CLIA: 10D0280394

2840 NW 2nd Ave, Suite 201, Boca Raton, FL 33431 · www.lab24inc.com · info@lab24inc.com · (800) 641-0133 · (800) 833-1066

55-GENE HEREDITARY CANCER TEST REQUISITION FORM

PATIENT INFORMATION

PATIENT'S FIRST NAME	PATIENT'S LAST NAME	SEX
		☐ FEMALE ☐ MALE
PATIENT'S DATE OF BIRTH (MM / DD / YYYY)	PATIENT'S ADDRESS	CITY / STATE / ZIP
PATIENT'S EMAIL ADDRESS	PATIENT'S PHONE NUMBER	MRN (OPTIONAL)

NAME OF YOUR INSURANCE COMPANY	MEMBER ID	CREDIT CARD NUMBER	EXPIRATON DATE	SECURITY CODE

RELATIONSHIP TO POLICY HOLDER

☐ SELF ☐ SPOUSE/PARTNER ☐ CHILD ☐ OTHER

☐ MY PATIENT WILL PROVIDE THEIR PAYMENT INFORMATION AT HOME

POLICY HOLDER'S FIRST NAME (IF NOT SELF)	POLICY HOLDER'S LAST NAME (IF NOT SELF)

YOU DO NOT NEED TO COMPLETE THE PATIENT'S PERSONAL AND FAMILY HISTORY OF CANCER SECTION IF YOU SELECT THE SELF-PAY OPTION

ORDERING PROVIDER

ORDERING PROVIDER'S NAME	PHONE NUMBER	ROLE OR TITLE
EMAIL ADDRESS	FAX NUMBER	NPI NUMBER
INSTITUTION OR PRACTICE	ADDRESS	CITY / STATE / ZIP

CGx PANEL

PANEL:	GENES:
☐ **COMPREHENSIVE** (55 GENES)	APC, ATM, AXIN2, BAP1, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDC73, CDH1, CDH1, CDKN1C, CDKN2A, CHEK2, DICER1, DIS3L2, EPCAM, FH, FLCN, GPC3, GREM1, MEN1, MET, MLH1, MSH2, MSH6, MUTYH, NBN, NF1, PRKAR1, PALB2, PMS2, POLD1, PTCH1, PTEN, RAD50, RAD51C, RAD51D, RB1, RECQL4, RET, SDHA, SDHB, SDHC, SDHD, SMAD4, SMARCA4, STK11, SUFU, TP53, TSC1, TSC2, VHL, WT1
☐ **BREAST** (16 GENES)	ATM, BARD1, BRCA1, BRCA2, BRIP1, NBN, NF1, PALB2, RAD50, RAD51C, RAD51D, STK11, CHEK2, TP53, PTEN, CDH1
☐ **BREAST/GYN** (23 GENES)	ATM, BARD1, BRCA1, BRCA2, BRIP1, NBN, NF1, PALB2, RAD50, RAD51C, RAD51D, MLH1, MSH2, MSH6, PMS2, EPCAM, STK11, CHEK2, TP53, PTEN, CDH1, DICER1, SMARCA4
☐ **PANCREATIC** (20 GENES)	APC, ATM, BMPR1A, BRCA1, BRCA2, CDKN2A, MEN1, NBN, PALB2, SMAD4, MLH1, MSH2, PMS2, EPCAM, STK11, TP53, VHL, TSC1, TSC2, WT1
☐ **PROSTATE** (11 GENES)	ATM, BRCA1, BRCA2, NBN, MLH1, MSH2, MSH6, PMS2, EPCAM, CHEK2, TP53
☐ **COLORECTAL** (18 GENES)	APC, BMPR1A, SMAD4, MLH1, MSH2, MSH6, PMS2, EPCAM, STK11, CHEK2, TP53, PTEN, CDH1, AXIN2, GREM1, MUTYH, POLD1, RET
☐ **RENAL/URINARY TRACT** (27 GENES)	MET, PTCH1, MLH1, MSH2, MSH6, PMS2, EPCAM, TP53, PTEN, VHL, DICER1, BAP1, CDC73, CDKN1C, CDC73, DIS3L2, FH, FLCN, GPC3, PRKAR1A, RB1, RECQL4 , SDHA, SDHB, SDHC, SDHD, SUFU

. Please note that research and screening guidelines for genes associated with hereditary prostate cancer are still In their early stages. It is part of the TCL service to keep you updated if any information related to your results changes.

