SECURE HEALTH

FAX - TIME SENSITIVE

PLEASE RETURN TO SECURE HEALTH FAX: +1 801-509-6879

To:
Fax:
Phone:
Date:
Subject:
Comments: PATIENT REQUESTED

Your patient _____ , is requesting a genetic cancer test due to concerns they have about hereditary cancer that they have had or has been in their family. Secure Health would like to include you in the process because you are the patients primary care physician and can implement the results of the test into the patient's existing care plan. **Please sign the attached requisition form, the physician authorization form, and the certificate of medical necessity. The results will be sent via fax or via online portal, depending on preference.**

Also, please note that the attached ICD-10 codes are typically associated with medical necessity for hereditary cancer screenings, but do not guarantee coverage for any genetic test. Providers are NOT required to use the attached examples. Secure Health and all associated companies do require ICD-10 codes that are:

1. Patient specific
2. Prove the medical necessity to support testing
3. Are billable to the highest specificity

Samples that are received without proper ICD-10 coding will be held for 30 days. After this period, if the correct ICD-10 codes are not included, the sample will be destroyed.

With any questions, please contact Secure Health at (801) 477-0474

AccurateDX
Accurate diagnosis for better patient care

CGX REQUISITION FORM

(210) 571-1300

422 W Nakoma Dr
San Antonio, TX 78216

Please submit both pages of this form:

LABORATORY USE ONLY: DATE RECEIVED: ACCESSION NO: SPECIMEN ID:

1.PATIENT INFORMATION (REQUIRED)

First Name: _____

Last Name: _____

DOB (MM/DD/YYYY) _____

☐ Male ☐ Female Age _____

Address: _____

City: _____ State: _____ Zip Code: _____

Phone: _____ E-mail: _____

Insurance Name: _____

Policy #: _____ *Must Provide Copy of Front & Back of Card.

2.ORDERING PHSICIAN INFORMATION (REQUIRED)

First Name: _____

Last Name: _____

Medical Credentials: _____ NPI# _____

Address: _____

City: _____ State: _____ Zip Code: _____

Direct Office Contact (Required) _____

Phone: _____

3.ADDITIONAL RESULTS RECIPIENT

Healthcare Professional Name: _____

Phone: _____ Fax: _____

E-mail (for notification of results only): _____

Mailing Address: _____

City: _____ State: _____ Zip Code: _____

4.SPCIMEN INFORMATION (REQUIRED)

Date of Collection: _____ Collected By: _____

Specimen Type: ☐ Buccal Swab ☐ Saliva

5.TEST(S) REQUESTED

Hereditary Cancers

- ☐ **BRCA1/2** – 2 genes
  Sequencing and duplication/deletion analysis.
- ☐ **Breast and Ovarian Cancer** – 15 genes
  ATM, BRCA1, BRCA2, BRIP1, CDH1, MLHI, MSH2, MSH6, PALB2PTEN, RAD51C, RET, STK11, TP53, VHL
- ☐ **Comprehensive Inherited Cancer Panel –** 45 genes linked to breast, ovarian, colon, pancreatic, and other major cancers
  APC, ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CDK4, P16(CDKN2A), CHEK2, ELAC2, EPCAM, FANCC, HRAS1, MEN1, MET, MLH1, MRE11a, MSH2, MSH6, MUTYH, NBN, NF1, NTRK1, PALLD, PMS2, PTCH1, PTEN, RAD50, RAD51, RAD51C, RAD51D,RET, SMAD4, STK11, TP53, VHL
- ☐ **Colorecta Cancer Panel** – 12 genes
  APC, BMPR1A, CDH1, EPCAM, MLH1, MSH2 MSH6, MUTYH, PMS2, PTEN, SMAD4, STK11
- ☐ **Lynch Syndrome** – 5 genes Sequencing and duplication/deletion analysis
  EPCAM, MLH1, MSH2, MSH6, PMS2

6.ICD 10 CODS (REQUIRED) : _____

7.MEDICAL NECESSITY / CGART NOTES: **Please complete the reverse side of this form and attach clinical notes for medical necessity**

8.PATIENT INFORMED CONSENT (Please sing here or the consent form)

- ☐ I have read the informed Consent Form and give permission to Accurate DX to perform the genetic tests as described.
- ☐ **Optional:** I consent to use of my de-identified test samples for research.
- ☐ **Optional:** I am a New York State resident and I consent to storing my test samples at the lab beyond 60 days for future use or testing.

