APC Health
2817 Miller Ranch Rd, 317, Pearland TX, 77584
Tel: (281) 240-0974 Fax: (844) 604-0145
CLIA # 45D2111506
Director's Name : Chesinta B. Voma, Ph.D.

Hereditary Cancer Test Requisition Form

Patient Information

Patient/Sample ID

First name Last name

Gender ❒ Male ❒ Female Date of birth (mm/dd/yy)_____

Ancestry ❒ Caucasian ❒ Eastern European ❒ Northern European
❒ Western European ❒ Native American ❒ Middle Eastern
❒ African American ❒ Asian ❒ Pacific Islander
❒ Caribbean ❒ Central/South American
❒ Ashkenazi Jewish ❒ Hispanic ❒ Other:_____

Mailing address

City State Zip code

Home phone Work phone

Email Patient's primary language if not English

Ordering Account Information

Acct # Account Name

Reporting Preference*. ❒ Care Evolve ❒ Fax ❒ Email

**If unmarked, we will use the account's default preferences or fax to new clients.*

Physician NPI #

Genetic Counselor

Street address 1

Street address 2

City State Zip code

Phone Fax (important)

Email Beeper

Send Additional Report Copies To:

Physician or GC/Acct # Fax#/Email/CE #

Physician or GC/Acct # Fax#/Email/CE #

Sample Information

Medical Record # Specimen ID **Date sample obtained (mm/dd/yy)**

Specimen Type

❒ Blood in EDTA (5-6 mL in lavender top tube)

❒ DNA (>20 ug): Tissue source _____ concentration _____ (ug/ml)
total Volume _____(ul)

❒ Oral Rinse (At least 30 mL of Scope oral rinse in a 50 mL centrifuge tube)

❒ Other _____(Call lab)

Patient has had a blood transfusion ❒ Yes ❒ No

Date of last transfusion ____/____/____ (2-4 weeks of wait time is required for some testing) Specimens are not accepted for patients who have had allogeneic bone marrow transplants.

Treatment-Related **RUSH**: _____ *(If known, please provide date)*

Clinical Diagnosis: _____

ICD-10 Codes: _____

Age at Initial Presentation:_____

Statement of Medical Necessity

This test is medically necessary for the diagnosis or detection of a disease, illness, impairment, symptom, syndrome or disorder. The results will determine my patient's medical management and treatment decisions. The person listed as the Ordering Physician is authorized by law to order the tests(s) requested herein. I confirm that I have provided genetic testing information to the patient and they have consented to genetic testing.

Medical Professional Signature (required) Date

Patient Consent (sign here or on the consent document)

I have read the Informed Consent form and I give permission to APC Health llc to perform genetic testing as described. I also give permission for my specimen and clinical information to be used in anonymized studies at APC Health llc and for publication, if appropriate. My name or other personal identifying information will not be used in or linked to the results of any studies and publications.

❒ Check this box if you wish to opt out of being contacted for research studies.

Patient/Guardian Signature Date

Billing Information

Benefit Investigation Requested ❒ Yes ❒ No

Referral/Prior Authorization # _____

Please attach copy of Referral/authorization

Insurance Information for Billing Purposes

Insurance Carrier Policy Name

Insurance ID # Group # Name of Insured Date of Birth Insurance Address City State Zip

Relationship to Insured ❒ Child ❒ Spouse ❒ Self ❒ Other

Secondary Insurance Carrier Policy Name

Insurance ID # Group # Name of Insured Date of Birth Insurance Address City State Zip

Relationship to Insured ❒ Child ❒ Spouse ❒ Self ❒ Other

Please include a copy of the front and back of the patient's insurance card (include secondary when applicable)

Patient Bill

Amount _____

I understand that my credit card will be charged the full amount for the testing.