.. Only positions known to impact cancer risk analyzed: COK4: only chr12:g.58145429-58145431 (codon 24) analyzed, EPCAM: only large deletions and duplications including 3' end of the gene analyzed, GREMI: only duplications in the upstream regulatory region analyzed, MITF: only chr3:g.70014091 (lncludJng c.952G>A) analyzed, POLDl: only chr19:g.50909713 (including c.1433G>A) analyzed, POLE: only chr12:g.133250250 (including c.1270C>G) analyzed.

... PMS2: Exons 12-15 not analyzed.

PATIENT'S PERSONAL HISTORY

CANCER/TUMOR	PERSONAL HISTORY		AGE AT Dx
☐ **BREAST** TRIPLE NEGATIVE(ER-,PR-,HER2-)	☐ YES	☐ NO	
☐ **BREAST** MULTIPLE PRIMARIES	☐ YES	☐ NO	
☐ **OVARIAN** CHECK IF NON-EPITHELIAL	☐ YES	☐ NO	
PROSTATE (GLEASON SCORE> 7)	☐ YES	☐ NO	
PANCREATIC	☐ YES	☐ NO	
ENDOMETRIAI/UTERINE	☐ YES	☐ NO	
COLON/RECTAL	☐ YES	☐ NO	
STOMACH	☐ YES	☐ NO	
MELANOMA	☐ YES	☐ NO	
OTHER CANCER(S)	☐ YES	☐ NO	
OTHER CANCER(S)	☐ YES	☐ NO	

PATIENT'S PERSONAL INFORMATION

☐ **PREVIOUS GENETIC TESTING FOR HEREDITARY CANCER**

☐ **BONE MARROW TRANSPLANT RECIPIENT**

☐ **BONE MARROW TRANSPLANT RECIPIENT**

FAMILY HISTORY OF CANCER

RELATIONSHIP	MATERNAL/PATERNAL	CANCER SITE(S)	AGE AT Dx

ICD-10 CODES

Informed consent, medical necessity and authorization. I attest that this test is medically necessary for the diagnosis or detection of a disease or disorder, and that the results will be used in medical management and care decisions for the patient. I attest that the patient has read the Lab 24 informed consent or had it read to him and her, and that I have fully informed the patient about the purpose, capabilities and limitations of the Lab 24 CGx test. The patient has voluntarily given full consent for Lab 24 CGx test, and signed a copy of this consent is available on file. Any Lab 24 informed consent that the patient agrees to you at a later date will supersede and replace this informed consent. By submitting this Test Requisition Form, I attest that I am ordering physician or am authorized under applicable laws and regulations to order genetic testing for the patient. If the patients credit card information has been submitted I also attest that the patient has authorized me to select the self-pay option and enter his or her payment information on his or her behalf the patient has authorized Lab 24 and it's designees to share the information on this form and related ordering information with his or her and sure for the purpose of processing receiving payment and appealing claims on behalf of the patient and has agreed that any insurance payment isn't directly sent to him or her will be remitted to lap 24 within 30 days. The patient has also been informed that he she shall be responsible for any co-pays deductibles and coinsurance and any other amounts not paid by insurance. I agree to Lab 24's transfer of the information in this form and ordering the physician's name to the Letter of Medical Necessity as authorization for insurance billing. I further attest that any information entered on this Test Requisition Form, or otherwise provided by me on behalf of the patient, is true and correct to the best of my knowledge, and the patient has consented to receive communications about his/her genetics test from Lab 24. This genetic test and related services are governed by Lab 24's Terms of Service, and information provided on this Test Requisition form is subject to Lab 24's Privacy Policy, both of which are available at www.lab24inc.com or upon request. **MEDICARE DOES NOT COVER SCREENING TESTS.**

