myriad | BRACAnalysis CDx® Test Request Form

Please submit both pages of this form

Make sure information is complete and legible

FOR LAB USE

SPECIMEN COLLECTION DATE (REQUIRED)

(MM/DD/YYYY)

NOTE: Affix Patient Identifier Label to Specimen Tube

1. Patient Information (Complete information required)

Name (last)	Name (first)	(m.i.)	Gender ☐ Male ☐ Female	Birthdate (MM/DD/YYYY)	Patient ID #
				/ /	

Email	Cell phone	Daytime phone

Address	City	State	Zip

2. Ordering Provider Information (Only name and HCP Account # required unless you're a new customer or HCP # is unknown)

Name (last)	Name (first)	Myriad HCP Account #	Degree	NPI #

Address	City	State	Zip

Office Contact Name	Phone	Fax	Email

3. Send Results To (Optional - additional clinician can be listed to receive test status updates and the patient's copy of the test results)

Name (last)	Name (first)	Myriad HCP Account #	Degree	NPI #

Address	City	State	Zip

Office Contact Name	Phone	Fax	Email

4. Test Requested (For test descriptions see reverse)

Tests ordered will be processed and billed based on payer criteria.

☐ **BRACAnalysis CDx® -** *BRCA1* and *BRCA2* gene sequence and large rearrangement analysis to identify the presence of *BRCA1/2* mutation(s). Results of the test are used as an aid in identifying breast cancer patients who are or may become eligible for treatment with Lynparza® (olaparib) or Talzenna® (talazoparib). In addition, results of the test are used as an aid in identifying ovarian cancer patients who are or may become eligible for treatment [treatment/maintenance] with Lynparza® (olaparib) or Rubraca® (rucaparib). A positive BRACAnalysis CDx result in ovarian cancer patients is also associated with enhanced progression-free survival (PFS) from Zejula® (niraparib) or with Rubraca® (rucaparib) maintenance therapy. Results of the test are also used for pancreatic and prostate cancer patients who are or may become eligible for treatment with Lynparza® (olaparib).

☐ **Myriad myRisk® Update Test -** Analysis of additional hereditary cancer genes for patients who have been tested with BRACAnalysis CDx®. When required by payer medical policy, myRisk Update may be performed as a reflex with genes from the original testing excluded. Note: the Myriad myRisk test has not been reviewed, cleared or approved by the FDA.

Risk Analysis Options (to be excluded on report, see reverse for details): ☐ riskScore® is not appropriate for this patient ☐ Tyrer-Cuzick and riskScore® are not appropriate for this patient

5. Confirmation of Informed Consent & Statement of Medical Necessity

I affirm each of the following: I have provided genetic testing information to the patient and the patient has consented to genetic testing. This test is medically necessary for the diagnosis of a disease or syndrome. The results will be used in the patient's medical management and treatment decisions. I authorize Myriad to assist my patients in obtaining pre-test genetic counseling services if required by the patient's insurance provider (see reverse). The person listed as the Ordering Provider is authorized by law to order the test(s) requested herein.

SIGN HERE: Medical Professional (required to process form) X _____ Date: ___/___/_____ (MM/DD/YYYY)

(Signature date is the specimen collection date if a different date is not provided above)

6. Billing/Payment Information

☐ **OPTION 1: BILL INSURANCE** (Please attach copy of authorization/referral)

Name of Policy Holder: _____ DOB: ___/___/_____ (MM/DD/YYYY)

Insurance ID#: _____ Patient Relation to Policy Holder: ☐ Self ☐ Spouse ☐ Child ☐ Other Authorization/Referral: _____

SIGN HERE: Patient/Responsible Party **I AGREE TO THE BILLING TERMS ON REVERSE** X _____ DATE: ___/___/_____ (MM/DD/YYYY)

Reminder: Include a copy of BOTH SIDES of your insurance card(s).

If you submit more than one card, indicate which is primary.

I understand that Myriad will contact me if I will be financially responsible for any non-covered service. To be considered for the Myriad Financial Assistance Program, please provide the following information: Annual household income $ _____. Number of family members in household _____.

