otogenetics® corporation

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 Panel – 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 Panel with Confirmation for Lynch Syndrome – 39 Genes**

☐ **Breast and Ovarian Cancer – 15 Genes** ATM, BRCA1, BRCA2, BRIP1, CDH1, MLH1, MSH2, MSH6, PALB2, PTEN, RAD51C, 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 have read the Informed Consent Form and give permission to Otogenetics to perform the genetic tests as described.

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

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

☐ **Optional**: I am a New York State resident and I consent to storing my test samples at Otogenetics 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 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 a copy of front and back of insurance card

I am covered by insurance and understand and authorize:

- Otogenetics to give my health insurance plan information on this form and other information provided by my healthcare provider that is necessary for reimbursement.
- Otogenetics to inform my plan of my test result only if required for preauthorization or payment of additional or reflex testing.
- Plan benefits to be payable to Otogenetics.
- Otogenetics to attempt to contact me about my out of pocket responsibility.
- I am responsible for sending Otogenetics all of the money I receive directly from my health plan for this test.

Patient Signature: ________________________Date:__________

☐ **CREDIT CARD** Please provide credit card information below

Name on Card_______________________________ **Exp**_____/_______

Card Number_______________________________ **Security Code**______

Billing Address____

City____________________________ **State**_____ **Zip**____________

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

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11. ANCESTRY (Select all that apply)

- ☐ African/African American
- ☐ Ashkenazi Jewish
- ☐ Caucasian
- ☐ East Indian
- ☐ French Canadian
- ☐ Hispanic/Latin American
- ☐ Mediterranean
- ☐ Middle Eastern
- ☐ Native American
- ☐ 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