HEREDITARY CANCER REQUISITION

sema4 | Ambry Genetics® Organization Code: 16655

1 Commercial Street, Branford, CT 06405
Tel: **833-486-6260** / Fax: 516-953-8154
Tax ID# 13-6171197 / CLIA# 07D2101517
CT Lic#: CL-0830 / CAP #9283362

123456-2-X

Please place green collection kit barcode here.

☐ **STAT** **Date of surgery:**___/___/___ **email: hcbranford@sema4genomics.com**

Please note that the STAT process will bypass insurance preauthorization and may result in unexpected out of pocket costs.

Please be sure to fill out all highlighted fields. Failure to fill them in may result in delayed testing and delivery of results.

PATIENT INFORMATION

Sema4 will use this information to contact the patient via automatic email, SMS, and/or phone regarding payment, testing status, and online results access. By submitting this requisition, I confirm that I have obtained the patient's authorization to be contacted by Sema4 by these means (email address must be specific to patient listed on form).

PATIENT EMAIL ADDRESS	PATIENT MOBILE/PRIMARY NUMBER
RECOMMENDED	REQUIRED
LAST NAME REQUIRED	**FIRST NAME** REQUIRED MI
DATE OF BIRTH MM / DD / YYYY	**BIOLOGICAL GENDER** ☐ M ☐ F REQUIRED
PATIENT/CLIENT MRN	
ADDRESS REQUIRED	**CITY / STATE / ZIP** REQUIRED

Ethnicity *(Check all that apply)*
☐ African American ☐ Ashkenazi Jewish ☐ Asian ☐ Caucasian ☐ Hispanic
☐ Middle Eastern ☐ Native American ☐ Pacific Islander ☐ Other ☐ Unknown

BILLING INFORMATION

Bill to: ☐ Client/Institution ☐ Insurance ☐ Self Pay/No Insurance

POLICYHOLDER LAST NAME	POLICYHOLDER FIRST NAME	POLICYHOLDER DOB
REQUIRED	REQUIRED	MM / DD / YYYY
INSURANCE CARRIER REQUIRED	**INSURANCE ID** REQUIRED	**GROUP NO.** REQUIRED

BILLING ADDRESS REQUIRED

SECONDARY INSURANCE ☐ YES ☐ NO

SECONDARY INSURANCE NAME	GROUP NO.

Pre-Authorization #: _____ *Please include a copy of all insurance paperwork.*

ASSIGNMENT AND RELEASE: I hereby authorize my insurance benefits be paid directly to the provider and I understand that I am financially responsible for uncovered services. I also authorize the release of any information required to process the claim. Billing inquiries, please call 800-298-6470, Option 3.

SIGNATURE **DATE** MM / DD / YYYY

REFERRING PROVIDER INFORMATION

Name	Genetic Counselor / Additional Clinician
REQUIRED	
NPI# REQUIRED	**Clinic / Institution** REQUIRED
Address REQUIRED	**Telephone** REQUIRED
	Fax
Sending Physician Practice: ☐ Doctor's Office ☐ Referral Lab	☐ Hospital - Inpatient ☐ Hospital - Outpatient

MEDICAL PROVIDER SIGNATURE OF CONSENT REQUIRED BELOW: I certify that the patient specified above and/or their legal guardian has been informed of the benefits, risks, and limitations of the laboratory test(s) requested. I have answered this person's questions. I have obtained informed consent from the patient or their legal guardian for this testing.