Ordering Physician Signature	Date	Patient Signature (Consent on back of or attached to this form)	Date

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P: (800) 641-0133 F: (800) 833-1066

INFORMED CONSENT FOR GENETIC TESTING

My signature on this form indicates that I have read, or had read to me, the information below and that I understand it I have had the opportunity to discuss both the clinical test and the use of my sample in research studies, including the purposes and possible risks, with my medical provider or someone my medical provider has designated. I know that I may obtain professional genetic counseling if I wish, before signing this consent I understand **Lab 24** may contact me in the future for research and marketing opportunities. I understand **Lab 24** may use my de-identified information and test results for validation, educational, and/or research purposes, and this data may be submitted in a HIPAA-compliant manner to research databases. I have all the information I want, and all my questions have been answered. Relevant patient educational materials are also available through **Lab 24**.

PATIENT NAME HAVING TESTING (PLEASE PRINT): _____

PATIENT SIGNATURE (OR LEGAL GUARDIAN*): _____

DATE: _____ / ___ /_____

*Genetic testing on children under the age of 18 requires that the ordering healthcare provider obtain an informed consent from a parent or legal guardian. If legal guardian, specify relationship to the patient: _____

Description: The Hereditary Cancer Test is a Lab Developed Test (LDT) developed by **Lab 24**, in which genetic testing is performed to determine a person's inherited susceptibility to cancer. This testing is usually done using a saliva sample, however, other types of cells may be submitted in some instances. **Lab 24** will analyze the DNA of a specific gene(s) to look for mutations associated with a particular hereditary cancer syndrome.

Purpose: The purpose of the Hereditary Cancer Test is to analyze gene(s) for genetic changes called mutations. The gene(s) analyzed are associated with a specific hereditary cancer syndrome. This test will help determine if a person has an increased risk of developing certain tumors due to a mutation(s) in a cancer-predisposing gene. Genetic testing allows a more precise estimate of an individual's risk for hereditary cancer than personal and family history alone.

Genetic Counseling: Prior to signing this consent, you may wish to obtain professional genetic counseling. Genetic counselors are health care professionals with training in the areas of medical genetics and counseling. Genetic counselors can explain complex genetic information and can help you make informed, personalized decisions about your health, and the decision to receive genetic testing and how to understand the testing results.

Appropriateness and Performance: This test is validated for Hereditary Cancer risk only. This test analyzes only certain key gene(s) associated with a specific hereditary cancer syndrome(s). Genetic testing clarifies cancer risks for only those cancers related to the genes analyzed.

Results: Your results should be evaluated in the context of a personal and family health history, the results of physical examination, laboratory and hospital tests, and the clinical impression of your healthcare provider. Possible result outcomes include positive, negative and uncertain.

- Positive – A mutation that is associated with an increased risk for hereditary cancer has been identified. Knowing this information may help you and your doctor make more informed choices about your health care, such as screening, risk-reducing surgeries and preventative medication strategies.
- Negative – A mutation was not identified.
    - If you are the first person tested in your family, you still have at least the same risk of cancer as does a person in the general population. You may still be at greater than average risk for hereditary cancer due to a genetic predisposition that cannot be detected by this test, either in the gene(s) you were tested for or in another gene linked to hereditary cancer.
    - If you test negative for a mutation known to be in your family, you are considered to have the same risks as others in the general population.

- Uncertain - A genetic change was detected but is not known if this change is linked to cancer risk You still have at least the same risk of cancer as the general population. In addition, you may still be at greater than average risk due to this change or genetic predisposition that cannot be detected by this test, either in the gene(s) you were tested for or in another gene linked to hereditary cancer.

Genetic test results have implications for blood relatives. In consultation with an appropriate healthcare provider, you may wish to discuss sharing your test results with certain blood relatives who may be at risk If you decide to do this, you should also consider the best way to make this disclosure.

Unauthorized Use of Sample: No tests will be performed and reported on my sample other than those explicitly authorized by my medical provider in writing,

Disclosure Lab 24 will disclose the test results ONLY to the medical provider listed on the front of this form, or to his/her agent, unless otherwise authorized by you as the patient or required by law.

