HEREDITARY CANCER GENETIC TESTING & COUNSELLING REQUISITION

Appointment Booking: www.lifelabs.com

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

CLEAR FORM

CONTRACT #	
Ordering Physician #	Physician OHIP# (Ontario): Physician MSC# (British Columbia): Other Provinces (Ontario Voyager): 999
Ordering Physician Name	Name
Ordering Physician Address & contact info:	Address Tel: Fax:
Physician Signature:	**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.** If the patient declines pre test counselling results will be available through the physician. ❑ 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: ❑ Genetic Counsellor ❑ Other Healthcare Provider	Copy-to Client name Tel: Fax:

LifeLabs Label

Bill to:	**Bill Type "Private Pay"** (ON: P; BC: PP; patient pays at time of collection)	**Patient Sex**: ☐ **Female** ☐ **Male**
Patient Last Name:	**Patient First Name:**	**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	**ON-LL TC#**	**Mnemonic**
❑ **Genetic Counselling + BRCA 1 & 2 analysis -** *TAT: 4-6 weeks*	**5501**	**BRCALL**
❑ **Genetic Counselling + Breast Cancer Panel analysis -** *TAT: 4-6 weeks*	**HCP**	**HCP**
❑ **Genetic Counselling + Breast/Gynecologic Cancer Panel analysis -** *TAT: 4-6 weeks*	**HCP**	**HCP**
❑ **Genetic Counselling + Colorectal Cancer Panel analysis -** *TAT: 4-6 weeks*	**HCP**	**HCP**
❑ **Genetic Counselling + Prostate Cancer Panel analysis -** *TAT: 4-6 weeks*	**HCP**	**HCP**
❑ **Genetic Counselling + Hereditary Cancer Panel analysis -** *TAT: 4-6 weeks*	**HCP**	**HCP**

Date Sample Collected	M M	D D	Y Y Y Y	**Time Collected**	H H	M M	**Collector Name**	

GENETIC TESTING CONSENT

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 Invitae have entered into a mutually binding distribution agreement whereby both organizations will comply with all applicable legislation. Invitae complies with U.S.A. 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 Invitae at their laboratory in the U.S.A. (1400 16th Street, San Francisco, CA 94103). To ensure accurate testing, I agree that the results of genetic testing that I have had previously completed by Invitae 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 Invitae, a copy of my results will also be sent to LifeLabs.

1. I understand that once the requested test(s) has/have been completed, any remaining sample will be stored at the testing laboratory.
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.

❑ 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.

Pre and post test counselling is included as part of the BRCA1&2 and hereditary cancer panel testing. A member of our genetics team will contact you to book these appointments. We strongly recommend the counselling sessions to ensure appropriate risk assessment, and understanding of the benefits and limitations of the test, results and follow-up.

❑ I decline pre-test counselling. If you decline pre-test counselling, results will be available through your physician.

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****

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Panel Content:	***BRCA1, BRCA2 panel*** → *BRCA1, BRCA2* ***Breast Cancer panel*** → *ATM, BRCA1, BRCA2, CDH1, CHEK2, NBN, NF1, PALB2, PTEN, STK11, TP53* ***Breast and Gynecologic Cancer panel*** → *ATM, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH6, NBN, NF1, PALB2, PMS2, PTEN, RAD51C, RAD51D, STK11, TP53* ***Colorectal Cancer panel*** → *APC, AXIN2, BMPR1A, CHEK2, EPCAM, GREM1, MLH1, MSH2, MSH3, MSH6, MUTYH, NTHL1, PMS2, POLD1, POLE, PTEN, SMAD4, STK11, TP53* ***Prostate Cancer Panel*** →*ATM, BRCA1, BRCA2, CHEK2, EPCAM, HOXB13, MLH1, MSH2, MSH6, NBN, PMS2, TP53* ***Hereditary Cancer panel*** → *AIP, ALK, APC, ATM, AXIN2, BAP1, BARD1, BLM, BMPR1A, BRCA1, BRCA2, BRIP1, CASR, CDC73, CDH1, CDK4, CDKN1B, CDKN1C, CDKN2A, CEBPA, CHEK2, CTNNA1, DICER1, DIS3L2, EGFR, EPCAM, FH, FLCN, GATA2, GPC3, GREM1, HOXB13, HRAS, KIT, MAX, MEN1, MET, MITF, MLH1, MSH2, MSH3, MSH6, MUTYH, NBN, NF1, NF2, NTHL1, PALB2, PDGFRA, PHOX2B, PMS2, POLD1, POLE, POT1, PRKAR1A, PTCH1, PTEN, RAD50, RAD51C, RAD51D, RB1, RECQL4, RET, RUNX1, SDHA, SDHAF2, SDHB, SDHC, SDHD, SMAD4, SMARCA4, SMARCB1, SMARCE1, STK11, SUFU, TERC, TERT, TMEM127, TP53, TSC1, TSC2, VHL, WRN, and WT1* **gene lists are subject to change over time. Most up to date information is available on theInvitae website and will be listed on the report.*
Other Test-Related Information	
Test Methodology:	❑ FULL ANALYSIS – *sequencing and copy number variants*
Sample Type:	❑ **Blood** (EDTA: 8- 10mL) ❑ **Saliva** (Oragene OG-510, available by request)
Patient Ancestry:	❑ Ashkenazi Jewish ❑ French Canadian ❑ Indigenous ❑ White/Caucasian ❑ Asian ❑ Hispanic ❑ Pacific Islander ❑ Black/African ❑ Mediterranean ❑ Sephardic Jewish ❑ Other – *please specify:* _____
Reason for Testing:	☐ **Personal history of cancer ☐ **Family history of cancer ☐ **Known familial mutation ☐ Personal Choice ☐ Other: ***Please fill in additional details in Clinical Information below*
Clinical Information:	**Additional patient medical information:** **Relevant family history:**
Additional Family Members:	**Have other family members submitted samples to LifeLabs for analysis?** ❑Y ❑ N If yes, Name:_____ Relationship to patient _____ D.O.B. *(MM/DD/ YYYY)*:_____