Please bill my credit card (all major cards accepted)

❒ MasterCard ❒ Visa ❒ Discover ❒ American Express

Name as it appears on card

Account Number Expiration date CVC

Signature Date

For APC Health Use Only

APC Health
2817 Miller Ranch Rd, 317, Pearland TX, 77584
Tel: (281) 240-0974 Fax: (844) 604-0145
CLIA # 45D2111506
Director's Name : Chesinta B. Voma, Ph.D.

Hereditary Cancer Testing

First Name _____ Last Name _____ Date of Birth (mm/dd/yy) _____

Patient Clinical History

❒ **No Personal History of Cancer**
❒ **Breast Cancer(s)** Age at Dx:_____ ER: + / - PR: + / - HER2: + / - Triple Negative ❒ Bilateral ❒ Two Primaries ❒ Invasive Ductal _____ ❒ Invasive Lobular ❒ DCIS ❒ LCIS
❒ **Ovarian Cancer(s)** Age at Dx: _____ ❒ Serous ❒ Mucinous ❒ Endometrioid ❒ Clear Cell ❒ LMP/Borderline ❒ Other: _____
❒ **Endometrial Cancer(s)** Age at Dx: _____ ❒ Serous ❒ Mucinous ❒ Endometrioid ❒ Clear Cell ❒ Sarcoma ❒ Other:_____
❒ **Pancreatic Cancer(s)** Age at Dx: _____ ❒ Adenocarcinoma ❒ IPMN ❒ Neuroendocrine ❒ Other: _____
❒ **Prostate Cancer** Age at Dx: _____ Gleason Score:_____
❒ **Hematologic disorder(s)** Age at Dx: _____ Diagnosis:_____
Status: ❒ Active/Residual Disease ❒ Remission
❒ **Gastric Cancer(s)/Tumor(s)** Age at Dx:_____ Pathology: _____
❒ **Other Cancer(s)/Tumor(s):**_____ Age at Dx:_____
❒ **Melanoma(s)** Age(s) at Dx: _____ ❒ Invasive ❒ In-Situ

❒ **Brain Cancer(s)/Tumor(s)** Age(s) at Dx:_____ Pathology: _____
❒ **Colorectal Cancer(s)** Age at Dx: _____ Pathology:_____
Location: ❒ Right ❒ Left ❒ Transverse ❒ Rectum
MSI: ❒ Not Done ❒ High ❒ Stable ❒ Low
IHC: ❒ Not Done ❒ Present ❒ Absent IHC of:_____
MLH1 Methylation: ❒ Not Done ❒ Unmethylated
❒ Methylated – Tumor Only ❒ Methylated – Tumor and Normal Tissue
BRAF V600E: ❒ Not Done ❒ Positive ❒ Negative
❒ **Polyps** Age of first polyp:_____ Adenomatous – total #: _____
❒ Other Pathology:_____ Other – total #: _____
❒ **Renal Cancer(s)/Tumor(s)** Age at Dx: _____ ❒ Bilateral
❒ Clear Cell: _____ ❒ Papillary Type (I or II): _____ ❒ Transitional Cell
❒ Other:_____
❒ **Endocrine Cancer(s)/Disease** Age(s) at Dx: _____ ❒ Thyroid
❒ Pathology/Diagnosis: _____ ❒ Pheochromocytoma (PCC)
❒ Paraganglioma (PGL) Location: _____ ❒ Bilateral

Family History of Cancer(s)/Tumor(s)

❒ Pedigree Attached ❒ Adopted ❒ Mat History Unknown ❒ Pat History Unknown

Relationship	Maternal	Paternal	Cancer/Tumor Site/Pathology/Polyp #	Age at Dx
_____	❒	❒	_____	_____
_____	❒	❒	_____	_____
_____	❒	❒	_____	_____
_____	❒	❒	_____	_____

Patient Genetic Testing History

❒ **No Personal History of Genetic Testing**
Gene(s) Tested: _____ ❒ Positive _____ ❒ VUS _____ ❒ Negative

Previous Familial Genetic Testing

❒ **No Known Family History of Genetic Testing**
❒ Relative Tested:_____ ❒ Gene(s) Tested: _____ ❒ Positive _____ ❒ VUS _____ ❒ Negative
Please include copies of family members' previous test results.