Patient Signature: _____ Date: _____

9.CONFIRMATION OF INFORMED CONSENT AND MEDICAL NECESSITY

The tests ordered are medically necessary for the risk assessment, diagnosis or detection of a disease, illness, impairment, symptom, syndrome or disorder. The results will determine the patient's medical management and treatment decision. The person listed as the Ordering Physician is legally authorized to or order the test(s) requested herein. The patient was provided with information about genetic testing and has consented to genetic testing.

Ordering Physician Signature: _____ Date: _____

10.PATIENT PAYMENT OPTIONS

- ☐ **INSURANCE:** Please attach copy of front and back of insurance card **INVOICE.**
- ☐ **PRACTICE / INSTITUITIONAL BILL / FACILITY BILL.**
- ☐ **CREDIT CARD** Accurate DX will contact you for additional information.

I am covered by insurance and understand and authorize:

- Accurate DX to give my health insurance plan information on this form and other information provided by my healthcare provider that in necessary for reimbursement.
- Accurate DX to information my plan of my test result only if required for preauthorization on or payment of additional or reflex testing.
- Plan benefits to be payable to Accurate DX.
- Accurate DX to attempt to contact me about my out of pocket responsibility.
- I am responsible for sending Accurate DX all pf the money I receive directly from my health plan for this test.
- Any genetic testing not performed by this laboratory will be forwarded to another accredited reference laboratory.

Patient Signature: _____ Date: _____

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Please submit both pages of this form:

11.ANCESTRY (Select all that apply)

- ☐ White / Non-Hispanic.
- ☐ Hispanic / Latino.
- ☐ Black / African.
- ☐ Ashkenazi Jewish.
- ☐ Asian.
- ☐ Native American.
- ☐ Pacific Islander.
- ☐ Middle Eastern.
- ☐ Other.

12.PATIENT PERSONAL HISTORY OF CANCER & OTHER CLINICAL INFORMATION

☐ Patient has No personal history pf cancer.

Patient has been diagnosed with:	Age at Diagnosis	Patient is Currently Being Treated	Pathology and Other Information
☐ Brest Cancer. ☐ Left. ☐ Right.		☐	☐ Ductal Invasive. ☐ Lobular Invasive. ☐ DCIS. ☐ Bilateral. ☐ Premenopausal. ☐ Triple Negative (ER-,PR-,HER2-)
☐ Endometrial/Uterine Cancer.		☐	☐ Tumor MSI-HIGH or IHC Abnormal Result _____
☐ Ovarian Cancer.		☐	☐ Non-epithelial.
☐ Prostate Cancer.		☐	Gleason Score _____
☐ Colon/Rectal Cancer.		☐	Type: ☐ Mucinous. ☐ Signet Ring. ☐ Medullary Growth Pattern. ☐ Tumor Infiltrating Lymphocytes. ☐ Crohn's-like Lymphocytic Reaction. ☐ Patient's tumor is MSI-HIGH or Abnormal Result _____
☐ Colon/Rectal Adenomas.		☐	Cumulative Adenomatous Polyp# ☐1 ☐2-5 ☐6-9 ☐10-19 ☐20-99 ☐100+
☐ Hematological Cancer.		☐	
☐ Other Cancer.		☐	

Check if applicable to patient: ☐ Bone marrow transplant recipient.

13.FAMILY HISTORY OF CANCER

☐ No Known Family History of Cancer. ☐ Limited Family Structure.

