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A MEMBER OF GENESIS BIOTECHNOLOGY GROUP

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COLLEGE of AMERICAN PATHOLOGISTS

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*BRCA*care® and Genetic Screening Test Requisition Form

Ordering Physician/Laboratory

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

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Physician to receive additional result report: | Date:

Patient Information (Please Print)

Name (Last, First) (Required): gokhale atul

In Care of:

Patient Address:

City: | State: | Zip:

Gender (Required): ☐ Female ■ Male | Date of Birth (Required): 2018-09-

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): Umr

Insured's SS#: | Insured's DOB:

Claims Address:

Medicare, Medicaid or Policy ID#:

Employer/Group Name: | Group#:

Test Selection (◆Not available in NY State)

*BRCA*care® Testing: Blood◆ or Mouthwash

1235 ☐ Breast Cancer High Risk Extended Panel Plus: 14 genes (BRCA1, BRCA2, CDH1, PTEN, TP53, STK11, ATM, CHEK2, PALB2, BARD1, BRIP1, MUTYH, RAD51C, RAD51D) 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

1221 ☐ *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 1235.)

1224 ☐ Gene Specific Site Analysis:
Specify Gene: _____ Variant (mutation):_____

OneSwab®, ThinPrep◆, or Mouthwash

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):_____

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 $149.00, 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):

Clinical Information (Necessary for accurate test interpretation of *BRCA*care® 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
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

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:	☐ IDC (invasive ductal carcinoma)	_____	☐ Bilateral	ER (+) ☐ (-) ☐
	☐ ILC (invasive lobular carcinoma)	_____	☐ Premenopausal	PR (+) ☐ (-) ☐
	☐ DCIS (ductal carcinoma *in situ*)	_____		HER2/neu (+) ☐ (-) ☐
	☐ LCIS (lobular carcinoma *in situ*)	_____		
Ovarian ☐				
Pancreatic ☐				
Prostate ☐			Gleason Score: 2 3 4 5 6 7 8 9 10	
Other (specify):				

Bone marrow transplant recipient? ☐ No ☐ Yes
Current diagnosis of hematological cancer? ☐ No ☐ Yes
Currently receiving radiation therapy/chemotherapy? ☐ No ☐ Yes

Note: This *BRCA*care® Test Requisition Form must be submitted with a Patient Informed Consent/Insurance Acknowledgment Form. Upd: 10/2018

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 Z85.43 Z80.3 Z80.41 Z80.8	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 Z31.440 Z84.81 Z15.01-Z15.02 Z31.5	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
Breast/Ovarian Cancer Diagnosis	C50.011 - C50.019 C50.111 - C50.119 C50.211 - C50.219 C50.311 - C50.319 C50.411 - C50.419 C50.511 - C50.519	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 C50.811 - C50.819 C50.911 - C50.919 C50.021 - C50.929 C56.1 - C56.9 C79.60 - C79.62 C79.81 D05.00 - D05.92 D07.39	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
Cystic Fibrosis	E84.0 E84.11 E84.19	Cystic fibrosis with pulmonary manifestations Meconium ileus in cystic fibrosis Cystic fibrosis with other intestinal manifestations	E84.8 E84.9 Z14.1	Cystic fibrosis with other manifestations Cystic fibrosis, unspecified Cystic fibrosis carrier
Endometrial Uterine Cancer	D07.0 N85.00	Carcinoma in situ of endometrium Endometrial hyperplasia, unspecified	N85.02 Z15.04	Endometrial intraepithelial neoplasia Genetic susceptibility to malignant neoplasm of endometrium

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)

1. Individual from a family with a **known BRCA1/2 pathogenic/likely pathogenic variant**.
2. **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 ≥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.
3. **Personal history** of ovarian carcinoma.
4. **Personal history** of male breast cancer.
5. **Personal history** of pancreatic cancer.
6. **Personal history** of metastatic prostate cancer.
7. **Personal history** of high-grade prostate cancer (Gleason score ≥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**.
8. A **BRCA1/2 pathogenic/likely pathogenic variant** detected by profiling of any tumor type in the absence of germline analysis.
9. **Family history** only:
    - At least one first- or second-degree blood relative meeting any of the above criteria.

ENDOMETRIAL AND COLORECTAL CANCER (Lynch Syndrome)

1. Individual from a family with **known Lynch syndrome mutation**.
2. **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**.
3. **Personal history** of colorectal or endometrial cancer at **any age** with tumor showing evidence of MMR deficiency.
4. **Personal history** of colorectal cancer with MSI-H histology diagnosed at ≤ **60** years.
5. **Personal history** of a Lynch syndrome-related cancer or unaffected individual with ≥5% risk of having an MMR gene mutation.
6. **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**.