Hereditary Cancer Test Menu

❒ B362-5 *BRCA1/BRCA2* Sequencing and Deletion Duplication Analysis[1]
If negative, reflex to test code: _____
❒ B361-7 *BRCA1/BRCA2* Ashkenazi Founder Panel (Three Targeted Pathogenic Variants)[1]
If negative, reflex to test code: _____
❒ J055-5 Breast Cancer High/Moderate Risk Panel (8 genes)
❒ B273-4 Breast/Ovarian Cancer Panel (20 genes)
❒ B344-3 Endometrial Cancer Panel (12 genes)
❒ B399-7 Familial Cutaneous Malignant Melanoma (2 genes)[1]
❒ B275-9 Comprehensive Cancer Panel (32 genes)

❒ B751-9 High/Moderate Risk Panel (23 genes)
❒ B522-4 Lynch/Colorectal High Risk Panel (7 genes)
❒ B274-2 Colorectal Cancer Panel (19 genes)
B890-5 Lynch Syndrome Custom Panel (Please select one or more of the listed genes) [1,2]:
❒ *MLH1* ❒ *MSH2* ❒ *MSH6* ❒ *PMS2* ❒ *EPCAM*
❒ J006-8 *MSH2* Exons 1-7 Inversion Analysis
❒ B343-5 Pancreatic Cancer Panel (16 genes)
❒ J665-1 Prostate Cancer Panel (12 genes)
❒ B394-8 Renal Cancer Panel (18 genes)[1]
❒ B363-3 Rest of Comprehensive Cancer Panel, if subpanel is negative

❒ Other Hereditary Cancer Test (include test code and name):_____

1. Reflex to Rest of Comprehensive Cancer Panel, if subpanel is negative, is not available.
2. Lynch Syndrome single gene tests include sequencing and deletion/duplication except for *EPCAM* which only includes deletion/duplication analysis.

Targeted Variant Testing

❒ **B370 Testing for a previously identified variant**
Gene: _____ Variant: _____
Proband Name:_____ Relationship to proband: _____
Proband GeneDx or GenPath Accession #:_____
❒ Positive control included/will be sent - **Positive control is recommended if previous test was performed at another lab.**
❒ Positive control not available. Please initial to acknowledge acceptance of caveat language on a negative report_____
❒ Family Member Test Report included - A clear copy of the test report on the positive family member is recommended if previous test was performed at another lab.

Variant Testing Program (requires lab approval)

❒ **B753 Previously identified variant of uncertain significance**
VTP Family ID: **F**_____
Gene(s): _____
Variant(s):_____
Proband Name: _____
Relationship to proband: _____
Proband GeneDx Accession #: _____

Informed Consent and Authoriation Form

2817 Miller Ranch Rd, 317, Pearland TX, 77584
Tel: (281) 240-0974 Fax: (844) 604-0145
CLIA # 45D2111506
Director's Name : Chesinta B. Voma, Ph.D.

My signature on this consent form indicates that I request genetic testing at APC Health for: _____

I understand that participation in genetic testing is voluntary.

General information about genetic testing for hereditary cancer:

