



**BRCAcare® and Genetic Screening Test Requisition Form**

**Ordering Physician/Laboratory** MDL-BRCA

(Required: Include the ordering physician's first & last name, NPI, practice name, complete address, phone number and fax number.)

Physician's Signature:

Date:

Physician to receive additional result report:

**Patient Information (Please Print)**

Name (Last, First) (Required):

In Care of:

Patient Address:

City:

State:

Zip:

Gender (Required):  Female  Male

Date of Birth (Required):

Patient SS#:

Patient ID#:

Phone Number (Required):

Ethnicity:

**Billing Information (Please include a copy of the front & back of card.)**

- Patient Billing
- Insurance Billing
- Path Lab/Hospital
- Physician Account

- Relation (Req.):
- Self
  - Spouse
  - Dependant

Diagnosis Codes (Required):  
Please provide ALL applicable diagnosis codes.

Primary Insurance Carrier:

Insured's Name (if not patient):

Insured's SS#:

Insured's DOB:

Claims Address:

Medicare, Medicaid or Policy ID#:

Employer/Group Name:

Group#:

**Clinical Information (Necessary for accurate test interpretation of BRCAcare® Testing)**

Race/ Ethnicity:  African American/Black  Asian  Jewish (Ashkenazi)  Other  
 Caucasian  Hispanic  Native American

**Patient Previous Genetic Testing:**

No history of Genetic Testing Positive test:  BRCA1  BRCA2 Negative test:  BRCA1  BRCA2

**Family History:**

Is there a known family history of BRCA genes mutations? (Please include a copy of the family mutation report.)  No family history Yes:  BRCA1  BRCA2  
 Is there any cancer in the family history?  No family history  Yes: (please, specify below)

Family Cancer Site	Age at Dx	Relationship	Maternal	Paternal
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>

**Test Selection (\*Not available in NY State)**

**BRCAcare® Testing: Blood♦, Saliva♦, Mouthwash** (Available in NY only)

- 2600  Breast Cancer High Risk Extended Panel Plus: 15 genes (BRCA1, BRCA2, CDH1, PTEN, TP53, STK11, ATM, CHEK2, PALB2, BARD1, BRIP1, RAD51C, RAD51D, NF1, NBN) by Gene Sequencing with BRCA1/2 Deletion/Duplication Analysis
- 1279  Lynch Syndrome Gene Panel: 5 Genes (EPCAM\*, MLH1, MSH2, MSH6, PMS2) by Gene Sequencing with Deletion/Duplication Analysis (\*Deletion/Duplication Analysis of Exon8-9 only)
- 2601  BRCA1/2: Comprehensive BRCA Analysis by Gene Sequencing with Deletion/Duplication Analysis
- 1222  BRCA1/2: Ashkenazi Jewish 3-site Mutation Analysis
- 1236  BRCA1/2: Ashkenazi Jewish 3-site Mutation Analysis ♦(Reflex to Breast Cancer High Risk Extended Panel Plus) (\* If the Ashkenazi Jewish 3-site Mutation Analysis is negative, reflex to 2600.)
- 1224  Gene Specific Site Analysis:  
Specify Gene: \_\_\_\_\_ Variant (mutation): \_\_\_\_\_

**OneSwab® , Blood♦, ThinPrep♦, Saliva♦, Mouthwash** (Available in NY only)

- 1231  Cystic Fibrosis Core Test by Next Generation Sequencing (23 major CFTR mutations approved by ACOG/ACMG)
- 1232  Cystic Fibrosis Comprehensive Test by Next Generation Sequencing (191 variants of the CFTR gene, including the 23 major mutations approved by ACOG/ACMG)
- 1233  Cystic Fibrosis Site Specific Analysis by DNA Sequencing  
Specify variant (mutation): \_\_\_\_\_
- 1274  Genetic Carrier Screening Panel (3 genes)♦ includes:  
 1231  Cystic Fibrosis Core Test (23 major CFTR variants approved by ACOG/ACMG) (CFTR)  
 1272  Fragile X Syndrome (FMR1)  
 1273  Spinal Muscular Atrophy (SMN1)

**OneSwab® Only**

- 1216  Sickle Cell Anemia by SNP Genotyping with Pyrosequencing♦
- 1215  Torsion Dystonia by Real-Time PCR♦

**Confirmation of Informed Consent and Medical Necessity for Genetic Testing**

My signature below certifies that I am a licensed medical professional or his/her representative or a genetic counselor authorized to order genetic testing. My signature further acknowledges the patient has been supplied information regarding genetic testing and has been informed about the purpose, limitation and possible risks. The patient has been given the opportunity to ask questions about this consent and seek outside genetic counseling.

