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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.)

Physician to receive additional result report: | Date:

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# (Required): | 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#:

Test Selection (◆Not available in NY State)

*BRCA*care® Testing: Blood◆ or Mouthwash

1241 ☐ Comprehensive Hereditary Breast and Gynecologic Cancer Panel: 19 genes analyzed by Gene Sequencing and/or Deletion/Duplication Analysis (BRCA1, BRCA2, ATM, BARD1, BRIP1, CDH1, CHEK2, MUTYH, PALB2, PTEN, RAD51C, RAD51D, STK11, TP53, EPCAM, MLH1, MSH2, MSH6, PMS2)

1268 ☐ Hereditary Breast and Gynecologic Cancer Panel (without BRCA1/2): 17 genes analyzed by Gene Sequencing and/or Deletion/Duplication Analysis (ATM, BARD1, BRIP1, CDH1, CHEK2, MUTYH, PALB2, PTEN, RAD51C, RAD51D, STK11, TP53, EPCAM, MLH1, MSH2, MSH6, PMS2)

1221 ☐ *BRCA1/2*: Comprehensive BRCA Analysis by Gene Sequencing with Deletion/Duplication Analysis

1222 ☐ *BRCA1/2*: Ashkenazi Jewish 3-site Mutation Analysis

1223 ☐ *BRCA1/2*: Ashkenazi Jewish 3-site Mutation Analysis (Reflex to Comprehensive BRCA Analysis) (*If the Ashkenazi Jewish 3-site Mutation Analysis is negative, reflex to 1221.)

1243 ☐ *BRCA1/2*: Ashkenazi Jewish 3-site Mutation Analysis◆ (Reflex to Comprehensive Hereditary Breast and Gynecologic Cancer Panel) (*If the Ashkenazi Jewish 3-site Mutation Analysis is negative, reflex to 1241.)

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, limitations and possible risks. The patient has been given the opportunity to ask questions about this consent and seek outside genetic counseling. 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.

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 2.2017 and Genetic/ Familial High-Risk Assessment: Colorectal Version 2.2016.

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 pathogenic *BRCA1* or *BRCA2* variant**.
2. **Personal history** of breast cancer AND one or more of the following:
   - Diagnosed at ≤ **45** years.
   - Diagnosed at ≤ **50** years with:
     - An additional breast cancer primary.
     - 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 prostate cancer (Gleason score ≥7).
     - An unknown or limited family history.
   - Diagnosed at ≤ **60** with triple-negative breast cancer.
   - Diagnosed at **any age** with:
     - At least two close blood relatives with breast, pancreatic or prostate cancer (Gleason score ≥7), at any age.
     - At least one close blood relative with breast cancer diagnosed at ≤ **50** years.
     - At least one close blood relative with ovarian carcinoma.
     - A close male blood relative with breast cancer.
     - Ashkenazi Jewish ancestry or another ethnicity associated with a higher variant frequency.
3. **Personal history** of ovarian carcinoma.
4. **Personal history** of male breast cancer.
5. **Personal history** of prostate cancer (Gleason score ≥7) at any age and **at least one close blood relative with**:
   - Ovarian carcinoma at any age or;
   - Breast cancer diagnosed at ≤ 50 years or;
   - Two relatives with breast, pancreatic, or prostate cancer (Gleason score ≥7), at any age.
6. **Personal history** of pancreatic cancer at any age and **at least one close blood relative with**:
   - Ovarian carcinoma at any age or;
   - Breast cancer diagnosed at ≤ 50 years or;
   - Two relatives with breast, pancreatic, or prostate cancer (Gleason score ≥7), at any age.
7. **Personal history** of pancreatic cancer and Ashkenazi Jewish ancestry.
8. **Personal history** of *BRCA1* or *BRCA2* mutation detected by tumor profiling in the absence of germline analysis.
9. **Family history** only:
   - First- or second-degree blood relative meeting any of the above criteria.
   - Third-degree blood relative who has breast cancer and/or ovarian carcinoma and who has at least two close blood relatives with breast cancer (at least one with breast cancer diagnosed at ≤50 years) and/or ovarian carcinoma.

ENDOMETRIAL AND COLORECTAL CANCER (Lynch Syndrome)

1. Individual from a family with **a known pathogenic *MLH1*, *MSH2*, *MSH6*, *PMS2* or *EPCAM* variant**.
2. **Personal history** of endometrial cancer diagnosed before age **50**.
3. **Personal history** of colorectal cancer before age **50**.
4. **Personal history** of colorectal cancer with MSI-H histology before age **60**.
5. **Personal history** of synchronous, or meta-synchronous, colorectal, endometrial, ovarian, gastric, pancreatic, ureter, renal-pelvis, biliary tract, brain or small intestine cancers, at any age.
6. **Personal history** of colorectal cancer AND one of the following:
   - At least one first-degree relatives with colorectal, endometrial, ovarian, gastric, pancreatic, ureter, renal-pelvis, biliary tract, brain or small intestine cancers, with one being diagnosed before age 50.
   - At least two first- or second-degree relatives with colorectal, endometrial, ovarian, gastric, pancreatic, ureter, renal-pelvis, biliary tract, brain or small intestine cancers, at any age.
7. **Family history** of at least three relatives with colorectal, endometrial, small bowel, ureter or renal-pelvis cancers, **with ALL the following criteria met**:
   - One relative must be first-degree of the other two.
   - At least two successive generations must be affected.
   - At least one relative must be diagnosed before age 50.