

Patient to read before signing Genetic Testing Consent on requisition

1-844-363-4357 Ask.Genetics@LifeLabs.com

Appointment booking can be done at www.lifelabs.com

Purpose of the Test + Genetic Counselling

Analysis of BRCA1 and BRCA2 genes (BRCA1/2) looks for changes in your DNA called mutations. Certain mutations within the BRCA1/2 genes can make it more likely that you could develop certain cancers, such as breast, ovarian, fallopian tube, peritoneal, melanoma, pancreatic and/or prostate cancer. Individuals with BRCA 1/2 mutations are more likely to develop cancer at a younger age and have high grade (aggressive) tumours. Among those who develop cancer, variable age at diagnosis and type of cancer is observed, even within the same family. If you have a family history of a BRCA1/2 mutation, you should inform the LifeLabs Genetics team of the specific gene mutation(s) present in your family. Private pay BRCA 1/2 analysis offered through LifeLabs includes next-generation sequencing and dosage analysis of BRCA1/2, in addition to a 30 minute pre-test telephone session with a board certified genetic counsellor prior to the start of the analysis and an optional 15-30 minute post-test counselling session. LifeLabs will make two attempts to contact you to schedule your pre-test counselling session once you submit your blood sample.

During the pre-test counselling session, the genetic counsellor will:

- Review your family history of cancer. Please inquire with relatives as to specific diagnosis and age of onset.
- Discuss the benefits, limitations and risks of genetic testing
 - You will have the option to decline further genetic testing once reviewing the benefits, limitations and risks.
- Review the possible outcomes of genetic testing (positive, true negative, uninformative negative and variants of unknown significance)
- Discuss possible implications to insurability
 - A positive genetic test result may affect an individual's eligibility for insurance such as (although not limited to) private medical, life, disability and travel insurance.
- Send a summary letter of the pre-test counselling session to you and your ordering physician

Benefits

You may use the results of genetic testing to help guide surveillance, prevention and medical management decisions in regards to cancer. This information can also affect your family members. In the two copies of our genes, only one copy needs to have a mutation for a person to be more likely to develop the cancers listed above. This is called autosomal dominant inheritance. If an individual is found to have a BRCA1/2 mutation, there is a 50% chance that their child could inherit the mutation as well, which means there is also a 50% chance that an individual's siblings and parents have the same mutation.

Risks

Genetic testing may reveal sensitive information about your health or that of your relatives. Test results may reveal incidental, unsought information, such as discovering that a man is not the father of a child (non-paternity). Results of genetic testing can create emotional burdens (feeling guilty, sad, worried, angry), which can impact yourself and family members. It can also potentially have negative impacts when applying for insurance, although the current data is uncertain when assessing genetic risks and insurance premiums.

Test Results

Once your blood is taken, your sample will be sent to our partner laboratory, Centogene, in Germany. **Your pre-test counselling session will be set up concurrently to your sample being sent to and processed by Centogene.** Testing will take 4-6 weeks from when Centogene receives the sample. Urgent results (7-15 business days) are available for an additional fee of \$250. Results will be sent to the ordering physician and to the patient if the physician has consented to release the results on the requisition.

Possible results:

- Positive:** A disease-causing mutation was identified. This individual has an increased risk for specific types of cancer. Family members are at increased risk of carrying the same mutation.
- True Negative:** This individual tested negative for a mutation previously identified in the family. This individual's risk for cancer is not expected to be increased above the general population risk.
- Uninformative negative:** No disease-causing mutation was identified. If an individual has a personal or family history of cancer, the exact cause of the cancers in the family remains unknown. This individual's risk for cancer remains increased based on family history assessment. If applicable, testing affected family members could be considered.
- Variant of Unknown Significance (VUS):** A VUS indicates that the pathogenicity (whether a mutation causes a predisposition to cancer) of the variant identified cannot be established. Testing other family members may help clarify the clinical significance. Over time, variants may be reclassified as pathogenic or non-pathogenic (eg, disease causing or not associated with disease).

Test Limitations

The genetic consultation provided with the purchase of BRCA1/2 genetic testing is not a substitute for a full genetic evaluation. Specialized care providers have or can obtain access to clinical records, which LifeLabs Genetics cannot. The focus of the pre and post-test counselling session is on the benefits and limitations of genetic testing for BRCA1 and BRCA2 specifically and implications of results. There are genes other than BRCA1/2 related to inherited breast and ovarian cancer and there remain many uncertainties, including the effects of as yet unknown genes, which may impact on the prevalence of breast/ovarian and other cancers. Although a pedigree (also known as a family tree, documenting family history related to cancer) will be drawn up for use by your healthcare provider, it will not be assessed to determine if other genes or conditions are appropriate for testing or the likelihood of developing cancer. Genetic counsellors at LifeLabs will rely on information provided by the patient and will not seek to confirm or disprove clinical information provided by requesting medical records.

