otogenetics®

Comprehensive Genetic Test Requisition Gx™

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 _____ Email_____

2. ORDERING PHYSICIAN INFORMATION (REQUIRED)

First Name_____ Last Name_____

Medical Credentials_____ NPI#_____

Facility Name_____

Address_____

City_____ State_____ Zip_____

Direct Office Contact (Required) _____

Phone_____

3. ADDITIONAL RESULTS RECIPIENT

Healthcare Professional Name _____

Phone_____ Fax_____

Email (for notification of results only)_____

Mailing Address_____

City_____ State_____ Zip_____

4. SPECIMEN INFORMATION (REQUIRED)

Date of Collection_____ Collected By_____

Specimen Type ☐ Saliva ☐ Blood (Lavender Top)

5. TEST(S) REQUESTED

Hereditary Cancers

☐ **Comprehensive Inherited Cancer Gene Tests – 39 Genes** linked to breast, ovarian, colon, pancreatic, and other major cancers. APC, ATM, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKn2A, CHEK2, ELAC2, EPCAM, FANCC, HRAS1, MEN1, MET, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, NF1, NTRK1, PALB2, PALLD, PMS2, PTCH, PTEN, RAD50, RAD51, RAD51C, RAD51D, RET, SMAD4, STK11, TP53, VHL

☐ **Comprehensive Inherited Cancer Gene Tests with Confirmation for Lynch Syndrome – 39 Genes**

☐ **Breast and Ovarian Cancer – 18 Genes** ATM, BRCA1, BRCA2, BRIP1, CDH1,CHEK2, MLH1, MSH2, MSH6, NBN, PALB2, PTEN, RAD51C, Rad51D, RET, STK11, TP53, VHL

☐ **Colorectal, Endometrial and Ovarian Cancer – 12 Genes** APC, BMPR1A, CDH1, EPCAM, MLH1, MSH2, MSH6, MUTYH, PMS2, PTEN, SMAD4, STK11

Pharmacogenomics

Please See Attached Medication & Gene List

☐ **Medical Management – 42 genes** ABCB1, ABCG2, ADRA2A, ADRB1, AGT, CACNA1C, CES1, CFTR, COMT, CYP1A2, CYP2C9, CYP2C19, CYP2D6, CYP3A4, CYP3A5, DPYD, DRD1, DRD2, DRD3, EDN1, F2, F5, GNB3, GRIK1, GSTA1, HTR1A, HTR2A, HTR2C, IFNL3, KCNIP1, LDLR, MTHFR, NAT1, NR1H3, OPRM1, RYR1, SLC6A2, SLCO1B1, TPMT, UGT2B10, UGT2B7, VKORC1

☐ **Cardiovascular -** ABCG2, CACNA1C, CYP2C19, CYP2C9, CYP2D6, CYP3A4, Factor II, Factor V, MTHFR, SLCO1B1, VKORC1

☐ **Mental Health -** ADRA2A , COMT, CYP1A2, CYP2C19, CYP2D6, DRD2, GRIK4, HTR2A, MTHFR, OPRM1

☐ **Pain Management -** COMT, CYP1A2, CYP2C19, CYP2C9, CYP2D6, OPRM1

☐ **Oncology –** ABCB1, COMT, CYP2D6, CYP3A4, CYP3A5, DPYD, MTHFR, OPRM1, SLCO1B1, TPMT

☐ **Thrombosis Risk:** F2, F5

Carrier Screening

☐ **Basic 5 with CF**

☐ **ACOG/ACMG 13**

☐ **AJ 38**

☐ **Pan-Ethnic 167**

☐ **Deafness Panel**

☐ **Cardiomyopathy**

☐ **Usher Syndrome**

☐ **Custom Gene Or Panel**

6. ICD10 CODES (REQUIRED)_____

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

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

I confirm that I have been informed about the details of the tests ordered for me by my provider that includes Otogenetics Inherited Cancer Risk Assessment, Carrier Screening, Pharmacogenomics, Hearing Loss, Usher Syndrome and Cardiomyopathy Test Panels. I understand the risks, benefits and limitations of testing and I voluntarily consent to testing. I give permission to Otogenetics to perform the genetic tests described. I understand I am financially responsible for services performed and for sending Otogenetics all of the money I receive directly from my health plan for this test. I authorize Otogenetics to submit claims to my medical insurance on my behalf, to give my health plan my health information on this form and other information provided by my healthcare provider that is necessary for reimbursement, to inform my health plan of my test result only if required for preauthorization or payment of additional reflex testing, for plan benefits to be payable to Otogenetics, for Otogenetics to contact me about my out of pocket responsibility.

☐ **Optional**: I consent to use of my de-identified test samples for research.

☐ **Optional**: I consent to be contacted by Otogenetics for research opportunities.

Patient Signature _____ **Date** _____

10. PATIENT PAYMENT OPTIONS

☐ **INSURANCE:** Please attach a copy of front and back of insurance card

☐ **SELF-PAY:** Otogenetics will contact patient to obtain payment

☐ **INVOICE PRACTICE / INSTITUTIONAL BILL / FACILITY BILL**

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 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:_____

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11. ANCESTRY (Select all that apply)

- ☐ African/African American
- ☐ American Indian
- ☐ Ashkenazi Jewish
- ☐ Caucasian
- ☐ East Indian
- ☐ French Canadian
- ☐ Hispanic/Latin American
- ☐ Mediterranean
- ☐ Middle Eastern
- ☐ Pacific Islander
- ☐ Sephardic Jewish
- ☐ South East Asian
- ☐ Other

12. PATIENT PERSONAL HISTORY OF CANCER & OTHER CLINICAL INFORMATION

☐ Patient has NO personal history of cancer

Patient has been diagnosed with:	Age at Diagnosis	Patient is Currently Being Treated	Pathology and Other Information
☐ Breast 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 Infilterating 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
Mother	☐	☐		
Aunt	☐	☐		
	☐	☐		
	☐	☐		

14. BREAST CANCER RISK INFORMATION (Only complete for patients 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 has 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___

15. FOR PHARMACOGENETICS TEST PANELS ONLY **For complete pharmaceutical drug & corresponding gene list – please see attached list**

Medical Necessity: Please check **ALL** that apply

Test Rationale

- ☐ Patient has a history of medication failure(s)
- ☐ Patient has experienced adverse drug reaction sensitivity to prescribed medication(s)
- ☐ Patient has experienced lack of symptom relief from prescribed medication(s)
- ☐ There is a "Warning" in the Package Insert of the medication being considered
- ☐ Medication Class is new to the patient
- ☐ Desired medication for patient is a "Controlled Substance"
- ☐ An "Inhibitor" or "Inducer" may affect therapeutic response to prescribed medication
- ☐ Other:

Results Application:

- ☐ A component of my medical decision making for which medication(s) to avoid for this patient
- ☐ A component of my medical decision making as to which medication(s) to prescribe for this patient
- ☐ A component of my medical decision making regarding dose initiation or titration for this patient
- ☐ A component of my medical decision making to manage patient's cardio or thrombotic risk