1. Genetic disorders may be caused by variants (changes) in the DNA sequence of a gene. Genetic disorders may also be due to a deletion (loss) or duplication (gain) of genetic material. The deletion or duplication may include part of a gene, an entire gene, or multiple genes.
2. The purpose of genetic testing is to evaluate for changes in the DNA sequence of a gene and, when clinically indicated, to look for deletions or duplications of gene(s). This test may help determine if I am affected with, or am at risk to someday develop, a form of hereditary cancer.
3. The genes included on this test are associated with several different types of cancer and with varying levels of cancer risk.
4. This test cannot identify all types of variants, deletions, or duplications causing hereditary cancers or other genetic disorders. Specifically, this test cannot identify any genetic changes involving genes not included in the specific test(s) ordered by my health care provider. In rare instances, the Next Generation Sequencing (NGS) and array Comparative Genomic Hybridization (aCGH) may identify a clinically significant genetic variant in a cancer gene not included on the panel ordered. These findings may be verbally disclosed to the ordering healthcare provider on a case-by-case basis.
5. I understand that this test is not the only way to look for genetic abnormalities. My health care provider may recommend this test before or after ordering other genetic or laboratory tests.
6. This test requires high-quality DNA. In some cases an additional sample may be needed if the volume, quality and/or condition of the initial specimen is not adequate.
7. Rarely, the test may reveal genetic gender information or genetic changes of clinical importance in gene(s) not included in the test, which will be disclosed to the ordering healthcare provider.

What could I learn from this genetic test?

1. **Negative result** - I may learn that no genetic abnormality was identified by this test. This reduces the likelihood, but does not exclude a hereditary form of cancer.
2. **Positive result** - I may learn that a genetic abnormality was identified that explains either the cause of cancer that I have and/or the risk that I have to develop cancer in the future. The type(s) of cancer for which I am at risk depends on the gene involved. These results may aid my physician in making decisions about my medical management, including but not limited to cancer screening, risk-reducing surgeries and preventive medication strategies.
3. **Variant of uncertain significance (VUS)** - I may learn that a VUS was identified by this test. This means that a genetic change (variant) was identified, but it is unknown whether the variant may cause cancer. The variant could be a normal genetic difference that does not cause medical problems, or it could be a cancer causing abnormality. Without further information, the effects of the variant may not be known, and an inconclusive result may be reported. Testing other affected family members may be necessary to determine the significance of the variant. The laboratory will provide additional information to my healthcare provider who is ordering this testing if this variant is determined to be benign or risk-causing.

What are the limitations and risks of this genetic test?

1. In some cases, testing may not identify an abnormality even though a genetic abnormality may exist. This may be due to limitations in current knowledge about a gene's complete structure. It may be due to the fact that some types of genetic abnormalities causing a specific hereditary cancer have not yet been identified. I understand that the methods used by APC Health llc are highly accurate. The chance of a false positive or false negative result, due to laboratory errors incurred during any phase of testing, or due to unusual circumstances (bone marrow transplantation, blood transfusion, presence of change(s) in such a small fraction of cells that they may not be detectable (mosaicism) or incorrect reporting of family history or relationships), cannot be completely excluded.
2. Accurate interpretation of the test results requires knowledge of the true biological relationships in a family. Failure to accurately disclose the biological relationships in a family may result in incorrect interpretation of results and/or inconclusive test results.
3. Genetic testing may reveal that the true biological relationships in a family are not as they were reported. For example, non-paternity means that the stated father of an individual is not the true biological father. It is possible that this test may detect non-paternity, and it may be necessary to report this finding to the individual(s) who requested testing.
4. You may be concerned about discrimination based on genetic test results. The federal government enacted the Genetic Nondiscrimination Act (GINA) of 2008 prohibiting this type of discrimination by health insurers and employers. Furthermore, genetic test results are deemed "Protected Health Information" per the Health Insurance Portability and Accountability Act (HIPAA) of 1996 which prohibits unauthorized disclosure of such information. These laws set a minimum standard of protection across the nation. Some states may have laws limiting the use of genetic information by other types of insurers as well.
5. The physical risk associated with this genetic test is that of the blood draw required in order to obtain the DNA. While the risk is low, some people may experience side effects such as soreness, bruising, dizziness, or fainting.