SIGNATURE **DATE** MM / DD / YYYY

INDICATIONS FOR TESTING

PATIENT CLINICAL HISTORY:	☐ None	☐ Yes (turn form over)
PATIENT TESTING HISTORY:	☐ None	☐ Yes (turn form over)
FAMILY HISTORY:	☐ None	☐ Yes (turn form over)

ICD10 Dx CODE(S) - REQUIRED

☐ **C61**- Malignant Neoplasm of **Prostate**
☐ **Z85.3**- Personal history of malignant neoplasm of **breast**
☐ **Z85.43**- Personal history of malignant neoplasm of **ovary**
☐ **Z80.3**- Family history of malignant neoplasm of **breast**
☐ **Z80.41**- Family history of malignant neoplasm of **ovary**
☐ **Z80.0**- Family history of malignant neoplasm of **digestive organs**
☐ **Z85.00**- Personal history of malignant neoplasm of unspecified **digestive organ**
☐ **Z85.07**- Personal history of malignant neoplasm of **pancreas**
☐ **Z85.46**- Personal history of malignant neoplasm of **prostate**
☐ **Z80.42**- Family history of malignant neoplasm of **prostate**
☐ **Z80.8**- Family history of malignant neoplasm of **other organ**
☐ Other: _____

COLLECTION DATE: MM / DD / YYYY

SPECIMEN TYPE: (# of samples sent): YELLOW _____ PURPLE _____ GREEN _____ SALIVA _____

LABORATORY TEST(S) ORDERED – SEE REVERSE FOR FULL GENE LISTING

Test Selection (Required)

☐ **Genetic counseling provided by GeneScreen**

Comprehensive Hereditary Cancer
☐ **CancerNext** sequencing and deletion/duplication testing
☐ **CancerNext-*Expanded*** sequencing and deletion/duplication testing

Hereditary Breast and Ovarian Cancer
☐ ***BRCA1* and *BRCA2*** sequencing and deletion/duplication testing
☐ **BRCA Ashkenazi** Jewish 3-site mutation panel
☐ **BRCAplus** sequencing and deletion/duplication testing
☐ **BreastNext** sequencing and deletion/duplication testing
☐ **GYNplus** sequencing and deletion/duplication testing
☐ **OvaNext** sequencing and deletion/duplication testing

Hereditary Colon Cancer
☐ **Lynch/HNPCC** Sequential
(Step1: *MLH1, MSH2,* and *MSH6* sequencing and deletion/duplication testing + *EPCAM* deletion/duplication testing.
Step2: *PMS2* sequencing and deletion/duplication testing)
☐ **Lynch/HNPCC** Concurrent
(*MLH1, MSH2, MSH6* and *PMS2* sequencing and deletion/duplication testing + *EPCAM* deletion/duplication testing)
☐ **MSH2** Inversion
☐ **ColoNext** sequencing and deletion/duplication testing

Hereditary Brain Tumors/Cancers
☐ **BrainTumorNext** sequencing and deletion/duplication testing

Hereditary Melanoma
☐ **MelanomaNext** sequencing and deletion/duplication testing

Hereditary Pancreatic Cancer
☐ **PancNext** sequencing and deletion/duplication testing

Hereditary Prostate Cancer
☐ **ProstateNext** sequencing and deletion/duplication testing

Hereditary Paragangliomas and/or Pheochromocytomas
☐ **PGLNext** sequencing and deletion/duplication testing

Hereditary Renal Cancer
☐ **RenalNext** sequencing and deletion/duplication testing

☐ **Single gene:** _____
☐ Targeted Testing: variant _____
Relationship to relative _____
(Please attach a copy of the relative's test report)

☐ **Reflex testing request:** _____

COMPLETE AND SUBMIT ALL PAGES TO LABORATORY

PATIENT CLINICAL HISTORY

Please include a copy of medical consult notes, if available, for billing investigation purposes.

☐ No personal history of cancer

Cancer/Tumor	Age at Dx	Pathology and Other info
Brain tumor		
Breast		Type: ER ☐ (+) ☐ (-) ☐ unk PR ☐ (+) ☐ (-) ☐ unk HER2/neu ☐ (+) ☐ (-) ☐ unk
2nd primary breast		Type: ER ☐ (+) ☐ (-) ☐ unk PR ☐ (+) ☐ (-) ☐ unk HER2/neu ☐ (+) ☐ (-) ☐ unk
Colorectal		Location:
Melanoma		
Ovarian		☐ Fallopian tube ☐ Primary peritoneal
Pancreatic		
Prostate		☐ Gleason Score: Metastatic: ☐ Y ☐ N
Uterine		
Hematologic		Type: ☐ Allogenic bone marrow or peripheral stem cell transplant*
Other Cancer		Type:
GI Polyps		☐ Adenomatous Polyp #: ☐1 ☐2-5 ☐6-9 ☐10-19 ☐20-99 ☐100+ ☐ Other type: Polyp #: ☐1 ☐2-5 ☐6-9 ☐10-19 ☐20-99 ☐100+

