A DIVISION OF GENESIS CLINICAL DIAGNOSTICS
A MEMBER OF GENESIS BIOTECHNOLOGY GROUP

MEDICAL DIAGNOSTIC LABORATORIES
2439 Kuser Road • Hamilton, NJ 08690-3303
(609) 570-1000 • Fax (609) 245-7665
Toll Free (877) 269-0090
www.mdlab.com

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

BRCA & Genetic Carrier 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:

Physician's Signature: | Date:

Confirmation of Informed Consent and Medical Necessity for Pharmacogenomic Genetic Testing

My signature below acknowledges the patient has been informed about the purpose, limitation and possible risks of genetic testing. The patient has been given the opportunity to ask questions about this consent and seek outside genetic counseling.

If the genetic 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's signed informed consent 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 **(Req.)**:_____ Date: _____

Clinical Information (required for Genetic Screening Panels and Tests)

Ethnicity (select all that apply):

- ☐ Northern European (e.g. British, German)
- ☐ Southern European (e.g. Italian, Greek
- ☐ French Canadian or Cajun
- ☐ Other/Mixed Caucasian
- ☐ Ashkenazi Jewish
- ☐ East Asian (e.g. Chinese, Japanese)
- ☐ South Asian (e.g. Indian, Pakistani)
- ☐ Hispanic
- ☐ Southeast Asian (e.g. Filipino, Vietnamese)
- ☐ African or African American
- ☐ Middle Eastern

Reason for testing (select all that apply):

- ☐ Genetic Carrier Testing
- ☐ Family History (specify below)
- ☐ Consanguinity
- ☐ Egg or Sperm Donor
- ☐ High-Risk Ethnicity
- ☐ Other (specify):

Family History:

1. Family history of genetic condition or carrier status? ☐ Yes ☐ No ☐ Unknown
2. Specify condition: _____
3. Relationship to patient or patient's partner (specify):
4. Is partner available for testing? ☐ Yes ☐ No
5. Has patient had a blood transfusion (in past 3 months) or a bone marrow/organ transplant? ☐ Yes ☐ No
6. Is patient pregnant? ☐ Yes ☐ No
7. Additional Information: _____

Genetic Testing Specimen Information

Date Collected (Req.): | Specimen Source: ☐ *OneSwab*® ☐ Blood ☐ Saliva

Genetic Testing-*OneSwab*® or Whole Blood® (ACD Solution A)

ICD10 codes (Req.):

1231 ☐ Cystic Fibrosis Core Test by Sanger Sequencing (23 major CFTR variants approved by ACOG/ACMG)

1232 ☐ Cystic Fibrosis Comprehensive Test by Next Generation Sequencing (191 variants of the CFTR gene, including the 23 major variants approved by ACOG/ACMG)

Other Tests/Panels:

ICD10 codes (required):

For a full menu of testing, please visit www.mdlab

Patient Information (Please Print)

Name (Last, First) (Required):

In Care of:

Patient Address:

City: | State: | Zip:

Assigned Sex at Birth (Required): ☐ Female ☐ Male | Date of Birth (Required): | Patient ID#:

Phone Number: ☐ Cell Phone ☐ Home Phone

Race: ☐ Alaska Native or American Indian ☐ Asian ☐ Black or African American ☐ Multiracial ☐ Native Hawaiian or other Pacific Islander ☐ Other race ☐ White ☐ Does not wish to disclose ☐ Not provided

Ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown

Gender Identity: ☐ Male ☐ Female ☐ Gender nonconforming ☐ Transgender male-to-female ☐ Transgender female-to-male ☐ Does not wish to disclose ☐ Not provided ☐ Not applicable

Sexual Orientation: ☐ Bisexual ☐ Straight ☐ Gay or Lesbian ☐ Something else ☐ Does not wish to disclose ☐ Not provided ☐ Not applicable

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

Billing Type: ☐ Patient ☐ Insurance ☐ Client | Relation (Required): ☐ Self ☐ Spouse ☐ Dependant

Insured's Name (if not patient):

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

Primary Insurance Carrier: | Medicare, Medicaid or Policy ID#:

Claims Address:

Employer/Group Name: | Group#:

Clinical Information (Necessary for accurate test interpretation of *BRCA* 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	Is relative available for testing?
			☐	☐	☐Yes ☐No (if not, why?)
			☐	☐	☐Yes ☐No (if not, why?)
			☐	☐	☐Yes ☐No (if not, why?)
			☐	☐	☐Yes ☐No (if not, why?)
			☐	☐	☐Yes ☐No (if not, why?)