Use for Future Genetic Research: With your consent, **Lab 24** may use leftover samples and information from testing for research. If you provide this consent, your information and left over samples will be permanently stripped of any identifying information and may be used or stored indefinitely. You will not be paid to participate in this research.

Period of Retention: Lab 24 intends to retain the sample indefinitely or as long as it is deemed useful for research purpose.

Confidentiality - Policies and Procedures: Lab 24 keeps test results confidential and is fully in compliance with all Health Insurance Portability and Accountability Act (HIPAA) requirements. **Lab 24** will only release test results to your healthcare provider, his or her designee, genetic counselor or to another healthcare provider as directed by you (or a person legally authorized to act on your behalf) in writing or as otherwise required by federal and state laws. You acknowledge that you have read and understand **Lab 24** Notice of Privacy Practices. You agree **Lab 24** is not liable for the unauthorized release of your results or medical information, unless such authorized release was the result of gross negligence or willful misconduct on the part of **Lab 24.** You acknowledge that certain email, SMS, telephone or video communications may not be encrypted and/or secure, and unless you request that **Lab 24** not contact you by these means, there are risks with such unsecured communications.

Non-Disclosure to Third Parties: In no event shall your family members be contacted for clinical, research, or other purposes without your consent with respect to the specific family members who will be contacted and the specific purpose of the contact.

Right to Withdraw Consent: You have the right to withdraw your consent to use of your sample for future use at any time. To withdraw your consent you should contact **Lab 24**.

Future Contact: Due to the emerging and dynamic nature of the field of genetics, new information and data continue to be developed. It is recommended that you keep in contact with your healthcare provider, annually, to learn of any new developments in genetics and to provide your healthcare provider with any updates to your medications, health, personal or family medical history.

Financial Authorization: I hereby authorize **Lab 24** 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 **Lab 24** directly for services rendered. **In the event of an underpayment or denial by my insurance carrier or denial of request for pre-authorization, I hereby authorize Lab 24 or their designee, to appeal to 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. (* Lab 24 and or designee may perform this appeal on my behalf, but is not obligated to do so).**

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Patient Name: _____

Date of Birth: _____

Today's Date: _____

Hereditary Cancer Questionnaire

DOES CANCER RUN IN YOUR FAMILY? CHECK THOSE THAT APPLY.

Please fill this form out to the best of your ability. Please only consider family members related to you **by blood**, such as your parents, grandparents, children, brothers, sisters, aunts, uncles, and cousins. If you share only one parent with a brother or sister, please indicate that.

	TYPE OF CANCER/ TUMORS	YOURSELF/PARENTS/ BROTHERS /SISTER/ CHILDREN	AGE AT DIAGNOSIS (estimates are OK)	EXTEND FAMILY (MOTHER'S SIDE) Aunts/Uncles/Cousins/ Grandparents/Others	AGE AT DIAGNOSIS (estimates are OK)	EXTEND FAMILY (FATHER'S SIDE) Aunts/Uncles/Cousins/ Grandparents/Others	AGE AT DIAGNOSIS (estimates are OK)
☐	EXAMPLE: Colorectal Cancer	Me	42			Aunt Uncle	46 55
☐	BREAST CANCER (in women or men)						
☐	OVARIAN CANCER (peritoneal/ Fallopian tube)						
☐	UTERINE (ENDOMETRIAL) CANCER						
☐	COLORECTAL CANCER						
☐	PANCREATIC CANCER						
☐	PROSTATE CANCER						
☐	KIDNEY (RENAL) CANCER						
☐	MELANOMA						
☐	BRAIN TUMOR Type: _____						
☐	OTHER CANCER Type: _____						
☐	MORE THAN 10 COLORECTAL POLYPS (indicate how many)						

☐ My family's heritage is Ashkenazi Jewish (an ethnic background that may have a higher likelihood of hereditary cancer)

☐ I, or someone in my family, have had genetic testing for a hereditary cancer syndrome.
(Please describe and provide a copy of test result if possible)

