LifeLabs GENETICS™

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

Counsyl Funded by MOHLTC

(Attach MOH approval letter OR write the MOH approval number below)

Counsyl

Appointment booking can be done at www.lifelabs.com

Contract #:	**LL: K254**	**MOHLTC Approval #:**	
Ordering Physician Billing #:	Physician OHIP# (Ontario) Physician MSC# (British Columbia) Other Provinces: 999		**LifeLabs** Demographic Label
Ordering Physician:	Name		
Ordering Physician Address & Contact Information:	Tel: Fax:		
Physician Signature			
Copy-to Client:	Name Tel: Fax:		Counsyl Barcode Label
Bill to:	**Bill type "C" ($0) – (Counsyl: bill to MOHLTC)**		

Patient Last Name:	**Patient First Name:**	**Sex:** ☐M ☐F	**Date of Birth:** M M D D Y Y Y Y

Unit #:	**Street:**	**City:**	**Prov.:**	**Postal Code:**	**Patient Telephone #:** ( ) -

PATIENT INFORMATION (REQUIRED)

Is the patient pregnant? ❑ Yes ❑ No

Reason for testing (select all that apply):

- ❑ Family history
- ❑ Screening for genetic carrier status
- ❑ Consanguinity
- ❑ Supervision, normal 1st pregnancy
- ❑ Supervision, other normal pregnancy
- ❑ High risk ethnicity
- ❑ Other: _____

Ethnicity (select all that apply):

- ❑ Northern European *e.g. British, German*
- ❑ Southern European *e.g. Italian, Greek*
- ❑ French Canadian or Acadian
- ❑ Ashkenazi Jewish
- ❑ Other/Mixed Caucasian
- ❑ East Asian *e.g. Chinese, Japanese*
- ❑ South Asian *e.g. Indian, Pakistani*
- ❑ Southeast Asian *e.g. Filipino, Vietnamese*
- ❑ African or African American
- ❑ Hispanic
- ❑ Middle Eastern
- ❑ Indigenous
- ❑ Pacific Islander
- ❑ Unknown

TESTS REQUESTED

Expanded Carrier Screen (Counsyl Foresight™)	**LL TC**
Carrier screening panel that performs sequencing of over 175 clinically significant conditions	**5622**
❑ **FIRST TIME USER** – please check this option if neither partner has been tested	**5623**
❑ **PARTNER** – please check this option if a previous sample has been submitted for your patient's partner	

Sample Type: ❑ Blood (EDTA: 4mL) ❑ Saliva (Oragene OG-510: Available by request)

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

PARTNER INFORMATION

** if your partner has already performed the Counsyl Expanded Carrier Screen*

Partner Name:	**Partner DOB:** M M D D Y Y Y Y	**Partner Barcode #:** From original report
	Date Partner tested: M M D D Y Y Y Y	

**** PHOTOCOPY REQUISITION AND INCLUDE ORIGINAL WITH SAMPLE ****

(Testing performed at Counsyl Inc., 180 Kimball Way South, San Francisco CA, 94080)

PATIENT CONSENT - MANDATORY:

I have read and signed the Patient Consent Form, which is available at LifeLabsgenetics.com and remains with the ordering physician. I understand that 1 blood sample will be taken by LifeLabs staff. I acknowledge that my sample and personal health information will be sent to Counsyl for the purpose of carrier screening at their lab in the United States (address above). 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 Counsyl 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 Sign Here: _____ **Date:** M M D D Y Y Y Y

PATIENT CONSENT FORM

This is not a prenatal screen

This consent form reviews the benefits, risks, and limitations of undergoing DNA testing for the genetic disorders available through the Counsyl Carrier Screen.

Purpose of the Test(s)

The Counsyl Carrier Screen 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 the Counsyl panel, you should inform the LifeLabs Genetics team of the specific gene mutation(s) present in your family. Screening for the diseases on the Counsyl 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 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. Counsyl 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 Counsyl used to interpret your results. Counsyl 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 Counsyl 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 Counsyl have entered into a mutually binding distribution agreement whereby both organizations will comply with all applicable legislation. Counsyl 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 Counsyl. Payment can be made by credit card or debit.

Genetic Counselling

If you have remaining questions about carrier screening after talking with your health care 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 Counsyl to discuss your Carrier Screen result. You will be provided information on how to register online for these services.

Disposition or Retention of Samples

Counsyl 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. Counsyl may also contact you in the future for research opportunities. Please contact Counsyl at support@counsyl.com or (888)-COUNSYL if you wish to opt out of such research or future contact.