In the event that the patient's health insurance plan determines for the test(s) I checked above that some of the genes that I requested for analysis are not covered, I understand that Medical Diagnostic Laboratories, L.L.C. shall perform and result the test(s) for the genes I selected, then submit the claim to the patient's health insurance plan for the testing of the genes covered under the patient's plan.

If the testing is covered by the patient's health plan and the out-of-pocket expense is less than \$150.00, testing will proceed without further delay or additional contact. The patient has given consent for genetic testing to be performed and the signed consent form is being provided with this requisition. I confirm that this testing is medically necessary for the specified patient and that these results will be used in the medical management and treatment decisions for this patient.

Medical Professional Signature (Required): \_\_\_\_\_ Date: \_\_\_\_\_

**Specimen Information**

Specimen Source:

Date Collected (Required):

**Personal Patient History:**

Is there any cancer in the personal history?  No history of cancer  Yes: (please, specify below)

Personal Cancer Site	Age at Dx	Comments/Details
Breast: <input type="checkbox"/> IDC (invasive ductal carcinoma) <input type="checkbox"/> ILC (invasive lobular carcinoma) <input type="checkbox"/> DCIS (ductal carcinoma in situ) <input type="checkbox"/> LCIS (lobular carcinoma in situ)	_____	<input type="checkbox"/> Bilateral <input type="checkbox"/> Premenopausal ER (+) <input type="checkbox"/> (-) <input type="checkbox"/> PR (+) <input type="checkbox"/> (-) <input type="checkbox"/> HER2/neu (+) <input type="checkbox"/> (-) <input type="checkbox"/>
Ovarian <input type="checkbox"/>	_____	
Pancreatic <input type="checkbox"/>	_____	
Prostate <input type="checkbox"/>	_____	Gleason Score: 2 3 4 5 6 7 8 9 10
Other (specify):		

- Bone marrow transplant recipient?  Yes
- Current diagnosis of hematological cancer?  Yes
- Currently receiving radiation therapy/chemotherapy?  Yes

Please indicate your Diagnosis Code selection on the front of this test requisition in the designated spaces under “Billing Information – Diagnosis Codes (Required)”.

Suspected Condition	ICD-10	Description	ICD-10	Description
BRCA Genetic Testing	Z85.3	Personal history of malignant neoplasm, breast Personal history of malignant neoplasm, ovary Family history of malignant neoplasm, breast Family history of malignant neoplasm, ovary Family history of malignant neoplasm of other organs or systems	Z31.430	Encounter of female for testing for genetic disease carrier status for procreative management Encounter of male for testing for genetic disease carrier status for procreative management Family history of carrier of genetic disease Genetic susceptibility to malignant neoplasm of breast, ovary Genetic counseling
	Z85.43			
	Z80.3			
	Z80.41			
Z80.8		Z15.01-Z15.02		
		Z31.5		
Breast/Ovarian Cancer Diagnosis	C50.011 - C50.019	Malignant neoplasm, nipple and areola of female breast Malignant neoplasm, central portion of female breast Malignant neoplasm, upper-inner quadrant of female breast Malignant neoplasm, lower-inner quadrant of female breast Malignant neoplasm, upper-outer quadrant of female breast Malignant neoplasm, lower-outer quadrant of female breast	C50.611 - C50.619	Malignant neoplasm, axillary tail of female breast Malignant neoplasm of overlapping sites of female breast Malignant neoplasm, breast (female), unspecified site Malignant neoplasm, male breast Malignant neoplasm, ovary Secondary malignant neoplasm, ovary Secondary malignant neoplasm, breast Carcinoma in situ of breast Carcinoma in situ of other female genital organs
	C50.111 - C50.119		C50.811 - C50.819	
	C50.211 - C50.219		C50.911 - C50.919	
	C50.311 - C50.319		C50.021 - C50.929	
	C50.411 - C50.419		C56.1 - C56.9	
C50.511 - C50.519	C79.60 - C79.62	C79.81	D05.00 - D05.92	
		D07.39		
Cystic Fibrosis	E84.0	Cystic fibrosis with pulmonary manifestations Meconium ileus in cystic fibrosis Cystic fibrosis with other intestinal manifestations	E84.8	Cystic fibrosis with other manifestations Cystic fibrosis, unspecified Cystic fibrosis carrier
	E84.11			
	E84.19			
Endometrial Uterine Cancer	D07.0	Carcinoma in situ of endometrium Endometrial hyperplasia, unspecified	N85.02	Endometrial intraepithelial neoplasia Genetic susceptibility to malignant neoplasm of endometrium
	N85.00		Z15.04	

This is a general, non-comprehensive guide for use by the healthcare provider to assist in the assignment of a diagnosis code to the laboratory testing ordered. The healthcare clinician must only order tests determined to be medically necessary for the diagnosis and treatment of the patient.