_____

_____

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LAB24

2840 NW 2nd Ave, Suite 201, Boca Raton, FL 33431
(800) 641-0133 (800) 833-1066 lab24inc.com info@lab24inc.com

HEREDITARY CANCER GENETIC TESTING LETTER OF MEDICAL NECESSITY

PATIENT INFORMATION	
PATIENT'S FIRST NAME	PATIENT'S LAST NAME
PATIENT'S DATE OF BIRTH (MM / DD / YYYY)	DATE OF SERVICE (MM / DD / YYYY)

ICD-10 CODES	

Dear Claim Specialist:

Cancer is a very serious medical issue and is a leading cause of death. The purpose of this letter is to document medical necessity for hereditary cancer genetic testing for my patient so that I will receive the test results in order to pursue care for my patient and to request full coverage of my patient's DNA-based hereditary cancer diagnostic test.

Through medical discovery and human genome sequencing, the medical community has isolated that mutations in genetic coding causes hereditary cancer. Hereditary cancer is caused by gene penetrant (hereditary) cancer predisposition syndromes. In 1994, the first cancer identified and isolated with hereditary genetic linkage was breast cancer. Since 1994, 11 additional cancers have been identified and isolated with hereditary genetic linkage. These 11 additional cancers are ovarian, endometrial, prostate, colorectal, pancreatic, endocrine, renal, brain, leukemia, lymphoma, and melanoma. Furthermore, gene mutations also increase the lifetime risk for certain cancers such as colorectal, sarcomas, brain, leukemia, gastric, thyroid, and prostate. These 12 hereditary cancers are sub-classified as over 50 different hereditary cancer predisposition syndromes. [1] Evaluating a patient's personal and family history is a standard of care and a major part of hereditary cancer risk assessment. This patient presents with an atypical personal and/or familial history of cancer. Without the ability to access patient specific genetic data, which ultimately provides guidance as to whether or not my patient should be subjected to increased monitoring/management techniques, I may be unable to provide this patient with advice on adequate levels of care.

There are over 240 unique known cancer genes.[2] At present, medically accepted estimates of certain cancer-related gene mutations and associated risks for the major hereditary cancers are: up to 87% risk for breast cancer for individuals with BRCA mutations; up to 44% risk for second cancer for individuals with BRCA mutations; up to 60% risk for serous ovarian carcinoma for individuals with BRCA mutations; up to 10% risk for endometrial cancer for individuals with BRCA; up to 90% risk for colon cancer for individuals with identified polyps with BRCA mutations; up to 9% risk for colon cancer for individuals without identified polyps with BRCA mutations; up to 50% risk for breast cancer for individuals with PTEN mutations; up to 10% risk for thyroid cancer for individuals with PTEN mutations; up to 10% risk for endometrial cancer for individuals with PTEN mutations; up to 35% risk for renal cell carcinoma for individuals with PTEN mutations; up to 90% risk for colon cancer for individuals with identified polyps with PTEN mutations; up to 9% risk for colon cancer for individuals without identified polyps with PTEN mutations; up to 80% for colorectal cancer for individuals with Lynch syndrome; up to 90% for individuals with Lynch syndrome have MLH1, MSH2, MSH6, and PMS2 mutations; up to 60% endometrial cancer for individuals with lynch syndrome; up to 52% risk for breast cancer (lobular) for individuals with CDH1 mutations; up to 83% risk for diffuse gastric cancer for individuals with CDH1 mutations; up to 20% risk for breast cancer for individuals with CHEK2 mutations; up to 20% risk for breast cancer for individuals with ATM mutations; and up to 10% risk for ovarian cancer for individuals with RAD51C, RAD51D and BRIP1 mutations. Additionally, other gene mutations linked to hereditary cancers include: BMPR1A-associated Juvenile Polyposis; Li-Fraumeni; Multiple Endocrine Neoplasia, Type 1 (MEN1); Multiple Endocrine Neoplasia, Type 2 (MEN2); MUTYH-associated Polyposis; PALB2-associated Hereditary Cancer; Peutz-Jeghers; SDHA- associated Hereditary Paraganglioma and Pheochromocytoma; SDHB-associated Hereditary Paraganglioma and Pheochromocytoma; SDHC-associated Hereditary Paraganglioma and Pheochromocytoma; SMAD4-associated Juvenile Polyposis; and Von Hippel Lindau. [3] Significant aspects of my patient's personal and / or family medical history suggest a reasonable probability of one or more hereditary cancer(s) and / or cancer syndromes.