☐ **OPTION 2: PATIENT PAYMENT** (Please call Customer Service for questions regarding test prices or for credit card payment)

☐ **OPTION 3: OTHER BILLING** (To establish an account, submit billing information with this form)

☐ Bill our institutional account #: or established research project code #: or Authorization/Voucher #:

MYRIAD GENETIC LABORATORIES, INC. A CLIA Certified Laboratory
320 Wakara Way • Salt Lake City, UT 84108 / **(800) 469-7423 • Fax (801) 584-3615** • myriad.com

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Testing for BRACAnalysis CDx®

IMPORTANT INFORMATION FOR PATIENT*

BILLING TERMS: I represent that I am covered by insurance and authorize Myriad Genetic Laboratories, Inc. (MGL) to give my designated insurance carrier, health plan, or third party administrator (collectively "Plan") the relevant health information necessary for reimbursement. I authorize Plan benefits to be payable to MGL. I understand MGL will contact me if I will be financially responsible for any non-covered service. By agreeing to testing I also authorize Myriad to obtain a consumer credit report on me from a consumer reporting agency selected by Myriad. I understand and agree that Myriad may use my consumer credit report to confirm whether my income qualifies me for financial assistance. I further understand that this is not a credit application and will not impact my credit score. I agree to assist MGL in resolving insurance claim issues and if I don't assist, I may be responsible for the full test cost. I permit a copy of this authorization to be used in place of the original.

NON-DISCRIMINATION: Federal law (GINA) and laws in most states prohibit discrimination regarding employment eligibility, health benefits, or health insurance premiums based solely on genetic information. Myriad Genetic Laboratories, Inc. (Myriad) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex.

AFFORDABILITY: Myriad Promise™

- The majority of appropriate patients pay $0
- Myriad will work with your insurance provider to help you get the appropriate coverage
- If you encounter ANY financial hardship associated with your bill, Myriad will work with you toward your complete satisfaction
- For more information please refer to the billing information at MyriadPromise.com

†Translation of Billing Terms are available in Mandarin and Spanish at MyriadPromise.com. Myriad also provides free language services to people whose primary language is not English through qualified interpreters. If you need these services, contact Customer Service at 800-469-7423.

TEST DESCRIPTIONS

BRACAnalysis CDx® - *BRCA1* and *BRCA2* gene sequence and large rearrangement analysis to identify the presence of *BRCA1/2* mutation(s). Results of the test are used as an aid in identifying breast cancer patients who are or may become eligible for treatment with Lynparza® (olaparib) or Talzenna® (talazoparib). In addition, results of the test are used as an aid in identifying ovarian cancer patients who are or may become eligible for treatment/maintenance with Lynparza® (olaparib) or Rubraca® (rucaparib). A positive BRACAnalysis CDx result in ovarian cancer patients is also associated with enhanced progression-free survival (PFS) from Zejula® (niraparib) or with Rubraca® (rucaparib) maintenance therapy. Pancreatic cancer patients with deleterious or suspected deleterious or suspected deleterious mutations in *BRCA1* and *BRCA2* genes are indicated for therapy with Lynparza® (olaparib).

Myriad myRisk® Update Test: Analysis of additional hereditary cancer genes for patients who have been tested with BRACAnalysis CDx®. When required by medical policy, myRisk Update may be performed as a reflex with genes from the original testing excluded.

Certain payers do not cover genetic testing when Single Nucleotide Polymorphisms (SNPs) are a component of the test. For payers who do not reimburse for a hereditary cancer test due to SNP analysis inclusion, Myriad will report the myRisk Hereditary Cancer Test without SNPs and these patents will not receive a SNP based riskScore®. Please visit www.myriadpro.com/payeroptout to determine if your patient's payer does not reimburse for hereditary cancer genetic testing with SNP analysis.

