



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



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:

- Family history of genetic condition or carrier status? Yes No Unknown
- Specify condition: _____
- Relationship to patient or patient's partner (specify): _____
- Is partner available for testing? Yes No
- Has patient had a blood transfusion (in past 3 months) or a bone marrow/organ transplant? Yes No
- Is patient pregnant? Yes No
- 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)

Genetic Testing - Whole Blood® (ACD Solution A) only

ICD10 codes (Req.):

- 1274 Genetic Carrier Screening Panel (2 genes) includes:
 - Cystic Fibrosis Core Test (23 major CFTR variants approved by ACOG/ACMG) (CFTR)
 - Spinal Muscular Atrophy (SMN1)

Genetic Testing - OneSwab® only

ICD10 codes (Req.):

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

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

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

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

Billing Type: Patient Insurance Client Relation (Required): Self Spouse Dependent

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
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>

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

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): _____

Other Tests/Panels:

ICD10 codes (required):




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

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.
Test by Real-Time PCR unless otherwise specified.

OneSwab® & UroSwab® are registered in the USPTO.

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	<ol style="list-style-type: none"> In accordance with the standard operating procedure of your facility, collect blood in two yellow top (ACD solution A) tubes. Allow the tubes to fill properly to ensure the proper blood to anticoagulant ratio. 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	<ul style="list-style-type: none"> 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. <ol style="list-style-type: none"> 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. Once filled, unscrew the funnel allowing the saliva to flow into the lower chamber of the tube containing the stabilizing solution. Discard the funnel. 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	<ol style="list-style-type: none"> Collect specimen with the sterile swab provided. 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/antibiotic resistance testing

‡ Pending QC review for sufficient specimen volume

OneSwab® is registered in the USPTO

Specimen Packaging:

- 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.
- Place the vial into the Styrofoam/Cardboard container. You can fit up to 3 vials in one container.
- Place the Styrofoam/Cardboard container into the central pocket of a biohazard bag containing absorbent material.
- Place a completed test requisition form for each vial in the front pocket of the biohazard bag.
- 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.
- 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



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