Expanded Carrier Screening – Private Pay Requisition

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

Appointments can be made at www.LifeLabs.com

ORDERING HEALTHCARE PROVIDER

Billing # _____

Name _____

Address _____
No Street

_____
City Province Postal Code

Telephone _____ Fax _____

I confirm that this patient has been informed about the details associated with the genetic test(s) ordered below including its risks, benefits and limitations, and has given consent to testing as may be required by applicable law. I authorize that the patient receives a copy of the test results via the testing laborator's portal, unless I check the box below.

☐ 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.

Physician Signature _____

COPY TO HEALTHCARE PROVIDER

Billing # _____

Name _____

Address _____
No Street

_____
City Province Postal Code

Telephone _____ Fax _____

REQUIRED PATIENT INFORMATION

Has carrier screening already been ordered for reproductive partner?* ☐ YES ☐ NO

Reason for testing
(select all that apply):

- ☐ Screening for genetic carrier status
- ☐ Family history
- ☐ Partner is a known carrier
- ☐ Patient / Partner is pregnant
- ☐ Egg/sperm donor
- ☐ High risk ethnicity
- ☐ Other: _____

Race/Ethnicity
(select all that apply):

- ☐ French Canadian or Acadian
- ☐ Ashkenazi Jewish
- ☐ Sephardic Jewish
- ☐ White
- ☐ Asian
- ☐ Black/African
- ☐ Hispanic
- ☐ Mediterranean
- ☐ Indigenous
- ☐ Pacific Islander
- ☐ Other: _____

PARTNER INFORMATION

REQUIRED if your partner has already performed the Invitae Carrier Screen

Partner DOB _____ (MM / DD / YYYY) Date Partner Tested _____ (MM / DD / YYYY)

Partner Name _____

Partner RQ # _____
From original report

COLLECTION INFORMATION

Sample type ☐ Blood (EDTA: 4mL) ☐ Other _____

Date & Time Blood Collected _____ (MM / DD / YYYY) _____ (HH / MM)

Collector Name _____

LIFELABS LABELS

PATIENT INFORMATION

Last Name _____

First Name _____

Date of Birth _____ (MM / DD / YYYY) Sex at birth ☐ M ☐ F

Address _____
No Street

_____
City Province Postal Code

Telephone _____

Email _____

TEST REQUESTED	COST	LL TC	Mnemonic
☐ **Expanded Carrier Screen, Single** Carrier screening panel that performs sequencing of over 569 clinically significant conditions (Includes all genes in the French Canadian Carrier Screen)	$813 CAD	4101	FP2
☐ **French Canadian Carrier Screen only** Carrier screening panel, including 8 conditions, specific to those with French Canadian Ancestry (Includes CFTR, FAH, GNPTAB, HEXA, LRPPRC, MPI, SACS, SLC12A6)	$813 CAD	4101	FP2

PATIENT CONSENT - MANDATORY

I have read the Patient Information Form (on reverse). I understand that 1 blood sample (or saliva in some cases) will be taken by LifeLabs staff. I acknowledge that my sample and personal health information will be sent to Invitae for the purpose of carrier screening at their lab in the United States. I also understand that LifeLabs will contact me for a new blood sample if a test result cannot be provided from the original blood sample. I acknowledge that LifeLabs will receive the results from Invitae and it will disclose the results to the ordering physician. I also understand that I will be contacted by LifeLabs to obtain consent should LifeLabs be asked to disclose my information for another reason, other than as required or permitted by law. I acknowledge that I am responsible for the full cost of testing.

Patient Name _____

Signature _____ _____ (MM / DD / YYYY)

The minimum amount of patient information is collected for provision of the service requested. This information is considered confidential. Unauthorized use and disclosure are prohibited.

PATIENT INFORMATION FORM
This is not a prenatal screen

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This reviews the benefits, risks, and limitations of DNA testing for the genetic disorders available through the Expanded Carrier Screen.

PURPOSE OF THE TEST(S)

The Expanded Carrier Screen (ECS), as performed by Invitae in California, analyzes specific changes in your DNA called mutations. Certain mutations can make it more likely that you could pass on a hereditary condition through a pregnancy. You may use this information to inform your decisions in preparing for a family. Information about diseases, such as description, course, and possible treatments, may be found in the Carrier Screen section of the LifeLabs Genetics website. For most of the conditions on the panel, both parents must carry a mutation in the same disease gene for their child to be at risk to be affected. This is called autosomal recessive inheritance. There are, however, a few diseases on the panel that can be transmitted when only one parent is a carrier. Fragile X is an example of a disease that requires only one parent to carry the mutation in order to be passed on. For some conditions on the panel, such as Gaucher's disease, it is possible to be diagnosed with a form of the condition that does not appear until adulthood (i.e., adult-onset). If you have a family history of one of the conditions on this panel, you should inform the LifeLabs Genetics team of the specific gene mutation(s) present in your family. Screening for the diseases on this panel may significantly reduce the likelihood that you are a carrier but does not guarantee that you are not a carrier.