Clinical features of many hereditary cancer syndromes overlap and there is also a reasonable probability of detecting one or more genetic mutation(s) in my patient. Therefore, I have ordered a single comprehensive hereditary cancer genetic test as an efficient and effective way to analyze the multiple genes associated with hereditary cancer conditions. The test may analyze up to 55 genes (of the over 240 unique known cancer genes) associated with hereditary cancer (listed alphabetically) that have suspected low, medium or high penetrance for my patient: APC, ATM, AXIN2, BAP1, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDC73, CDH1, CDH1, CDKN1C, CDKN2A, CHEK2, DICER1, DIS3L2, EPCAM, FH, FLCN, GPC3, GREM1, MEN1, MET, MLH1, MSH2, MSH6, MUTYH, NBN, NF1, PRKAR1, PALB2, PMS2, POLD1, PTCH1, PTEN, RAD50, RAD51C, RAD51D, RB1, RECQL4, RET, SDHA, SDHB, SDHC, SDHD, SMAD4, SMARCA4, STK11, SUFU, TP53, TSC1, TSC2, VHL, WT1

A positive test result would confirm a genetic diagnosis and / or risk in my patient, and would ensure my patient is being managed appropriately. An aggressive approach to medical management is necessary for my patient if identified as having a genetic mutation. Test results are important in reducing cancer risk and promoting early cancer detection. A positive result would indicate that my patient has an inherited predisposition to cancer and could help guide treatment strategies and allow for surveillance of associated organ systems known to be of increased risk for cancer.

The successive steps with my patient would be specific to the genetic mutation, degree of penetrance, and potential cancer type. Specific actions may include: utilization of appropriate guidelines (i.e., including but not limited to National Comprehensive Cancer Center Clinical Practice Guidelines in Oncology) to help guide decisions toward possible preventative measures; referral to a specialist such as an oncologist, surgeon, geneticist, or other; increased screening(s) including self-examinations, clinical examinations, ultrasound, and / or MRI (specific screening recommendations are dependent on the gene and hereditary cancer predisposition syndrome implicated); if prostate cancer, prostate cancer screening (PSA and DRE); if thyroid, thyroid ultrasound and exam; if gastric or other, more frequent colonoscopy; avoidance of radiation treatment when possible; consideration of MRI-based screening/technologies; specific pathway of genes to target with the help of potential chemotherapeutic treatment; other genetic mutation specific step-wise strategies; other cancer specific step-wise algorithms of care; provide an answer to the family about the underlying cause of my patient's condition and prevents the need for further rounds of expensive and / or painful testing; and isolate the underlying genetic cause allows for accurate family counseling and more precise estimation of recurrence risks for family members thus allowing family members to make informed, efficient and effective choices. Fortunately screening and early diagnosis of cancer is proven to extend life expectancy, patient and family quality of life, and proven treatment algorithms cost effectively manage the disease treatment. There are multiple government agencies, medical societies, healthcare regulators, and insurance plans that mandate and / or embrace hereditary cancer genetic testing. Below you will find prominent medically accepted evidence-based guidelines, governmental agencies and other major insurance plans' justification for the medical necessity of hereditary cancer genetic screening/ testing:

Medical Guidelines

1. National Comprehensive Cancer Network ® Genetic/Familial High-Risk Assessment: Colorectal, NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines ®) Version 2.2016. [4]

2. American Society of Clinical Oncology recommends that genetic testing be offered to individuals with suspected inherited cancer risk in which test results will aid in medical management decision-making. ASCO Policy Statement Update: genetic testing for cancer susceptibility. [5]