Other clinical history:

PATIENT TESTING HISTORY (IF APPLICABLE) ☐ NO PREVIOUS GENETIC TESTING

☐ Germline genetic testing Test(s) performed: _____
Result(s): _____

☐ Somatic test/tumor profile Test(s) performed: _____
Result(s): _____

☐ Microsatellite instability analysis:
☐ Stable (MSS) ☐ Unstable/high (MSI-H) ☐ Unstable/low (MSI-L)

☐ IHC, if multiple primaries, tumor used: _____
☐ Proteins present: _____ ☐ Proteins absent: _____

FAMILY HISTORY

Maternal (mother's side) family history of cancer ☐ Yes ☐ No ☐ Unknown			Paternal (father's side) family history of cancer ☐ Yes ☐ No ☐ Unknown			Other (siblings/children) family history of cancer ☐ Yes ☐ No ☐ Unknown		
Relation to patient	H/o cancer/polyps	Dx age	Relation to patient	H/o cancer/polyps	Dx age	Relation to patient	H/o cancer/polyps	Dx age

☐ There is a known variant identified in the family. Gene: _____ Variant: _____ (please attach report)

Hereditary Breast and Ovarian Cancer

BRCA1 and ***BRCA2*** sequencing and deletion/duplication testing

BRCA Ashkenazi Jewish 3-site mutation panel
(*BRCA1* gene c.68_69delAG and c.5266dupC and *BRCA2* gene c.5946delT)

BRCAplus (sequencing and deletion/duplication testing of the following 8 genes):
ATM, BRCA1, BRCA2, CDH1, CHEK2, PALB2, PTEN, TP53

BreastNext (sequencing and deletion/duplication testing of the following 17 genes): *ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, MRE11A, MUTYH, NBN, NF1, PALB2, PTEN, RAD50, RAD51C, RAD51D, TP53*

GYNplus (sequencing and deletion/duplication testing of the following 13 genes):
BRCA1, BRCA2, BRIP1, EPCAM, MLH1, MSH2, MSH6, PALB2, PMS2, PTEN, RAD51C, RAD51D, TP53*

OvaNext (sequencing and deletion/duplication testing of the following 25 genes):
ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, DICER1, EPCAM, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, NF1, PALB2, PMS2, PTEN, RAD50, RAD51C, RAD51D, SMARCA4, STK11, TP53*

Hereditary Colon Cancer

Lynch/HNPCC Sequential
(Step1: *MLH1, MSH2,* and *MSH6* sequencing and deletion/duplication testing + *EPCAM* deletion/duplication testing.
Step2: *PMS2* sequencing and deletion/duplication testing)

Lynch/HNPCC Concurrent
(*MLH1, MSH2, MSH6* and *PMS2* sequencing and deletion/duplication testing + *EPCAM* deletion/duplication testing)
MSH2 Inversion

ColoNext (sequencing and deletion/duplication testing of the following 17 genes):
APC, BMPR1A, CDH1, CHEK2, EPCAM, GREM1*, MLH1, MSH2, MSH6, MUTYH, PMS2, POLD1, POLE, PTEN, SMAD4, STK11, TP53*

Comprehensive Hereditary Cancer

CancerNext (sequencing and deletion/duplication testing of the following 34 genes associated with increased risk for breast, ovarian, colorectal, uterine, and other cancers):
APC, ATM, BARD1, BRCA1, BRCA2, BRIP1, BMPR1A, CDH1, CDK4, CDKN2A, CHEK2, DICER1, EPCAM, GREM1*, HOXB13, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, NF1, PALB2, PMS2, POLD1, POLE, PTEN, RAD50, RAD51C, RAD51D, SMAD4, SMARCA4, STK11, TP53*