Medical information and technology change constantly, and therefore we encourage you to review the recommendations from the LifeLabs genetics consultation regularly with your healthcare provider to ensure that they are still aligned with current practice. LifeLabs Genetics bases their clinical management recommendations on "The Canadian Consensus Guidelines [Horsman et al: JGOC 28(1): 45-60 (2007)]" and NCCN guidelines.

Alternatives to privately paying for BRCA1/2 testing

The ordering physician may consider referring a patient to a local cancer genetics clinic, which can be found through <https://www.cagc-accg.ca>. Provincial Ministry of Health funding in Canada for genetic testing for BRCA1/2 and counselling may be available for individuals with a personal and/or family history of breast, ovarian, fallopian tube, peritoneal, melanoma, pancreatic and/or prostate cancer. Wait times vary per clinic, and can range from 2 months to 2 years.

Who should have BRCA1/2 testing?

There are certain individuals who are considered to be at a higher risk of having a BRCA1/2 mutation:

- Breast cancer diagnosed at age 50 or younger
- Multiple primary breast cancers either in the same breast or opposite breast
- Triple-negative breast cancer at age 60 or younger (ER-, PR- and HER2/neu -)
- Ovarian cancer, fallopian tube or primary peritoneal cancer at any age
- Both breast and ovarian cancer
- Pancreatic cancer with breast or ovarian cancer in the same individual or on the same side of the family
- A previously identified BRCA1 or BRCA2 pathogenic mutation in the family
- Two or more relatives with breast cancer, one under age 50
- Three or more relatives with breast, ovarian, pancreatic, and/or aggressive prostate cancer
- Ashkenazi Jewish ancestry with history of breast, ovarian or pancreatic cancer
- Male breast cancer at any age

Some individuals who do not meet the above criteria above may still choose elect to pursue BRCA1/2 genetic testing to find out more information about their susceptibility risk for to cancer, even though the chance of finding a BRCA1/2 mutation might be low.

Cancellation of Samples

You can withdraw your consent to the analysis at any time in full or in part without stating reasons. You have the right not to be informed about test results (right not to know), to stop the testing processes that have been started at any time up to being given the results and to request the destruction of all test material and all results collected up to that time. If a test is cancelled after the pre-test counselling session, you will be refunded less the amount of \$200, which is incurred for processing and counselling. Once testing is initiated, the full price of the analysis will be charged.