PATIENT CONSENT STATEMENT

I have read or have had read to me the above informed consent information about the Counsyl Carrier Screen. I have had the opportunity to ask questions of my health care provider regarding this test, including the benefits, risks, limitations, and the alternatives prior to giving my informed consent. I acknowledge that I am at least 18 years of age and that my sample and personal health information will be sent to Counsyl for the purpose of carrier screening at their lab in the United States (180 Kimball Way South, San Francisco CA, 94080). I also understand that LifeLabs will contact me for a new sample (blood or saliva) if a test result cannot be provided from the original sample. I acknowledge that LifeLabs will receive the results from Counsyl and will send the result to my ordering healthcare provider. LifeLabs will not provide the test result directly to me. I understand that genetic counselling is available to me after receiving my Carrier Screen result to discuss the test result and that counselling is provided by Counsyl's online team of genetic counsellors at no cost to me. I understand that a summary letter describing the information shared during the counselling will be sent to my ordering healthcare provider. I acknowledge that I am responsible for the full cost of testing. I acknowledge that I must sign the consent statement located on the test requisition form that will be sent with my sample to Counsyl. I understand that I must sign this consent form which will remain in my clinic chart.

Signature of Patient _____ Date _____ Printed Name _____

Ontario

Ministry of Health and Long-Term Care

Completion Instructions for the Request for Prior Approval for Full Payment of Insured Out-of-Country (OOC) Health Services for Diagnostic Laboratory Testing

Instructions

All sections of this form must be fully completed and legible.

The form is required to request prior approval for full payment by the ministry for insured **OOC diagnostic laboratory testing services** on behalf of your patient. The ministry does not cover travel and accommodation costs associated with traveling OOC for prior approved treatment.

Information about the OOC prior approval program and application forms are available on the ministry's website at http://www.health.gov.on.ca/english/providers/forms/form_menus/ohip_prof_fm.html

These forms are available in a fill and print format or can be downloaded for completion. Completed forms may be sent to the ministry by **fax: 416-326-2211 or 1-844-642-0202**.

Physician Responsibilities

By signing the application, you, as the attending Ontario doctor, are recommending the requested testing based on your professional knowledge.

Do Not Complete This Form If:

- You do not know the answer to the questions in Part 4. In most cases, you will have to research the availability of current services in Ontario and wait times in several areas of the province.
- Treatment is required as a result of a work-related accident. Please complete a Health Professional's Report (Form 8) and contact the Workplace Safety and Insurance Board (WSIB) at www.wsib.on.ca to discuss coverage. OHIP does not insure service(s) to which a person is entitled under the *Workplace Safety and Insurance Act*.
- The required testing has already been rendered as services will be ineligible for reimbursement.
- You are requesting Emergency/911/CritiCall Transfers. If these services are required, please complete the Application for Approval of Full Payment of Insured OOC Health Services Emergency/911/CritiCall Transfers Form 4524-84.
- You are requesting medical treatment/health services such as cancer treatment, bariatric surgery, MRI, etc. If these services are required, please complete the Request for Prior Approval for Full Payment of Insured OOC Health Services Form 4520-84.

Full payment of medically necessary therapeutic or diagnostic laboratory services will be authorized only when the proposed OOC service or procedure is:

- not experimental or for research or for a survey; and
- generally accepted in Ontario as appropriate for a person in the same medical circumstances as the insured person; and
- not performed in Ontario.

Please ensure that all sections of the form are legible; otherwise, it will be returned by fax asking for clarification of the information.

If you require clarification or additional information in order to complete this application form, please call the ministry's toll-free number **1-844-648-7944**, or send an e-mail inquiry to: Outofcountrylabsgenetics@ontario.ca

Part 1 - Patient Information

When completing this section, the Ontario physician's office should verify that the patient's health number and address are current and correct.

If the patient is under the age of 16, the parent or legal guardian must sign on the patient's behalf.

If the application is signed on behalf of a person over the age of 16 who is not the applicant, documentation must be provided which establishes that the person signing the form is legally authorized to do so. Acceptable documentation includes, for example, Power of Attorney for property or personal care.

Part 2 - Referring Ontario Physician

Please provide your name, OHIP billing number and office address. Please also provide a telephone number where the ministry can reach you. If your office telephone does not accept messages, please provide an alternate number such as your private line.

Part 3 - Proposed OOC Health Facility/Diagnostic Laboratory/Hospital

Please provide the name and address of the OOC treatment facility and the name of the physician or contact person at this facility.

Part 4 - Testing Requested

This section must be fully completed and must include the clinical diagnosis in full and the reason the service is required. You are also required to advise if this patient has made a previous attempt to receive this treatment in Ontario and/or OOC.

Please specify test(s) requested and **attach a copy of the laboratory requisition**.

Applications received without a copy of the laboratory requisition will be considered incomplete and will not be processed until the necessary documentation has been provided.

Part 5 - Signatures

This application must be signed and dated by both the patient (or their authorized representative) and the referring Ontario physician. If this application has not been signed by the patient, please explain why.