CancerNext-*Expanded* (sequencing and deletion/duplication testing of the following 67 genes associated with increased risk for breast, colon, ovarian, pancreatic, renal, uterine, and many other cancers):
AIP, ALK, APC, ATM, BAP1, BARD1, BLM, BRCA1, BRCA2, BRIP1, BMPR1A, CDH1, CDK4, CDKN1B, CDKN2A,CHEK2, DICER1, EPCAM, FANCC, FH, FLCN, GALNT12, GREM1, HOXB13, MAX, MEN1, MET, MITF, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, NF1, NF2, PALB2, PHOX2B, POT1, PMS2, POLD1, POLE, PRKAR1A, PTCH1, PTEN, RAD50, RAD51C, RAD51D, RB1, RET, SDHA, SDHAF2, SDHB, SDHC, SDHD, SMAD4, SMARCA4, SMARCB1, SMARCE1, STK11, SUFU, TMEM127, TP53, TSC1, TSC2, VHL, XRCC2

Hereditary Brain Tumors/Cancers

BrainTumorNext sequencing and deletion/duplication testing
AIP, ALK, APC, CDKN1B, CDKN2A, DICER1, MEN1, MLH1, MSH2, MSH6, NBN, NF1, NF2, PHOX2B, PMS2, POT1, PRKAR1A, PTCH1, PTEN, SMARCA4, SMARCB1, SMARCE1, SUFU, TP53, TSC1, TSC2, VHL

Hereditary Melanoma

MelanomaNext (sequencing and deletion/duplication testing of the following 8 genes): *BAP1, BRCA2, CDK4, CDKN2A, MITF, PTEN, RB1, TP53*

Hereditary Pancreatic Cancer

PancNext (sequencing and deletion/duplication testing of the following 13 genes):
APC, ATM, BRCA1, BRCA2, CDKN2A, EPCAM, MLH1, MSH2, MSH6, PALB2, PMS2, STK11, TP53*

Hereditary Prostate Cancer

ProstateNext (sequencing and deletion/duplication testing of the following 14 genes): *ATM, BRCA1, BRCA2, CHEK2, EPCAM, HOXB13, MLH1, MSH2, MSH6, NBN, PALB2, PMS2, RAD51D, TP53*

Hereditary Paragangliomas and/or Pheochromocytomas

PGLNext (sequencing and deletion/duplication testing of the following 12 genes):
FH, MAX, MEN1, NF1, RET, SDHA, SDHAF2, SDHB, SDHC, SDHD, TMEM127, VHL

Hereditary Renal Cancer

RenalNext (sequencing and deletion/duplication testing of the following 19 genes):
BAP1, EPCAM, FH, FLCN, MET, MITF* (genotyping for c.952G>A ONLY), *MLH1, MSH2, MSH6, PMS2, PTEN, SDHA, SDHB, SDHC, SDHD, TP53, TSC1, TSC2, VHL*

* = sequencing is not available for this gene, (deletion/duplication testing ONLY)

COMPLETE AND SUBMIT ALL PAGES TO LABORATORY

Informed Consent for Hereditary Cancer Genetic Testing

I, _____, hereby request genetic testing for

☐ Myself

☐ My child _____

I have received verbal and written information (please see sema4.com/testcatalog for test-specific information sheet) from my physician or from a genetic counselor that described, in words that I understood, the nature of the genetic testing that I/my child am about to undergo.

The nature of the genetic test,_____, has been explained to me and the accuracy of the test and its risks and limitations have been detailed. I understand that specimen(s), such as peripheral blood, saliva, cheek swab, or skin biopsy will be taken from me/my child. I understand that the samples will be used for determining if I have /my child has a genetic disease, are carriers of a genetic disease or are more susceptible to develop a genetic disease or medical condition. The results may also suggest that I am/my child is affected with a condition that is different than, and/or that is in addition to, those considered for the purpose of consenting for this test. I further understand that my or my child's genetic test results may have implications for the rest of the family as genetic changes can be inherited.

