Hereditary Cancer Testing & Genetic Counselling
Requisition Form

Appointment Booking: www.LifeLabs.com | 1-844-363-4357 · Ask.Genetics@LifeLabs.com

Ordering healthcare provider information

Name: _____

Billing #: _____

Email: _____ Phone: _____

Institution: _____ Fax: _____

Address:

_____

LifeLabs use only

Ordering healthcare provider 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 to review the results of testing with a post-test genetic counselling appointment. I can confirm that the patient was informed that s/he/they has the right to revoke his/her/their 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, post-test counselling will be offered. If declined, results will be available through the healthcare provider.

☐ I do NOT authorize that the patient receives results or a copy of the test results or summary letters directly and I have made the patient aware of this. I will be informing the patient of the results.

Please sign here:

Copy-to client:

☐ Genetic Counsellor

☐ Other healthcare provider

Copy-to client name: _____

Address: _____

Phone:

Fax:

Patient information

First name: _____ Last name: _____

Phone: _____ Date of birth: _____
YYYY/MM/DD

Address: _____ Sex assigned at birth: ☐ Male ☐ Female

PHN or OHIP #: _____ Preferred Pronoun: ☐ She/her ☐ They/them ☐ He/him ☐ Prefer not to answer

Email: _____

If the ordering healthcare provider authorizes the patient to receive results and summary letters, it is LifeLabs' preference to release these documents via email.

Billing information

☐ Private-Pay (patient must pay at time of collection)

☐ LifeLabs Store AL628 (ON) or A8972 (BC) Enter Order ID: _____

☐ Contract Contract/account number: _____

Test requested	ON - Test Code	BC - Mnemonic
☑ Hereditary cancer panel + genetic counselling	6548	HCPBP

Date sample collected: _____ Time sample collected: _____ Phlebotomist: _____
MM/DD/YYYY

Genetic testing consent

I have read the Patient Information Form. I understand that my specimen will be sent to LifeLabs for genetic testing. LifeLabs and Blueprint Genetics have entered into a mutually binding distribution agreement whereby both organizations will comply with all applicable legislation. Blueprint Genetics complies with the General Data Protection Regulation of the European Union; 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 healthcare provider 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, personal health and family history information will be sent to Blueprint Genetics at their laboratory in Finland (Blueprint Genetics, Keilaranta 16 A-B, 02150 Espoo, Finland). I understand that LifeLabs will contact me for a new specimen if a test result cannot be provided from the original specimen. I further agree that for any test(s) performed by Blueprint Genetics, a copy of my results will also be sent to LifeLabs. I understand that once the requested test has been completed, any remaining sample will be stored at the testing laboratory for up to 12 months, after which it will be disposed per the laboratory's sample disposal schedule. I agree that my de-identified sample may be used for product development or for the disclosure of scientific genetic findings. I understand that I will not receive any royalties, resultant payments, benefits or rights to products or discoveries. The testing laboratory will delete my data after 20 calendar years or sooner if required. For more information I may contact LifeLabs Genetics at 175 Galaxy Boulevard, Toronto ON, M9W 0C9, or email ask.genetics@lifelabs.com within 60 days after test results have been issued.

Pre and post-test counselling is included as part of 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, understanding of the benefits and limitations of the test results, and follow-up.

☐ I decline pre-test counselling. If you decline pre-test counselling, you will be offered a post-test counselling session to review results. If this is declined, results will be available through your healthcare provider.

Patient or Substitute Decision Maker: Signature: _____ **Date:** _____
YYYY/MM/DD