Please verify the criteria for hereditary breast, ovarian, endometrial and colorectal cancer genetic testing using the following guidelines. Meeting one or more of these criteria is required for hereditary cancer genetic testing to be deemed appropriate, as established by the National Comprehensive Cancer Network (NCCN) Guidelines - Genetic/Familial High-Risk Assessment: Breast and Ovarian Version 2.2019 and Genetic/Familial High-Risk Assessment: Colorectal Version 1.2018.

If your patient does not meet the following criteria, the testing may be deemed not medically necessary and may not be covered by your patient's health insurance.

#### **BREAST AND OVARIAN CANCER (HBOC)**

- Individual from a family with a **known BRCA1/2 pathogenic/likely pathogenic variant**.
- Personal history** of breast cancer with any one or more of the following:
  - Diagnosed at **≤ 45** years.
  - Diagnosed at **46-50** years with any one or more of the following:
    - An additional breast cancer primary at **any age**.
    - At least one close blood relative with breast cancer at **any age**.
    - At least one close relative with pancreatic cancer.
    - At least one relative with high-grade prostate cancer (Gleason score  $\geq 7$ ).
    - An unknown or limited family history.
  - Diagnosed at **≤ 60** years with triple-negative breast cancer.
  - Diagnosed at **any age** with any one or more of the following:
    - At least one close blood relative with breast cancer diagnosed at **≤ 50** years.
    - At least one close blood relative with ovarian carcinoma.
    - At least one close male blood relative with breast cancer.
    - At least one close blood relative with metastatic prostate cancer or pancreatic cancer or prostate cancer.
    - At least two additional diagnoses of breast cancer at any age **in patient and/or in close blood relatives**.
  - Ashkenazi Jewish ancestry.
- Personal history** of ovarian carcinoma.
- Personal history** of male breast cancer.
- Personal history** of pancreatic cancer.
- Personal history** of metastatic prostate cancer.
- Personal history** of high-grade prostate cancer (Gleason score  $\geq 7$ ) at **any age** with any one or more of the following:
  - Ashkenazi Jewish ancestry
  - At least one close blood relative with breast cancer diagnosed at **≤ 50** years.
  - At least one close blood relative with ovarian, pancreatic, or metastatic prostate cancer at **any age**.
  - At least two close blood relatives with breast or prostate cancer (any grade) at **any age**.
- A **BRCA1/2 pathogenic/likely pathogenic variant** detected by profiling of any tumor type in the absence of germline analysis.
- Family history** only:
  - At least one first- or second-degree blood relative meeting any of the above criteria.

#### **ENDOMETRIAL AND COLORECTAL CANCER (Lynch Syndrome)**

- Individual from a family with **known Lynch syndrome mutation**.
- Personal history** of colorectal or endometrial cancer with any one or more of the following:
  - Diagnosed at **<50** years.
  - An additional synchronous or meta-synchronous Lynch syndrome-related cancer.
  - At least one first- or second-degree relative with Lynch syndrome-related cancer diagnosed at **<50** years.
  - At least two first- or second-degree relative with Lynch syndrome-related cancer diagnosed at **any age**.
- Personal history** of colorectal or endometrial cancer at **any age** with tumor showing evidence of MMR deficiency.
- Personal history** of colorectal cancer with MSI-H histology diagnosed at **≤ 60** years.
- Personal history** of a Lynch syndrome-related cancer or unaffected individual with  $\geq 5\%$  risk of having an MMR gene mutation.
- Family history** of any of the following:
  - At least one first-degree relative with colorectal or endometrial cancer diagnosed at **<50** years.
  - At least one first-degree relative with colorectal or endometrial cancer and an additional synchronous or meta-synchronous Lynch syndrome-related cancer.
  - At least two first- or second-degree relatives with Lynch syndrome-related cancers, including at least one diagnosed at **<50** years.
  - At least three first- or second-degree relatives with Lynch syndrome-related cancers diagnosed at **any age**.