I understand that there are several types of genetic test results, including:

- **Positive,** meaning that a mutation that is associated with an increased risk to develop cancer has been identified. The specific type(s) of these risks can vary depending on the gene in which the mutation is found. A positive result may have medical management implications. For certain genes/mutations, the cancer risks are not well established at this time, and more data and specific medical management recommendations related to these genes may evolve over time.
- **Negative,** meaning that no mutations were identified. A negative result reduces, but does not eliminate, the possibility that I carry /my child carries mutations in the genes analyzed or in other genes that are not included in the test. I/my child still have the general population's risk for developing cancer and may also be at a higher risk to develop cancer based on personal/family history.
- **Inconclusive,** meaning that an alteration was identified in the genes tested where there is insufficient information at this time to determine if such alteration is associated with increased cancer risks.

I will discuss any appropriate medical intervention with my healthcare provider before taking any action based on my/my child's results, and I will provide my/my child's genetic test result and personal/family history to my healthcare providers so that they can make an appropriate recommendation.

I understand that although the likelihood of an incorrect diagnosis or a misinterpretation of the result is extremely small, infrequent errors may occur. I understand that this testing may yield results that are of unknown clinical significance and that parental and/or other relative's specimens may also be tested or requested to determine whether a specific finding is inherited. In addition, incidental findings that are not related to the primary diagnosis may be identified in me/my child. An error in the diagnosis may occur if the true biological relationships of the family members involved in this study are not as I have stated.

There are some federal and state laws that address genetic discrimination. The US Genetic Information Nondiscrimination Act (GINA) may prohibit discrimination by employers and health insurances. This law, however, does not protect people in the military nor possible discrimination by other types of insurance such as life, disability or long-term care.

De-identified research

Sema4 may de-identify and use all data and information generated and received in connection with this test to support medical and academic research relating to health, disease prevention, drug development, and other scientific purposes, and I will receive no compensation in connection with such research. Data and information are "de-identified" by removing any information that could be used to identify a specific person, such as a name, email address, or date of birth. Sema4 may also give the de-identified data and information to its research partners and may submit it to research databases for use in scientific and medical research, including scientific databases that are maintained by the federal government, such as a database kept by the National Institutes of Health ("NIH") (an agency of the federal government that funds research). Researchers have to apply to the NIH to see the information in the database.

If I do not want to have any of my/my child's de-identified data and information used in research consistent with this consent, I may initial here _____ , or I may withdraw this consent by contacting Sema4, including by emailing privacy@sema4.com.

Permission to contact

I understand that Sema4 may wish to contact me/my child in the future, including for the following reasons: research purposes, the provision of general information about research findings, and/or the provision of information about the results of tests on my/my child's sample(s). I understand that I may notify Sema4 to opt out of such future contact, including by emailing privacy@sema4.com.

The results of my/or my child's test will be explained to me by a genetic counselor or by my physician who will have the opportunity to discuss my results with a geneticist. I have had the opportunity to have all of my questions answered. If I am signing this form on behalf of a minor for whom I am the legal guardian, I am satisfied that I have received enough information to sign on his or her behalf.

I understand that this consent is being obtained in order to protect my right to have all of my questions answered before testing. I understand that the results of this testing will become part of my medical record and may only be disclosed to individuals who have legal access to this record or to individuals who I designate to receive this information.

SAMPLE STORAGE

_____
Initials

By initialing here, I agree that Sema4 may store, de-identify, and use my/my child's sample and information to support medical and academic research relating to health, disease prevention, drug development, and other scientific purposes, and that I/my child will receive no compensation in connection with such research. If I do not initial here, my/my child's sample will be destroyed at the end of the testing process or not more than 60 days after collection. I understand that I may withdraw this consent by contacting Sema4 (including by emailing privacy@sema4.com).

_____ _____

Signature of person being tested (or guardian) Date

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