ☐ Male ☐ Female		Buccal Swab Sample Collection Date (MM/DD/YY)_____/_____/_____

Patient Ethnicity

☐ White ☐ Hispanic/Latino ☐ Asian ☐ Other/Unknown
☐ Mixed Race ☐ American Indian/Native Alaskan ☐ Hawaiian/Pacific Islander ☐ African American

2. Payment and Insurance Information:

☐ Medicare ☐ Commercial:_____ ☐ Other ☐ Patient Direct Pay

☐ Bill Insurance

Primary Insurance	ID Number	Group Number
Secondary Insurance	ID Number	Group Number
Name of Primary Insured	Relationship to Primary Insured	Primary Insured Date of Birth (MM/DD/YY) _____/_____/_____

3. ICD-10 Codes *(SEE SEPARATE DOCUMENT and list all applicable codes)*

_____ _____ _____ _____

4. Testing Options

☐ ALK (Lung, CNS)	☐ MLH1 (Ovarian, Uterine, Colorectal, Pancreatic, Gastric, Prostate, CNS, Renal)
☐ APC (Colorectal, Pancreatic, Gastric, CNS, Endocrine)	☐ MSH2 (Ovarian, Uterine, Colorectal, Pancreatic, Gastric, Prostate, CNS, Renal)
☐ ATM (Breast, Pancreatic, Prostate)	☐ MSH6 (Ovarian, Uterine, Colorectal, Pancreatic, Gastric, Prostate, CNS, Renal)
☐ BARD1 (Breast, Ovarian)	☐ NF1 (Breast, Gastric, Prostate, CNS, Sarcoma, Hematologic, Endocrine)
☐ BRCA1 (Breast, Ovarian, Pancreatic, Prostate)	☐ NF2 (CNS)
☐ BRCA2 (Breast, Ovarian, Skin, Pancreatic, Prostate)	☐ PMS2 (Ovarian, Uterine, Colorectal, Pancreatic, Gastric, Prostate, CNS, Renal, Sarcoma, Hematologic)
☐ CDKN1B (CNS, Endocrine)	☐ PTEN (Breast, Ovarian, Uterine, Colorectal, Skin, CNS, Renal)
☐ CDKN2A (Skin, Pancreatic, Prostate, CNS)	☐ RET (Endocrine)
☐ EGFR (Lung)	☐ SDHB (Gastric, Renal, Sarcoma, Endocrine)
☐ EPCAM (Ovarian, Uterine, Colorectal, Pancreatic, Gastric, Prostate, Lung, CNS, Renal, Sarcoma, Hematologic)	☐ STK11 (Breast, Ovarian, Uterine, Colorectal, Pancreatic, Gastric)
☐ KIT (Gastric, Sarcoma)	

The following genes will also be tested for mutations:

AXIN2, BAP1, BLM, BMPR1A, BRIP1, CDC73, CDH1, CDK4, CHEK2, DICER1, FH, FLCN, GPC3, HOXB13, MAX, MEN1, MET, MITF, MUTYH, NBN, PALB2, PDGFRB, PHOX2B, POLD1, POLE, PRKAR1A, PTCH1, RAD50, RAD51C, RAD51D, RB1, RECQL4, RUNX1, SDHA, SDHAF2, SDHC, SDHD, SMAD4, SMARCB1, SMARCE1, SUFU, TERT, TMEM127, TP53, TSC1, TSC2, VHL, WRN, WT1

5. Patient authorization and informed consent

I request and authorize a CLIA certified laboratory to perform the above designated test(s) on the DNA sample provided by me. My signature below constitutes my acknowledgment that I have been informed of the benefits and limitations of this testing which have been explained to my satisfaction by a qualified health professional. I hereby authorize my physician to release personal health information to SureTox or their designee for any purposes, consistent with HIPAA, including for billing, audits, and other purposes. I hereby authorize SureTox or their designee to bill my insurance company and receive payment from them on my behalf. I acknowledge, however, that I am responsible for payment of my account and any and all charges associated with its collection. I hereby authorize my insurance company to pay SureTox or their designee directly for services rendered. In the event of an underpayment or denial by my insurance carrier, I hereby authorize SureTox or their designee, to appeal my health plan on my behalf* to provide the actions and information necessary to overturn the denial or receive reimbursement for the underpaid claim. This authorization shall remain valid until the charges for the orders on this form are paid in full. (*SureTox or their designee may perform this appeal on my behalf, but is not obligated to do so). In some circumstances, a patient's DNA may be used anonymously as a negative or positive control sample in future testing, but in this circumstance, all identifiers will be removed prior to re-testing and the DNA sample and results obtained will remain anonymous.