Genes & Associated Cancers*	Br	Ov	Co	En	Me	Pa	Ga	Pr
BRCA1	●	●				●		●
BRCA2	●	●			●	●		●
*MLH1, MSH2, MSH6, PMS2, EPCAM***		●	●	●		●	●	●
APC			●			●	●	
MUTYH			●					
CDK4, CDKN2A (p16INK4a, p14ARF)					●	●		
TP53	●	●	●	●	●	●	●	●
PTEN	●		●	●	●			
STK11	●	●	●	●		●	●	
CDH1	●		●				●	
BMPR1A, SMAD4			●			●	●	
PALB2, ATM	●					●		
CHEK2	●		●					
NBN	●							●
BARD1	●							
BRIP1		●						
RAD51C, RAD51D		●						
POLD1, POLE, GREM1			●					
AXIN2, GALNT12, MSH3, NTHL1, RPS20, RNF43			●					
HOXB13								●

Br: Breast / **Ov**: Ovarian / **Co**: Colorectal / **En**: Endometrial / **Me**: Melanoma / **Pa**: Pancreatic / **Ga**: Gastric / **Pr**: Prostate

*Additional risks may be associated with each gene/syndrome. **Large rearrangement only.

The genes associated with Myriad myRisk® Hereditary Cancer Panel are subject to change. To ensure you have a current version of the TRF and the genes included with the Myriad myRisk panel please visit www.myriadmyrisk.com/documents-and-forms and www.myriadmyrisk.com/gene-table.

Turnaround Time:
- The majority of Myriad myRisk® results are completed within 14 days
- We will notify you in the unusual event results take longer than 21 days

Myriad myRisk® Report includes:
- myRisk Genetic Result
- riskScore® Result
  - Personalized breast cancer risk assessment based on an analysis of biomarkers combined with patient clinical and family history data
- myRisk Management Tool
  - Guideline based (NCCN, CAPS, Amsterdam, and others) cancer management for both positive and negative results
  - Includes a Tyrer-Cuzick breast cancer risk estimate

Completing the Test Request Form:
- Please include:
  - Age, cancer diagnosis, ancestry, gender, and cancer family history

The myRisk Management Tool and riskScore may not be reported without an accurate and specific personal and family history included on the Patient Cancer Family History in Sections 7 - 11.

riskScore® is only calculated for women who meet the eligibility criteria listed below. riskScore® is not valid, and may significantly over- or under-estimate breast cancer risk for a woman who does not meet these criteria: 1) ancestry is exclusively White/Non-Hispanic (includes Ashkenazi Jewish), 2) age is 18 to 84 years, 3) no personal history of breast cancer, LCIS, hyperplasia (with or without atypia), or a breast biopsy with unknown results, 4) no known mutation or inconclusive result in a breast cancer risk gene has been found in the woman or any of her relatives, and 5) the sample was submitted with a current Test Request Form and the ordering healthcare provider has not determined that riskScore® is inappropriate for the patient. riskScore® and Tyrer-Cuzick model will not be calculated if provider indicates that they are not appropriate for the patient by selecting the check box in Section 4. Not all data collected on the TRF is incorporated into Tyrer-Cuzick or riskScore® calculations. Some fields may be used for anonymized, internal validation studies only.

AUTHORIZATION OF REFERRAL TO GENETIC COUNSELING

In signing **Section 5** of the test request form, you hereby authorize Myriad to assist your patient in obtaining genetic counseling from a third-party service. The specific process will vary by third-party counseling service but in most situations the Genetic Counselor will be added as the healthcare provider receiving a copy of the patient's results, and also be allowed to change the test order should there be a clinical or payer-related reason to do so. You authorize the Genetic Counselor to facilitate the completion of any test requisition forms and/or submit any prior authorization, if necessary, on your behalf and identifying you as the Ordering Provider in any such forms by including your name and NPI.

Special Instructions (if applicable): *Please note: some options may not be possible if an alternate is required by the patient's insurance or if the patient requests otherwise.