TEST RESULTS AND INTERPRETATION

One tube of blood or saliva is required from each person consenting to testing. Your test results will be sent to the healthcare provider who ordered the test. The following describes the possible results outcomes:

- **Carrier (Positive):** A positive result indicates that a gene mutation has been identified and that you are a carrier of this disorder. You may be identified as a carrier for more than one disorder. Carriers usually do not experience symptoms of the disease.
- **No mutations detected (Negative):** A negative result indicates that no gene mutation was identified. This reduces but does not eliminate the possibility of being a carrier.
- **Indeterminate:** An "indeterminate" result indicates that we cannot confidently report a positive or negative result using stringent quality-control guidelines.
- **Homozygote or compound heterozygote:** This result indicates the presence of two disease-causing mutations in the same gene, which would typically indicate that you are affected now or may be affected in the future. However, some of the disorders in this panel may be mild or may vary in severity, so you may not experience clinically significant symptoms. In rare cases, a person may have two disease-causing mutations on the same chromosome, which may be revealed by further testing of either that person or their family.

There is a chance that the sample(s) submitted will not return results. In this case, your healthcare provider will be informed by LifeLabs Genetics and you may be asked to provide a second sample to repeat the test. There is no charge for a repeat. In rare instances, results may take longer than the posted turnaround time and the ordering healthcare provider will be notified of the delay. ECS testing is highly reliable with >99% accuracy for targeted mutations and regions. As with all medical screening tests, there is a chance of a false positive or false negative result. A "false positive" refers to identifying a gene mutation that is not present. A "false negative" is the failure to find a mutation that is present in the sample. Result interpretation is based on currently available information in the medical literature and scientific databases. Because literature and scientific knowledge are constantly being updated, new information may replace or add to the information that Invitae used to interpret your results. Invitae does not routinely re-analyze test results or issue new test reports, and has no obligation to do so.

BENEFITS

Your carrier screening results may help you and your partner make more informed decisions regarding your family, particularly if screening is performed prior to conceiving a pregnancy. Your results may also benefit family members. If you test positive, your biological relatives are more likely to test positive for the same mutation(s), thereby discovering previously unknown risks.

RISKS

Genetic testing may reveal sensitive information about your health or that of your relatives. If you and your partner are receiving simultaneous testing, each of your test results may be revealed to one another. Test results may reveal incidental, unsought information, such as discovering that a man is not the father of a child (non-paternity).

TEST LIMITATIONS

This test is designed to detect known DNA mutations associated with genetic disease. It cannot detect every mutation associated with each disease, nor does it look for all known genetic diseases. Because of this, the ECS test is risk-reducing, not risk-eliminating. Negative results do not guarantee that you or your offspring will be healthy. If you wish to further reduce your reproductive risks, your partner's carrier risk or the risk to potential pregnancies, additional testing may be available. Mutation scanning or sequence analysis for some disorders may not be available. Some biological factors, such as a history of bone marrow transplantation or recent blood transfusions, may limit the accuracy of results. Diagnostic errors may occur due to sample mix-up or contamination.

CONFIDENTIAL REPORTING PRACTICES

LifeLabs and Invitae have entered into a mutually binding distribution agreement whereby both organizations will comply with all applicable legislation. Invitae complies with HIPAA confidentiality laws; LifeLabs Genetics complies with Canadian privacy rules. LifeLabs will only report test results to the ordering healthcare provider(s) or genetic counsellor involved. You must contact your provider to obtain the results of the test. Additionally, the test results could be released to those who, by law, may have access to such data.

FINANCIAL RESPONSIBILITY

Some provincial and/or personal medical insurance plans may cover the cost of the test. Check with your insurance provider. Otherwise, you are responsible for the cost of the test and will provide payment to LifeLabs Genetics, who in turn will provide payment to Invitae. Payment can be made by credit card or debit.

GENETIC COUNSELLING

If you have remaining questions about carrier screening after talking with your healthcare provider, we recommend that you speak with a genetic counsellor who can give you more information about your testing options. You can find a genetic counsellor in your area by going to the Canadian Association of Genetic Counsellors website at https://cagc-accg.ca/. The cost of the test includes genetic counselling services provided by Invitae to discuss your Carrier Screen result. They can be reached at 1-800-436-3037 or by email at gcservices@invitae.com.

DISPOSITION OR RETENTION OF SAMPLES

Invitae may also keep your leftover de-identified samples for ongoing research and development. You and your heirs will not receive any payments, benefits, or rights to any resulting products or discoveries. Invitae may also contact you in the future for research opportunities.
Please contact Invitae at clientservices@invitae.com or 1-800-436-3037 if you wish to opt out of such research or future contact.