Patient Name	Patient Signature Date_____/_____/_____

6. Physician informed consent and medical necessity statement (Required rational and application options on back)

Physician Certification: By their signature below, the healthcare provider authorizes performance of the test(s) and indicates that he or she has explained the purpose of the test, the procedures, the benefits and the risks that are involved in testing to their patient and obtained the patient's informed consent in accordance with state and local laws. I affirm each of the following: I have provided genetic testing information to the patient and the patient has consented to genetic testing. This test is medically necessary for the diagnosis or detection of a disease, illness, impairment, symptom, syndrome or disorder. The results will be used for the patient's medical management and treatment decisions. The person listed as the Ordering Physician is authorized by law to order the test(s) requested herein.

Authorizing Physician Name	Authorizing Physician Signature Date_____/_____/_____

241 Molnar Drive, Elmwood Park, NJ 07407
P: (201) 791-7293 F: (866) 425-4630

7.

Pt. Name _____

Date_____ D.O.B._____

BAR CODE/////////

SUREGx
a division of Suretox laboratory

8. Genetic Counseling

PRE-GENETIC COUNSELING: If genetic counseling is required by the patient's insurance company for the test ordered, the ordering provider agrees to:

☐ Refer to Genetic Counselor (Informed DNA) ☐ Provider would like to be contacted so they can refer patient locally

POST-GENETIC COUNSELING: SureTox laboratory will facilitate genetic counseing for any patient with abnormal test results (ie. Pathogenic or Likely Pathogenic variant) through Informed DNA (IDNA) at no charge. Provider, please check one of the following:

☐ Yes, please refer my patient to IDNA for genetic counseling if test results are abnormal.

☐ No, please do not refer my patient to IDNA for genetic counseling if test results are abnormal. I will recommend another genetic counseling resource for my patient.

If Physician selected "yes" to refer to IDNA for post-test counseling a letter confirming this will be sent with all reports for patients with pathogenic/likely pathogenic results.

Physician Signature:_____ **Date:**_____

9. Patient Personal History of Cancer & Other Clinical Information (Select all that apply.) ☐ No Personal History of Cancer

Patient has been diagnosed with:	Diagnosis Age	Currently Being	Pathology/ Other Info
☐ **Breast cancer** ☐ **L** ☐ **R**		☐ Yes ☐ No	☐ Ductal Invasive ☐ Lobular Invasive ☐ Premenopausal ☐ Metastatic ☐ Bilateral ☐ DCIS
☐ **Endometrial / Uterine**		☐ Yes ☐ No	☐ Tumor MSI-High or IHC Abnormal - Result: ☐ Tumor not available for MSI-High or IHC Abnormal Testing
☐ **Ovarian Cancer**		☐ Yes ☐ No	☐ Non-epithelial
☐ **Prostate Cancer**		☐ Yes ☐ No	☐ Gleason Score :_____ ☐ Metastatic
☐ **Colon / Rectal Cancer**		☐ Yes ☐ No	**Type:** ☐ Mucinous ☐ Tumor Infiltrating Lymphocytes ☐ Medullary Growth Pattern ☐ Signet ring ☐ Crohn's-like Lymphocytic Reaction ☐ Tumor is MSI-High or IHC Abnormal- Result:_____ ☐ Tumor not available for MSI-High or IHC Abnormal Testing
☐ **Colon / Rectal Adenomas**		☐ Yes ☐ No	Cumulative Adenomatous Polyp #: ☐ 1 ☐ 2-5 ☐ 6-9 ☐ 10-19 ☐ 20-99 ☐ 100+
☐ **Hematologic Cancer**		☐ Yes ☐ No	
☐ **Other Cancer**		☐ Yes ☐ No	**TYPE:**
☐ **Other Cancer**		☐ Yes ☐ No	**TYPE:**

10. Family History of Cancer (Provide complete and specific information to ensure proper insurance reimbursement, determine cancer risk estimates, and optimize medical management recommendations.)