☐ Expedite genetic counseling for immediate management decision

☐ Maintain my test as ordered

☐ Allow me to review results with my patient prior to their follow-up counseling session

☐ Other: _____

7. Patient Information (Make sure information is the same as entered on page 1)

Name (last)	(first)	(m.i.)	Birthdate (MM/DD/YYYY)

8. Ancestry (riskScore® is currently only validated and provided for patients of solely White/Non-Hispanic and/or Ashkenazi Jewish ancestry)

Select all that apply: ☐ Ashkenazi Jewish ☐ Asian ☐ Black / African ☐ Hispanic / Latino ☐ Middle Eastern ☐ Native American ☐ Pacific Islander ☐ White / Non-Hispanic

9. Patient Personal History of Cancer & Other Clinical Information (Select all that apply)

☐ **No personal history of cancer**

Patient has been diagnosed with:	Age at Diagnosis	Patient is Currently Being Treated	Pathology / Other Info
☐ **Breast Cancer** ☐ **Left** ☐ **Right**		☐	☐ Ductal Invasive ☐ Lobular Invasive HER2 Status: ☐ + ☐ – ☐ DCIS ☐ Bilateral Previous Chemotherapy: ☐ Yes ☐ No ☐ Triple-Negative (ER-, PR-, HER2-) ☐ Metastatic If ER/PR+, previous Endocrine Therapy: ☐ Yes ☐ No ☐ N/A or inappropriate
☐ **Ovarian Cancer**		☐	☐ Non-epithelial
☐ **Pancreatic Cancer**		☐	
☐ **Prostate**		☐	
☐ **Other Cancer**		☐	Type
☐ **Other Cancer**		☐	Type

Check if applicable to patient:

☐ Bone marrow transplant recipient Type: ☐ Autologous ☐ Allogeneic (If allogeneic please call 800-469-7423 x3850)

☐ Blood transfusion recipient Type: ☐ Whole blood ☐ Packed red blood cells Date: (MM/DD/YYYY)

☐ Diagnosis of a hematologic cancer Type:

10. Family History of Cancer

Provide complete and specific information to ensure proper insurance reimbursement, determine cancer risk estimates, and optimize medical management recommendations.

☐ **No Known Family History of Cancer**

☐ **Limited Family Structure** Limited family history available such as fewer than two female 1st or 2nd degree maternal or paternal relatives having lived beyond age 45

Relationship to Patient	Maternal (mother's side)	Paternal (father's side)	Cancer Site or Polyp Type (add # for colon/rectal adenomas)	Age at Each Diagnosis
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		

11. Breast Cancer Risk Model Information

Patient information:

Height - ft: in: **Weight** (lbs):

Patient's age at time of first menstrual period:

Is patient currently: ☐ Pre-menopausal ☐ Peri-menopausal ☐ Post-menopausal Age of post-menopausal onset:

Has this patient had a live birth?: ☐ No ☐ Yes: **patient's age at 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 _____ years ago Intended use for _____ more years ☐ **Past User:** Stopped _____ years ago

INFORMATION about PATIENT'S FEMALE RELATIVES:

Number of daughters:

Number of sisters:

Number of maternal aunts (mother's sisters):

Number of paternal aunts (father's sisters):

OTHER INFORMATION:

Mammographic Density:

Has the patient had her breast density assessed? ☐ No ☐ Yes

If yes, complete one of the following for the most recent assessment:

☐ **Volpara® Volumetric Density:** _____ ___ %

☐ **VAS Percentage Density:** _____ ___ %

☐ **BI-RADS® ATLAS Density (Select one of the following):**

☐ Almost entirely fatty ☐ Heterogeneously dense ☐ Scattered fibroglandular density ☐ Extremely dense ☐ Unknown

NOTE: Risk associated with mammographic density is not incorporated into riskScore (v.1), nor Tyrer-Cuzick (v.7) calculations provided on the clinical report.

Please indicate if the patient has had a breast biopsy showing one or more of the following results: ☐ N/A (No biopsy or none of the listed results)

☐ Hyperplasia ☐ Atypical Hyperplasia ☐ LCIS ☐ Biopsy with unknown or pending results