3. American Academy of Family Physicians Summary of Recommendations for Clinical Preventive Services; The AAFP Recommendations for Genetic and Genomic Tests is provided to aid members their delivery of evidence-based practices to their patients; recommendations for hereditary genetic cancer testing.[6]

4. The American College of Gastroenterology Clinical Guideline: Genetic Testing and Management of Hereditary Gastrointestinal Cancer Syndromes. [7]

5. American Gastroenterological Association Medical Position Statement: Hereditary colorectal cancer and genetic testing; recommendations for hereditary genetic cancer testing. [8]

6. Hereditary diffuse gastric cancer: updated consensus guidelines for clinical management and directions for future research; International Gastric Cancer Linkage Consortium Consensus Guidelines 2010; recommendations for hereditary genetic cancer testing. [9]

7. Medullary Thyroid Cancer: Management Guidelines of the American Thyroid Association; recommendations for hereditary genetic cancer testing. [10]

The genes in the test are warranted to identify the risk for cancer and / or detect cancer early, and to reduce morbidity and mortality. This genetic testing will help estimate my patient's risk to develop (and potentially die of) cancer. It will also directly impact my patient's medical management.

The test will take at least ten to twelve weeks for completion. Therefore, we are requesting that the authorization remain valid for at least 180 days. I request your written, timely response to the laboratory, given the importance of this matter. Thank you for your time.

Best regards,

NAME OF PRACTICE	ORDERING CLINICIAN SIGNATURE	DATE

1.National Cancer Institute at the National Institutes of Health http://www.cancer.gov/about- cancer/causes-prevention/genetics/genetic-testing-fact-sheet

Atlas of Genetics and Cytogenetics in Oncology and Hematology http://atlasgeneticsoncology.org

1. National Cancer Institute at the National Institutes of Health www.cancer.gov, Susan G. Komen ww5.komen.org, and the Baylor Human Genome Sequencing Center www.bcm.edu.
2. Source: NCCN https://www.nccn.org/professionals/physician_gls/f_guidelines_nojava.asp
3. Source ASCO https://www.asco.org and J Clin Oncol 2003;21[12]:2397-2406
4. http://www.aafp.org/dam/AAFP/documents/patient_care/clinical_recommendations/cps-recommendations.pdf
5. http://gi.org/wp-content/uploads/2015/02/ACG_Guideline_Hereditary-Gastrointestinal-Cancer-Syndromes_February_2015.pdf
8. https://www.med.upenn.edu/gastro/documents/AGApositionstatementhereditarycoloncancertesting.pdf
9. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2991043/
10. http://www.thyca.org/download/document/280/MTCguidelines.pdf 11http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact/

Cancer Genetic Screening ICD-10 Code Key

CLIA # 10D0280394

Pay Payable Codes for Colorectal Cancer & Breast Cancer Genes	
Ovarian	
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
Z85.43	Personal history of malignant neoplasm of ovary
Pancreatic	
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.4	Malignant neoplasm of endocrine pancreas
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified
Z85.07	Personal history of malignant neoplasm of pancreas

Payable Codes for Breast Cancer Genes	
Breast	
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast

Cancer Genetic Screening ICD-10 Code Key

Payable Codes for Breast Cancer Genes	
Breast	
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
D05.00	Lobular carcinoma in situ of unspecified breast
D05.01	Lobular carcinoma in situ of right breast
D05.02	Lobular carcinoma in situ of left breast
D05.10	Intraductal carcinoma in situ of unspecified breast
D05.11	Intraductal carcinoma in situ of right breast
D05.12	Intraductal carcinoma in situ of left breast
D05.80	Other specified type of carcinoma in situ of unspecified breast
D05.81	Other specified type of carcinoma in situ of right breast
D05.82	Other specified type of carcinoma in situ of left breast
D05.90	Unspecified type of carcinoma in situ of unspecified breast
D05.91	Unspecified type of carcinoma in situ of right breast
D05.92	Unspecified type of carcinoma in situ of left breast
Prostate	
C61	Malignant neoplasm of prostate
Z85.46	Personal history of malignant neoplasm of prostate