CONTRACT #		LL: K012-01 / BC: no contract# (private pay)				LifeLabs Demographic Label	
Ordering Physician #		Physician OHIP# (Ontario): Physician MSC# (British Columbia): Other Provinces: 999 (Ontario voyager)					
Ordering Physician Name		Name					
Ordering Physician Address & contact info:		Address				Additional Label (if needed)	
		Tel: _____ Fax: _____					
Physician Signature:		<p>Confirmation of patient consent: I confirm that this patient has given consent to testing as may be required by applicable law. I have provided the patient with the Patient Information form and the opportunity for pre-test counselling, where details associated with the genetic test(s) ordered below including its risks, benefits and limitations are discussed. I have encouraged the patient review the result of testing with the appropriate genetic counseling. I can confirm that the patient was informed that s/he has the right to revoke his/her consent at any time. I authorize that the patient receives a copy of the test results in addition to summary letters of the counseling sessions, unless I check the box below.</p> <input type="checkbox"/> I do NOT authorize that the patient receives a copy of the test results or summary letters directly and I have made the patient aware of this.					
		Please sign here					
Copy-to Client: <input type="checkbox"/> Genetic Counsellor <input type="checkbox"/> Other Healthcare Provider		Copy-to Client name					
		Tel: _____ Fax: _____					
Bill to:		Bill Type "Private Pay" (ON: P; BC: PP; patient pays at time of collection)			Patient Sex: <input type="checkbox"/> Female <input type="checkbox"/> Male		
Patient Last Name:		Patient First Name:		Patient Health Card:		Date of Birth:	
						M M D D Y Y Y Y	
Unit #:	Street:	City:	Prov.:	Postal Code:	Patient Telephone:		
					() -		
Patient email:		If the ordering physician authorizes the patient to receive results and summary letters, it is LifeLabs' preference to release these documents via email.					
TEST REQUESTED							
<input type="checkbox"/> Genetic Counselling + BRCA 1/2 analysis (for LL Genetics) - \$600 TAT: 4-6 weeks <input type="checkbox"/> Expedited Genetic Counselling + BRCA 1/2 analysis (for LL Genetics) - \$850 TAT: 2-3 weeks						ON-LL TR#	
						5501	
						5520	
Date Sample Collected		M	M	D	D	Y	Y
		Y	Y	Y	Y		
Time Collected		H	H	M	M	Collector Name:	
GENETIC TESTING CONSENT							
<p>I have read the Patient Information Form. I understand that my specimen for DNA analysis will be sent to LifeLabs for genetic testing. LifeLabs and Centogene have entered into a mutually binding distribution agreement whereby both organizations will comply with all applicable legislation. Centogene complies with German confidentiality laws; LifeLabs Genetics complies with Canadian privacy laws. LifeLabs will only report test results to the ordering healthcare provider(s) or genetic counsellors involved and the patient when authorized by the ordering healthcare provider to do so. Additionally, the test results could be released to those who, by law, may have access to such data. My physician has told me about the condition(s) being tested and its genetic basis. I am aware that correct information about my family members is important and can affect the outcome of my results. I agree that my specimen and personal health information may be sent to Centogene AG at their laboratory in Germany (address above). To ensure accurate testing, I agree that the results of genetic testing that I have had previously completed by Centogene AG may be shared with LifeLabs. I understand that LifeLabs will contact me for a new specimen if a test result cannot be provided from the original specimen. I agree that a copy of my results will be sent to my ordering physician. I further agree that for any test(s) performed by Centogene AG, a copy of my results will also be sent to LifeLabs.</p>							
<p>1. I understand that once the requested test(s) has/have been completed, any remaining sample will be stored at the testing laboratory.</p> <p>2. I agree that my de-identified sample may be used for product development or research purposes. I understand that I will not receive any royalties, resultant payments, benefits or rights to products or discoveries.</p>							
<input type="checkbox"/> I do not want my remaining sample or data from my results to be stored and/or used for product development or research purposes. Please destroy any remaining sample once the final report has been issued. By ticking this box I disagree with points 1 and 2 listed above.							
Patient/Substitute Decision Maker: Signature: _____ ; Date: _____							
Printed name: _____ ; Relationship to person being tested: _____							
OR: I certify that verbal consent was obtained from the patient / substitute decision maker for the requested genetic testing							
Signature of Physician : _____ ; Date: _____							

****PHOTOCOPY REQUISITION AND INCLUDE 1 COPY WITH SAMPLES****

Patient Name: _____		Patient DOB (MM/DD/ YYYY): _____	
Testing Instructions: Please use the online catalogue to find test code & names: www.lifelabsgenetics.com /hereditary-conditions	Test Code(s): <u>CN5046</u>		
	Test Name(s): <u>BRCA1/BRCA2 Panel</u>		
Test methodology <input checked="" type="checkbox"/> FULL ANALYSIS - sequencing+ reflex to deletion/duplication <input type="checkbox"/> URGENT ANALYSIS REQUESTED (only check marked if Expedited Genetic Counselling + BRCA1/2 has been selected on page 1) <input type="checkbox"/> Familial Mutation (Familial Report attached Y/N) Gene: _____ Mutation (HGVS): _____			
Sample Type:		<input checked="" type="checkbox"/> *Blood (EDTA: 8- 10mL) <input type="checkbox"/> Saliva (Oragene OG-510, available by request)	
Patient Information:		<input type="checkbox"/> African/African American <input type="checkbox"/> Caucasian <input type="checkbox"/> French Canadian or Cajun <input type="checkbox"/> Middle Eastern <input type="checkbox"/> Northern European e.g. <i>British, German</i> <input type="checkbox"/> South Asian e.g. <i>Indian, Pakistani</i> <input type="checkbox"/> East Asian e.g. <i>Chinese, Japanese</i> <input type="checkbox"/> Other – please specify: _____	
		<input type="checkbox"/> Ashkenazi Jewish <input type="checkbox"/> Other/Mixed Caucasian <input type="checkbox"/> Indigenous <input type="checkbox"/> Hispanic <input type="checkbox"/> Southern European e.g. <i>Italian, Greek</i> <input type="checkbox"/> Southeast Asian e.g. <i>Filipino, Vietnamese</i> <input type="checkbox"/> Pacific Islander	
Additional patient medical information: Relevant family history:			
Have other family members submitted samples to LifeLabs/Centogene for analysis? <input type="checkbox"/> Y <input type="checkbox"/> N If yes, Name: _____ Relationship to patient _____ DOB (MM/DD/ YYYY): _____			
Billing Status:		<input checked="" type="checkbox"/> Institution (Complete information below)	
Institution Billing ONLY:		Institution Name: _____ Contact Name: _____ Address: _____ Phone: () - Fax: () - Email: _____	

****PHOTOCOPY REQUISITION AND INCLUDE 1 COPY WITH SAMPLES****