Patient confidentiality and counseling

1. To maintain confidentiality, I understand that results will be reported to the indicated healthcare provider or ordering laboratory and upon request copied to additional healthcare provider(s) indicated on the test requisition form. I understand that results may only be disclosed to others by my written consent and/or if demanded by an order of a court of competent jurisdiction.
2. Information obtained from the test may be used in scientific publications or presentations, but the identity of all individuals studied will not be revealed in such publications or presentations.
3. It is recommended that I receive genetic counseling before and after having this test. Further testing or additional consultations with physicians may be necessary.

Specimen retention

1. Submitted specimens are not banked at APC Health llc. DNA samples are not returned to individuals or to referring physicians.
2. In some cases, if further diagnostic tests are needed, a referring physician may request in writing that additional tests be performed on an existing DNA sample (additional costs apply). Additional testing will not be performed unless requested by an authorized healthcare professional.
3. In some cases, anonymized DNA may be used by the laboratory for new test development and/or laboratory quality assurance purposes after all identifiers have been removed._____ (Please initial)
4. NY residents: DNA sample can be retained for greater than 60 days after the completion of testing._____ (Please initial to consent)

Patient Name: _____ Date of Birth: _____
(Please Print) First Name Last Name mm/dd/yyyy

Patient Signature: _____ Date: _____

Health care Provider's Statement: By my signature below, I indicate that I am the referring physician or authorized health care provider. I have explained the purpose of the test described above. The patient has been given the opportunity to ask questions and/or seek genetic counseling. The patient has voluntarily decided to have the test performed by APC Health llc.

Healthcare Provider's Signature: _____ Date: _____

Hereditary Cancer Testing Panel Components

BRCA1/BRCA2 Ashkenazi Founder Panel
BRCA1 c.68_69delAG, BRCA1, c.5266dupC, BRCA2 c.5946delT
Breast Cancer High/Moderate Risk Panel
ATM, BRCA1, BRCA2, CDH1, CHEK2, PALB2, PTEN, TP53
Breast/Ovarian Cancer Panel
ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, FANCC, MLH1, MSH2, MSH6, NBN, PALB2, PMS2, PTEN, RAD51C, RAD51D, TP53, XRCC2*
Colorectal Cancer Panel
APC, ATM, AXIN2, BMPR1A, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH6, MUTYH, PMS2, POLD1, POLE, PTEN, SCG5/GREM1*, SMAD4, STK11, TP53*
Comprehensive Cancer Panel
APC, ATM, AXIN2, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, EPCAM, FANCC, MLH1, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, POLD1, POLE, PTEN, RAD51C, RAD51D, SCG5/GREM1*, SMAD4, STK11, TP53, VHL, XRCC2*
Endometrial Cancer Panel
BRCA1, BRCA2, CHEK2, EPCAM, MLH1, MSH2, MSH6, MUTYH, PMS2, POLD1, PTEN, TP53*
Familial Cutaneous Malignant Melanoma
CDKN2A, CDK4
High/Moderate Risk Panel
APC, ATM, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDKN2A, CHEK2, EPCAM, MLH1, MSH2, MSH6, MUTYH, PALB2, PMS2, PTEN, RAD51C, RAD51D, SMAD4, STK11, TP53, VHL*
Lynch/Colorectal High Risk Panel
APC, EPCAM, MLH1, MSH2, MSH6, MUTYH, PMS2*
Pancreatic Cancer Panel
APC, ATM, BRCA1, BRCA2, CDK4, CDKN2A, EPCAM, MLH1, MSH2, MSH6, PALB2, PMS2, STK11, TP53, VHL, XRCC2*
Prostate Cancer Panel
ATM, BRCA1, BRCA2, CHEK2, EPCAM, HOXB13, MLH1, MSH2, MSH6, NBN, PMS2, TP53
Renal Cancer Panel
BAP1, EPCAM, FH, FLCN, MET, MITF*, MLH1, MSH2, MSH6, PMS2, PTEN, SDHB, SDHC, SDHD, TP53, TSC1, TSC2, VHL*

EPCAM and SCG5/GREM1 testing includes deletion/duplication analysis only; MITF testing only includes the evaulation of c.952G>A.