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? ☐ Yes
Current diagnosis of hematological cancer? ☐ Yes
Currently receiving radiation therapy/chemotherapy? ☐ Yes

BRCA Specimen Information

Date Collected (Req.): | Specimen Source: ☐ Blood ☐ Saliva

BRCA Test Selection

ICD10 codes (Required.):

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

2602 ☐ **Lynch Syndrome Gene Panel: 5 Genes** - (EPCAM*, MLH1, MSH2, MSH6, PMS2) by Gene Sequencing with Deletion/Duplication Analysis

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):_____

Medical Necessity Guidelines:

Physicians must only order tests that they have determined are medically necessary for the diagnosis and treatment of a patient. MDL offers individual tests, as well as a limited number of customized panels. MDL provides practitioners with the flexibility to choose appropriate individual tests for each specimen to assure that the convenience of ordering panels does not impede them from ordering tests/panels that are medically necessary. All tests listed in panels may be ordered individually using this test requisition form. If you choose to order a panel, please make certain that each and every test is medically necessary. If you check off a panel as your choice, MDL understands that the physician has determined that all of the component tests are medically necessary, and will perform, report and bill for all such component tests.

** This test can only be performed when the test in parenthesis is positive. All tests performed will be billed.

OneSwab® & *UroSwab®* are registered in the USPTO.

Test by Real-Time PCR unless otherwise specified.

Specimen Collection Platform		TAT*	Stability	Test Additions¥	Specimen Collection
Whole Blood	Yellow Top Tube (ACD Solution A)	3-5 days	48 hours	30 days to add tests	1. In accordance with the standard operating procedure of your facility, collect blood in two yellow top (ACD solution A) tubes. 2. Allow the tubes to fill properly to ensure the proper blood to anticoagulant ratio. 3. Invert gently several times to mix and prevent clot formation. Do not shake the tubes. Do not centrifuge.
Saliva		5 - 10 days	48 hours	30 days to add tests	• **Vigorously rinse mouth with clean water 5 minutes prior to specimen collection (30 minutes prior is ideal).** • **After rinsing, do not brush teeth, use mouthwash, eat, drink, chew gum or smoke prior to sample collection.** 1. Begin collecting your sample by allowing saliva to pool in your mouth. Then spit into the wide funnel of the tube allowing saliva to collect in the upper chamber of the tube. Fill the tube until the amount of saliva (not bubbles) reaches the fill line as shown. 2. Once filled, unscrew the funnel allowing the saliva to flow into the lower chamber of the tube containing the stabilizing solution. Discard the funnel. 3. Use the blue cap to close the tube tightly. Shake the capped tube for 5 seconds.
OneSwab®		24 - 72 hours	7 days	30 days to add tests	1. Collect specimen with the sterile swab provided. 2. Insert swab into the transport media, break off swab handle, and tightly re-secure the cap on the transport media vial.

** Up to 72 hours with reflex/antiobiotic resistance testing* *¥ Pending QC review for sufficient specimen volume*

OneSwab® is registered in the USPTO

Specimen Packaging:

1. Label every vial with a minimum of 2 patient identifiers including the patient's name and date of birth. Be sure the name on the vial is written exactly the same way as on the test requisition form.
2. Place the vial into the Styrofoam/Cardboard container. You can fit up to 3 vials in one container.
3. Place the Styrofoam/Cardboard container into the central pocket of a biohazard bag containing absorbent material.
4. Place a completed test requisition form for each vial in the front pocket of the biohazard bag.
5. Place the biohazard bag into the prepaid Lab pack Envelope that has a preaddressed airbill attached. One envelope will accommodate 6-7 containers. Package as many containers in one Labpack as possible.
6. Be sure to seal the Lab pack by removing the plastic from the top of the adhesive.

Specimen Pick-up:

- If you have a specimen pick-up for a local courier in the NJ, PA, DE, D.C., MD, VA, KS, MO or Phoenix, AZ area, please call (877) 205-0005 no later than 2 hours prior to the closing of your facility.
- If you have a specimen pick-up, please call your sales representative or MDL customer service at 877.269.0090 no later than 2 hours prior to the closing of your facility.

Helpful Hints Checklist

Please review these helpful hints to reduce specimen discrepancies and enhance turnaround time.

Verify Patient Name - did you:
- ✓ attach the correct demographics sheet?
- ✓ write the patient's name on the requisition form?

Patient Name Matches on Vial & Requisition Form- did you:
- ✓ make sure names on vial and requisition form match?
- ✓ list the patients married or maiden name?
- ✓ list a nickname by mistake?

Verify Date of Collection- did you:
- ✓ write the correct year?
- ✓ write the correct month?
- ✓ list the date of birth instead?

Verify Tests- did you:
- ✓ clearly mark each box?
- ✓ order tests appropriate for the specimen type?

No Tests Ordered- did you:
- ✓ mark the boxes for the tests/panels ordered?

Supply Orders:

Easily place supply orders online by visiting our website:

http://www.mdlab.com/physicians/supplies/#

Supply orders may also be placed by contacting our Client Services department toll free 877.269.0090 or by fax 609.570.1050. Supply requests are processed and shipped on a daily basis. Please allow 3 to 5 business days for delivery, depending upon your location.

MDL Contact Information	TOLL FREE	FAX
GBS Hotline *24 hours - 7 days a week* *Group B Strep & HSV results only*	877.MDL.GBS7 877.635.4277	
Quality Control Department *For Technical Assistance*	877.269.0090	609.245.7665
Client Services *General Questions, Results*	877.269.0090	609.570.1050
Client Services *Billing Questions*	877.333.9233	609.245.7683