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

Healthcare provider signature: **Date:** _____
YYYY/MM/DD

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

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Panel content	Hereditary Cancer Panel: *AIP, ALK, APC, ATM, AXIN2, BAP1, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDC73, CDH1, CDK4, CDKN1B, CDKN2A, CEBPA, CHEK2, CTNNA1, DDX41, DICER1, EGFR, EGLN1, EPCAM, ETV6, EXT1, EXT2, FH, FLCN, GALNT12, GATA2, GREM1, HOXB13, KIF1B, KIT, LZTR1, MAX, MEN1, MET, MITF, MLH1, MSH2, MSH3, MSH6, MUTYH, NF1, NF2, NTHL1, PALB2, PDGFRA, PHOX2B, PMS2, POLD1, POLE, POT1, PRKAR1A, PTCH1, PTEN, RAD51C, RAD51D, RB1, RECQL, RET, RNF43, RPS20, RUNX1, SDHA, SDHAF2, SDHB, SDHC, SDHD, SMAD4, SMARCA4, SMARCB1, SMARCE1, STK11, SUFU, TERT, TMEM127, TP53, TSC1, TSC2, VHL, WT1* *Please note that the gene list is subject to change over time. Most up to date information will be listed on the results report.*
Other test-related information:	Has the patient received a hematopoietic stem cell transplantation? ☐ Yes Has the patient received granulocyte transfusions in the past two weeks? ☐ Yes
Test methodology:	☐ FULL ANALYSIS – sequencing and copy number variants
Patient ancestry:	☐ Ashkenazi Jewish ☐ Asian ☐ Black/African ☐ French Canadian ☐ Hispanic ☐ Mediterranean ☐ Indigenous ☐ Pacific Islander ☐ Sephardic Jewish ☐ White/Caucasian ☐ Other – please specify: _____
Reason for testing:	☐ **Personal history of cancer ☐ **Family history of cancer ☐ **Known familial pathogenic variant/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? ☐ Yes ☐ No If yes, Name: _____ Relationship to patient: _____ Date of birth: _____ **MM/DD/YYYY**

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

Hereditary Cancer Testing & Genetic Counselling

Patient Information Form

Patient to read before signing Genetic Testing Consent on requisition form

Purpose of the Test + Genetic Counselling

Analysis of genes look for changes in your DNA called pathogenic variants/mutations. For example, certain pathogenic variants/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 pathogenic variants/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 pathogenic variants/mutations in the following genes: *AIP, ALK, APC, ATM, AXIN2, BAP1, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDC73, CDH1, CDK4, CDKN1B, CDKN2A, CEBPA, CHEK2, CTNNA1, DDX41, DICER1, EGFR, EGLN1, EPCAM, ETV6, EXT1, EXT2, FH, FLCN, GALNT12, GATA2, GREM1, HOXB13, KIF1B, KIT, LZTR1, MAX, MEN1, MET, MITF, MLH1, MSH2, MSH3, MSH6, MUTYH, NF1, NF2, NTHL1, PALB2, PDGFRA, PHOX2B, PMS2, POLD1, POLE, POT1, PRKAR1A, PTCH1, PTEN, RAD51C, RAD51D, RB1, RECQL, RET, RNF43, RPS20, RUNX1, SDHA, SDHAF2, SDHB, SDHC, SDHD, SMAD4, SMARCA4, SMARCB1, SMARCE1, STK11, SUFU, TERT, TMEM127, TP53, TSC1, TSC2, VHL, WT1*. A list of the genes and their associated cancers is available on the supplemental Hereditary Cancer Panel sheet. If you have a family history of a pathogenic variant/mutation related to an inherited cancer syndrome, you should inform the LifeLabs Genetics team of the specific pathogenic variant/mutation present in your family. Private pay Hereditary Cancer Panel analysis offered through LifeLabs includes next-generation sequencing, CNV analysis and select intronic variants, in addition to a 30-45 minute pre-test telephone or videoconference session with a board-certified genetic counsellor and a 15-30 min 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 healthcare provider.

Benefits

You may use the results of genetic testing to help guide surveillance, prevention and medical management decisions regarding cancer. This information can also affect your family members. In the two copies of our genes, only one copy needs to have a pathogenic variant/mutation for a person to be more likely to develop the cancers listed above, although having a pathogenic variant/mutation does not mean that you will definitely develop cancer. This is called autosomal dominant inheritance, with reduced penetrance. If an individual is found to have a pathogenic variant/mutation on one of the LifeLabs hereditary cancer tests, there is a 50% chance that their child could inherit the pathogenic variant/mutation as well, which means there is also a 50% chance that an individual's siblings and parents have the same pathogenic variant/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, Blueprint Genetics, located in Finland. Your pre-test counselling session will be set up concurrently to your sample being sent to and processed by Blueprint Genetics. Testing will take 4-6 weeks from when Blueprint Genetics receives the sample. Results will be sent to the ordering healthcare provider and to the patient if the healthcare provider has consented to release the results on the requisition unless the patient declines pre-test and post-test counselling, in which case they will be sent to the healthcare provider only.

Possible results:

Positive: A pathogenic variant/mutation was identified. This individual has an increased risk for specific types of cancer. Family members are at increased risk of carrying the same pathogenic variant/mutation.

True Negative: This individual tested negative for a pathogenic variant/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 pathogenic variant/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 variant 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 (e.g., 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 healthcare provider 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 a higher risk of having a pathogenic variant/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 variant/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 pathogenic variant/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.

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