Relationship to Patient	Maternal	Paternal	Cancer Site or Polyp Type *(add # for colon/rectal adenomas)*	Diagnosis Age

11. PATIENT CONSENT FOR NGS (Next Generation Sequencing) CANCER TESTING

What is NGS Testing: The purpose of this molecular genetics test is to ascertain if you carry any mutation(s) causing increased cancer susceptibility. This test will include analysis of relevant genes included on the cancer panel indicated above.

General Purpose and Clinical Information. NGS refers to a test that uses massively parallel platforms, allowing sequencing of large stretches of DNA. All genes on our NGS panel have been implicated in cancer predisposition and are associated with increased lifetime cancer risk(s). If mutations are identified in more than one gene on this panel, there may not be sufficient information available to determine your precise cancer risk. Therefore, the results of this genetic test may or may not have implications for your medical management and options including preventive screening/intervention or therapeutics based on your genetic testing result may change over time. If you are found to carry a mutation/variant in any of the genes analyzed, this may also have implications for your family members. This should be discussed with your healthcare provider. There are several types of results that can be generated as a result of genetic testing, including:

Pathogenic/Likely Pathogenic- a mutation was identified in a gene(s) associated with increased cancer susceptibility that is clinically significant from the evidence that has been found in research papers and case-studies. This means that you may be at an increased risk of developing certain cancer(s). This risk is associated with specific cancers based upon the type of variant and which gene it is present in. Your healthcare provider will make cancer screening and medical management recommendations based on what is known about the mutation that was found.

Variant of Unknown Significance- An alteration was identified in one or more genes; however, there is not enough information to determine whether this change is associated with an increased risk for cancer. A thorough review of the variant and the associated literature may suggest that a variant is more likely to be disease-causing or benign. However, in some cases the significance remains unclear. Your healthcare provider will make cancer screening and medical management recommendations based on your personal and/or family history.

Description and principle of the test: This test uses targeted next-generation sequencing (NGS) to analyze coding regions of the genes listed in this requisition. This panel represents genes with known implications in hereditary cancer risk and is intended to provide information for physicians that assist them with cancer screening decisions.

Technical Limitations of this test: While this test is designed to identify most detectable mutations in the genes analyzed, it is still possible that there are mutations that this testing technology is unable to detect. In addition, there may be other genes associated with cancer susceptibility that are not included on this panel or that are not known at this time.

What is required to perform this test? You will be asked to provide 2 buccal swabs containing brushings from the inside of your cheeks. DNA will be extracted from these samples and tested according to our validated SOPM and compliance policies. As a CLIA-certified laboratory, we strictly adhere to all the rules regarding compliance with regulations related to patient confidentiality, diagnosis coding, professional courtesy, proficiency testing and other similar regulatory requirements. Your sample and DNA will be discarded at the end of testing process and stored for no more than 60 days. In some circumstances, a patient's DNA may be used anonymously as a negative or positive control sample in future testing, but in this circumstance, all identifiers will be removed prior to re-testing and the DNA sample and results obtained will remain anonymous.

☐ I consent that SureTox laboratory may use my DNA for the above duration and purpose. **Patient Name:**_____ **Patient Signature:**_____

☐ I grant consent to SureTox laboratory to use my sample for further research if deemed useful: **Patient Name:**_____ **Patient Signature:**_____

How will I obtain results from this test? Due to the complexity of DNA-based testing in general and NGS-testing in particular, as well as the important implications of the test results, these results will be reported through your designated physician or genetic counselor. To the extent permitted by law, all of your laboratory records and results are confidential and shall not be disclosed without written authorization.

Patient Attestation of Informed Consent: My signature indicates that I have received information about this test, and I have read and understood the material in this document. I have been given a full opportunity to ask questions that I may have about the testing procedure and related issues. I agree to undergo this testing. The decision to consent to, or to refuse, the above testing is entirely mine. No test(s) will be performed and reported on my sample other than the one(s) authorized by my doctor, and any unused portion of my original sample will be destroyed within 60 days of receipt of the sample by the laboratory.