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

PATIENT INFORMATION FORM
Hereditary cancer testing

1-844-363-4357· Ask.Genetics@LifeLabs.com **Patient to read before signing Genetic Testing Consent on requisition**

Purpose of the Test + Genetic Counselling

Analysis of genes looks for changes in your DNA called mutations. For example, 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. The Hereditary Cancer Panel offered through LifeLabs looks for mutations in the following genes: AIP, ALK, APC, ATM, AXIN2, BAP1, BARD1, BLM, BMPR1A, BRCA1, BRCA2, BRIP1, CASR, CDC73, CDH1, CDK4, CDKN1B, CDKN1C, CDKN2A, CEBPA, CHEK2, CTNNA1, DICER1, DIS3L2, EGFR, EPCAM, FH, FLCN, GATA2, GPC3, GREM1, HOXB13, HRAS, KIT, MAX, MEN1, MET, MITF, MLH1, MSH2, MSH3, MSH6, MUTYH, NBN, NF1, NF2, NTHL1, PALB2, PDGFRA, PHOX2B, PMS2, POLD1, POLE, POT1, PRKAR1A, PTCH1, PTEN, RAD50, RAD51C, RAD51D, RB1, RECQL4, RET, RUNX1, SDHA, SDHAF2, SDHB, SDHC, SDHD, SMAD4, SMARCA4, SMARCB1, SMARCE1, STK11, SUFU, TERC, TERT, TMEM127, TP53, TSC1, TSC2, VHL, WRN, and WT1. A list of the genes and their associated cancers is available on the supplemental Hereditary Cancer Panel sheet. Additional condition-specific panels are also available. If you have a family history of a genetic mutation related to an inherited cancer syndrome, you should inform the LifeLabs Genetics team of the specific gene mutation(s) present in your family. Private pay BRCA ½ and Hereditary Cancer Panel analysis offered through LifeLabs includes next-generation sequencing and dosage analysis, 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
- 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 genetic mutation on one of the LifeLabs hereditary cancer tests, 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, Invitae in USA. **Your pre-test counselling session will be set up concurrently to your sample being sent to and processed by Invitae.** Testing will take 4-6 weeks from when Invitae receives the sample. Results will be sent to the ordering physician and to the patient if the physician has consented to release the results on the requisition unless the patient declines pre-test counselling, in which case they will be sent to the physician only.

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 a hereditary cancer 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 relating to inherited cancer syndromes specifically and implications of results. There may be genes other than those presently offered related to inherited cancer syndromes and there remain many uncertainties, including the effects of as yet unknown genes, which may impact on the prevalence of 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: JOGC 28(1): 45-60 (2007)]" and NCCN guidelines.

Alternatives to privately paying for hereditary cancer genetic 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 relating to inherited cancer syndromes and counselling may be available for individuals with a personal and/or family history of cancer that meets high risk criteria. Wait times vary per clinic, and can range from 2 months to 2 years.

Who should have genetic testing relating to inherited cancer syndromes?

There are certain individuals (5-10% of all cancers) who are considered to be at a higher risk of having a mutation related to an inherited cancer syndrome:

• Cancer diagnosed at age 50 or younger	• Male breast cancer at any age
• Multiple primary cancers (could be in the same organ)	• Two or more relatives with the same cancer, one under age 50
• Triple-negative breast cancer at age 60 or younger (ER-, PR- and HER2/neu -)	• Three or more relatives with similar or patterning cancers, likely in more than one generation on one side of the family
• Ovarian cancer, fallopian tube or primary peritoneal cancer at any age	• Ashkenazi Jewish ancestry with history of breast, ovarian or pancreatic cancer
• Clustering of certain cancers (e.g.: breast and ovarian cancer; colon and uterine cancer)	• A previously identified pathogenic mutation relating to an inherited cancer syndrome in the family
• Multiple colon polyps (10-100+)	• Atypical tumour pathology (e.g.: colon cancer IHC deficient, MSI-H)

Some individuals who do not meet the above criteria above may still choose elect to pursue genetic testing to find out more information about their susceptibility risk for to cancer, even though the chance of finding a 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 to not 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 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 test price will be charged. **Given the short turnaround on results, you should aim to accept to the earliest available appointment to ensure you are able to avail yourself of this option.**