Cancer Genetic Screening ICD-10 Code Key

Payable Codes for Colorectal Cancer Genes

Brain	
C71.0	Malignant neoplasm of cerebrum, except lobes and ventricles
C71.1	Malignant neoplasm of frontal lobe
C71.2	Malignant neoplasm of temporal lobe
C71.3	Malignant neoplasm of parietal lobe
C71.4	Malignant neoplasm of occipital lobe
C71.5	Malignant neoplasm of cerebral ventricle
C71.6	Malignant neoplasm of cerebellum
C71.7	Malignant neoplasm of brain stem
C71.8	Malignant neoplasm of overlapping sites of brain
C71.9	Malignant neoplasm of brain, unspecified
Z85.841	Personal history of malignant neoplasm of brain
Digestive	
C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of body of stomach
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.3	Meckel's diverticulum, malignant
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.2	Malignant neoplasm of cloacogenic zone
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C22.0	Liver cell carcinoma
C22.1	Intrahepatic bile duct carcinoma
C22.2	Hepatoblastoma
C22.3	Angiosarcoma of liver
C22.4	Other sarcomas of liver
C22.7	Other specified carcinomas of liver
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
C24.0	Malignant neoplasm of extrahepatic bile duct
C24.9	Malignant neoplasm of biliary tract, unspecified
D12.0	Benign neoplasm of cecum
D12.1	Benign neoplasm of appendix
D12.2	Benign neoplasm of ascending colon
D12.3	Benign neoplasm of transverse colon
D12.4	Benign neoplasm of descending colon
D12.5	Benign neoplasm of sigmoid colon
D12.6	Benign neoplasm of colon, unspecified
K63.5	Polyp of colon
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ
Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.048	Personal history of other malignant neoplasm of rectum, rectosigmoid junction, and anus
Z86.010	Personal history of colonic polyps

Cancer Genetic Screening ICD-10 Code Key

Payable Codes for Colorectal Cancer Genes	
Renal	
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C66.1	Malignant neoplasm of right ureter
C66.2	Malignant neoplasm of left ureter
C66.9	Malignant neoplasm of unspecified ureter
C68.8	Malignant neoplasm of overlapping sites of urinary organs
Z85.53	Personal history of malignant neoplasm of renal pelvis
Z85.54	Personal history of malignant neoplasm of ureter
Z85.59	Personal history of malignant neoplasm of other urinary tract organ
Skin	
L85.3	Xerosis cutis
Uterine	
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C54.9	Malignant neoplasm of corpus uteri, unspecified
C55	Malignant neoplasm of uterus, part unspecified
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
Z85.42	Personal history of malignant neoplasm of other parts of uterus

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Genetic Susceptibility Codes (Should be reported with Appropriate FH codes)	
Z15.01	Genetic susceptibility to malignant neoplasm of breast
Z15.02	Genetic susceptibility to malignant neoplasm of ovary
Z15.03	Genetic susceptibility to malignant neoplasm of prostate
Z15.04	Genetic susceptibility to malignant neoplasm of endometrium
Z15.09	Genetic susceptibility to other malignant neoplasm
Family History Codes	
Z80.3	Family history of malignant neoplasm of breast
Z80.41	Family history of malignant neoplasm of ovary
Z80.42	Family history of malignant neoplasm of prostate
Z80.4	Family history of malignant neoplasm of genital organs
Z80.0	Family history of malignant neoplasm of digestive organs
Z80.1	Family history of malig neoplasm of trachea, bronc and lung
Z80.2	Family hx of malig neoplm of resp and intrathorac organs
Z80.43	Family history of malignant neoplasm of testis
Z80.49	Family history of malignant neoplasm of other genital organs
Z80.5	Family history of malignant neoplasm of urinary tract
Z80.51	Family history of malignant neoplasm of kidney
Z80.52	Family history of malignant neoplasm of bladder
Z80.59	Family history of malignant neoplasm of urinary tract organ
Z80.6	Family history of leukemia
Z80.7	Fam hx of malig neoplm of lymphoid, hematpoetc and rel tiss
Z80.8	Family history of malignant neoplasm of organs or systems
Z80.9	Family history of malignant neoplasm, unspecified