Relationship to Patient	Maternal	Paternal	Cancer Site or Polyp Site	Age at Each Diagnosis
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		

14.BREAST CANCER RISK INFORMATION (Only complete for Patient NEVER diagnosed with breast cancer)

Height _____ Weight _____
Age at first menstrual Period _____
Is Patient: ☐ Pre-menopausal. ☐ Peri-menopausal.
☐ Post-menopausal: Age of Onset _____
Has this patient had a live birth? ☐ No ☐ Yes
Age at time of first child's birth _____

Has patient ever used Hormone Replacement Therapy? ☐ No ☐ Yes
If Yes, Treatment Type:
☐ Combined ☐ Estrogen Only ☐ Progesterone Only
If Yes, is patient a: ☐ Current User: Started _____ yrs. ago
Plans to use for ____ yrs. ☐ Past User: Stopped _____ yrs. ago
If patient had a breast biopsy, were the results: ☐ No Benign Disease
☐ Hyperplasia ☐ Atypical Hyperplasia ☐ LCIS ☐ Unknown

Patient's Female Relatives
Number of Daughters ____
Number of Sisters _____
Number of Maternal Aunts _
Number of Paternal Aunts _

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HEREDITARY CANCER GENETIC TESTING LETTER OF MEDICAL NECESSITY

Date of Service :

Patient Name :

Patient Date of Birth :

ICD-10 Diagnosis Code :

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 heredity 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 genetic hereditary 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.i 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.ii 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 PTEN mutations; up to 10% risk for endometrial 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 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, Type1 (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.iii 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 32 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, BARD1, BMPR1A. BRCA1, BRCA1, BRIP1, CDH1, CDKN2A, CHEK2, EPCAM, FH, FLCN, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, PTEN, RAD50, RAD51C, RAD51D, RINT1, SDHB, SMAD4, STK11, TP53, VHL, XRCC2. 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 increased risk of 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 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

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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, government agencies and other major insurance plans' justification for the medical necessity of hereditary caner genetic screening/testing:

Medical Guidelines

a) National Comprehensive Cancer Network® Genetic/Familial High-Risk Assessment: Colorectal, NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Version 2.2016.iv
b) 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. v
c) American Academy of Family Physicians Summary of Recommendations for Clinical Preventative 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. vi
d) The American College of Gastroenterology Clinical Guideline: Genetic Testing and Management of Hereditary Gastrointestinal Cancer Syndromes. vii
e) American Gastroenterological Association Medical Position Statement: Hereditary colorectal cancer and genetic testing; recommendations for hereditary genetic cancer testing. viii
f) 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 testing.ix
g) Medullary Thyroid Cancer: Management Guidelines of the American Thyroid Association; recommendations for hereditary cancer testing. x

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,

Provider Name:

Ordering Clinician Signature: **Date:**

(MD/DO, Clinical Nurse Specialist, Nurse-Midwives, Nurse Practitioner, Physician Assistant, Genetic Counselor*) *Clinician prescribing requirements vary by state

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

VR23240819

Physician Authorization Form

Name _____ **Date:** ____/_____/_____

I authorize E.H.E., Inc. to process test ordering documentation on my behalf. My signature also serves as verification that I will ensure any and all laboratory tests are ordered under my authorization and are medically necessary to ensure patient compliance with the therapy I have prescribed. I understand that E.H.E., Inc. may use any of its laboratory relations or reference partners to perform the ordered tests. I agree to notify E.H.E., Inc. when I choose to no longer serve as an ordering physician within a processing relationship with E.H.E., Inc.

Signature Record

Provider Name	Signature	NPI # (REQUIRED)
_____ (Please Print)	_____	☐☐ ☐☐ ☐☐ ☐☐☐☐ ○ MD ○ DO ○ PA ○ ARNP ○ Other
_____ (Please Print)	_____	☐☐ ☐☐ ☐☐ ☐☐☐☐ ○ MD ○ DO ○ PA ○ ARNP ○ Other
_____ (Please Print)	_____	☐☐ ☐☐ ☐☐ ☐☐☐☐ ○ MD ○ DO ○ PA ○ ARNP ○ Other
_____ (Please Print)	_____	☐☐ ☐☐ ☐☐ ☐☐☐☐ ○ MD ○ DO ○ PA ○ ARNP ○ Other

Note: I understand and hereby acknowledge that I will only order tests that I believe to be medically necessary to ensure patient compliance with the therapy that I have prescribed. I acknowledge that if required by Medicare, Medicaid, or any payers that I will supply E.H.E., Inc. with supporting medical records justifying medical necessity so that they may be relayed to the testing laboratory. The Office of Inspector General (OIG) also takes the position that a provider who orders medically unnecessary tests for which Medicare reimbursement is claimed, may be subject to civil penalties.