Ontario

Ministry of Health and Long-Term Care

For Ministry Use Only
Reference Number
Date Received (yyyy/mm/dd)

Request for Prior Approval for Full Payment of Insured Out-of-Country (OOC) Health Services for Diagnostic Laboratory Testing

An attending Ontario physician must complete the entire form.
Print clearly to ensure form is legible.

Is the OOC testing required as a result of a work-related accident? ☐ Yes ☐ No

If yes, **do not** complete this form. Please complete a Health Professional's Report (Form 8) and contact the Workplace Safety and Insurance Board (WSIB) at www.wsib.on.ca to discuss coverage. OHIP does not insure service(s) to which a person is entitled under the *Workplace Safety and Insurance Act*.

Please return to: Laboratories and Genetics Branch, Out of Country Program, 1075 Bay Street, 9th Floor, Toronto ON M7A 0A5.
Applications may be faxed to 416-326-2211 or 1-844-642-0202. For information or clarification regarding this form, please call 1-844-648-7944.

Part 1 - Patient

Last Name	First Name	Initials

Date of Birth (yyyy/mm/dd)	Sex	Health Number	Version
	☐ Male ☐ Female		

Current Mailing Address

Unit Number	Street Number	Street Name	PO Box

City/Town	Province	Postal Code

Telephone Number (Home)	Telephone Number (Business/Daytime) ext.

Parent/Legal Guardian's Last Name (if applicable)	Parent/Legal Guardian's First Name (if applicable)

Where this form is signed by a person who is not the applicant, indicate the relationship between the applicant and the person completing the form.

☐ parent of child under 16 years of age ☐ legal guardian ☐ attorney under power of attorney

☐ other (specify) ▶

If legal guardian, attorney or other, please provide copy of document which establishes that status or provide a consent signed by the patient permitting you to apply and communicate with the ministry on behalf of the patient if form is signed on behalf of person over the age of 16.

Part 2 - Referring Ontario Physician

Last Name	First Name	Provider Billing No.

Office Address

Unit Number	Street Number	Street Name	PO Box

City/Town	Province	Postal Code

Telephone Number where we can reach you ext.	Fax Number	Email Address (optional)

Part 3 - Proposed OOC Health Facility / Diagnostic Laboratory / Hospital

Facility
COUNSYL INC.

Address

Unit Number	Street Number	Street Name	PO Box
	180	KIMBALL WAY SOUTH	

City/Town	State/Country	Postal Code
SAN FRANCISCO	CALIFORNIA	94080

Name of: ☐ OOC physician ☐ Contact person

Last Name	First Name
ZEIBERG	MAX

Telephone Number	ext.	Fax Number	Email Address
888 268-6795		608 541-2450	BILLING@COUNSYL.COM

Part 4 - Testing Requested

Clinical Diagnosis (condition for which treatment is sought): CLINICAL INDICATION

Diagnostic Code

Reason service is required:

Please specify the laboratory test(s) required and attach a copy of the laboratory **requisition**:

COUNSYL FORESIGHT CARRIER SCREEN

Have you previously requested and/or obtained this service in Ontario?

☐ Yes (specify when and where) _____

☑ No (specify reasons) _____

Have you previously requested and/or obtained this service out of the country?

☐ Yes (specify when and where and provide reason for reapplication) _____

☑ No

Is this treatment generally accepted in **Ontario as appropriate** for a person in these medical circumstances?

☑ Yes ☐ No

Is this testing generally accepted as **research or experimental in Ontario**?

☐ Yes ☑ No

Is this testing performed in Ontario?

☐ Yes ☑ No

Is this a genetic test?

☑ Yes ☐ No

Part 5 - Signatures

Note: Written approval must be received from the ministry before OOC health services are rendered. OHIP does not pay for ambulance services, transportation costs, or out-of-hospital food, accommodation, drugs or prescriptions, including take-home prescriptions.

All accompanying documents will be considered as part of this application. I understand that the MOHLTC or its agents may collect, use or disclose personal health information and/or records relating to this application for the purposes of the administration of the *Health Insurance Act* including the administration of the OOC program. I understand that this may involve disclosure of personal health information and/or records related to any health care providers, institutions and agencies that require it as determined necessary by OHIP. Collection of any of this information is authorized by section 4.1 of the *Health Insurance Act*. For information about MOHLTC collection practices, see our website at http://www.health.gov.on.ca/english/public/legislation/bill_31/stat_info_practices.pdf.

It is an offence to knowingly give false information to the Ontario Health Insurance Plan in any application or statement made to the plan.

Comments

Name of Patient or Parent/Guardian	Signature of Patient or Parent/Guardian	Date (yyyy/mm/dd)
Relationship to Patient (if not signed by patient)	Please explain why form has not been signed by patient	

I hereby declare the information provided by me to be true.

Signature of Referring Physician	Date (yyyy/mm/dd)