

Protocol: Out-of-Province Genetic Testing Coordination

Division of Laboratory Genetics, Molecular Genetics Laboratory

The following protocol is the responsibility of the Ordering Physician; MGL provides 'shipping and handling' services only.

STEP ONE: Request Funding.

FUNDING MUST BE SECURED PRIOR TO SAMPLE COLLECTION.

1. Choose a Testing Laboratory. Resources: <http://www.ncbi.nlm.nih.gov/gtr/> and www.genetests.org.
2. Obtain from the Testing Laboratory:
 - a. Requisition;
 - b. Consent form, if applicable;
 - c. Billing form, if applicable;
 - d. Cost of the test;
 - e. Turnaround time;
 - f. Sample Requirements: confirm that 4 mL EDTA peripheral blood is sufficient.
 - i. For other sample sources (frozen or paraffin tissue, amniocentesis, CVS): Discuss with MGL prior to arranging testing.
3. Submit the MSP application form: <http://www2.gov.bc.ca/assets/gov/health/forms/2810fil.pdf>

If MSP Funding is Approved:

STEP TWO: Complete the Required Paperwork.

1. **Testing Laboratory Requisition** and any associated paperwork such as billing form or consent form.
Ensure that you provide complete information, including Ordering Physician name and contact information.

Request "institutional billing" and state:

Bill at your institutional rate to:
Ms. Kelly Braithwaite
Authorization Coordinator
HIBC Out of Country Claims
P.O. Box 9480 Stn Prov Govt
Victoria, BC V8W 9E7 CANADA

Include the patient name, PHN, referring physician name, and report with the invoice.

2. **Request for Shipment for Out-of-Province Genetic Testing Form**
3. **Consent to Release Information Form**
This form is only required if the Testing Laboratory is located outside of Canada, and MUST be completed in full at the time of patient signature.

STEP THREE: Fax completed paperwork to MGL at 604-875-2707, in the following order:

- a. Request for Shipment for Out-of-Province Genetic Testing Form
- b. Testing laboratory requisition, billing form, and consent form, if applicable
- c. MSP funding approval letter
- d. Consent to Release Information form, if applicable

STEP FOUR: Arrange Sample Collection.

1. Complete the MGL General Requisition:
 - a. Sample type: EDTA blood
 - i. If > 4 mL EDTA blood required for testing, specify volume.
 - b. Test requested: Other "MSP funded: [Test Name]"
2. Send patient for blood collection. Patient's can have their sample collected at *any* BC collection facility.

Upon sample receipt, MGL will:

- ship the entire blood sample and paperwork to the referral laboratory;
- send a letter to the referring physician, confirming the shipment, including date sent, to allow for tracking.

STEP FIVE: Track results and report directly with the Testing Laboratory.



Children's & Women's Health Centre of BC
DEPARTMENT OF PATHOLOGY & LABORATORY MEDICINE
Division of Laboratory Genetics



CONSENT FOR RELEASE OF INFORMATION

All fields must be completed legibly (patient demographics label acceptable).

Patient Name (Last, First): _____

Date of birth (dd/Mmm/yy): _____

PHN: _____

The Freedom of Information and Protection of Privacy Act of British Columbia prohibits the disclosure of personal information outside of Canada without your explicit consent. Personal information, held by any testing site located outside of Canada, is potentially subject to disclosure demands under the local legal requirements of the country in which the testing site resides.

A test has been ordered by your physician, which will be performed at a testing site outside of Canada.

In order to test the sample and report the results to the ordering physician, the following personal information must be provided with the sample: Patient Name, Date of Birth and Personal Health Number. Brief clinical information relevant to test interpretation may also be provided.

A sample, and the above stated personal information, will be sent to the following testing site:

Laboratory /Institution

Address

I hereby consent to the transfer of a sample and the release of the defined personal information stated above, to the testing site named above, for the purpose of performing testing on the sample.

Person giving consent:

Name (Print)

Signature for consent

Relationship to patient

Date signed

Molecular Genetics Laboratory

BC Children's Hospital & BC Women's Hospital
 2J40 - 4500 Oak Street, Vancouver, BC V6H 3N1
 Phone (604) 875-2852 • Fax (604) 875-2707
 • moleculargenetics@cw.bc.ca • www.genebc.ca
 • Facility Code L1050

Request for Shipment Out-of-Province Genetic Testing

To: Molecular Genetics Laboratory (MGL)**Fax:** 604-875-2707**Phone:** 604-875-2852

From:
Fax:
Date:
Pages:

COMPLETE FOR EACH SAMPLE & EACH REFERRAL LABORATORY

PRIORITY	SAMPLE TYPE	
<input type="checkbox"/> STAT (affects pregnancy management) EDD: _____ <small>DD/MMM/YY</small> <input type="checkbox"/> ROUTINE	<input type="checkbox"/> BLOOD <input type="checkbox"/> TISSUE ; Path #: Á _____ <input type="checkbox"/> DNA* ; MGL Sample ID: _____ <small>*prior approval required, as per policy</small> Quantity: _____ ug OR _____ ug/ul & _____ ul	MEDICAL GENETICS ONLY: CVS OR AMNIOCENTESIS: <input type="checkbox"/> DNA <input type="checkbox"/> Cultured <input type="checkbox"/> Uncultured* <small>*consultation required</small> SPECIAL INSTRUCTIONS: (quantity, # flasks, etc.) _____

REQUESTOR INFORMATION		PATIENT INFORMATION	
Ordering Physician Last Name	Ordering Physician First Name	Last Name	First Name
Contact Person (if differs from Ordering Physician)		Personal Health Number	Date of Birth (DD/MMM/YY)
Contact Phone Number (if differs from above)		Gender <input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> UNK	Referring Clinic ID

REFERRAL LABORATORY & TEST INFORMATION	
Referral Laboratory	Disorder or Test Requested
Shipping Address:	

CHECKLIST:	MGL USE ONLY
<input type="checkbox"/> MSP funding approval letter <input type="checkbox"/> Referral lab paperwork (requisition, consent form, etc) <input type="checkbox"/> Consent to Release Information Form (Bill 73 consent)** <small>** Only required for shipment outside of Canada</small>	SHIPMENT LABEL CM_PW <input type="checkbox"/>

Document # CWMG_REQ_0210F Version # 3.2 Revised: October 2014

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FAQs: Out-of-Province Genetic Testing

Division of Laboratory Genetics, Molecular Genetics Laboratory

ABOUT SELECTING A REFERRAL LABORATORY

1. There are many referral labs listed on www.genetests.org (or <http://www.ncbi.nlm.nih.gov/gtr/>) that offer this genetic test. Which should I choose?

ABOUT MSP FUNDING APPROVAL

2. Do I need to provide a copy of the MSP funding approval letter in the package of paperwork faxed to MGL?
3. The dollar amount for the test that MSP approved has changed, do I need to request an updated letter?
4. What information do I include to ensure that the referral laboratory bills MSP?
5. The referral laboratory does not offer the option of institutional billing; they are requesting prepayment.
6. What do I do if the patient wants to pay for his/her own testing?

ABOUT REQUISITIONS AND BILLING FORMS

7. Why do I have to complete an MGL requisition AND the referral laboratory's requisition?
8. Do I need to provide the sample collection date on the referral lab requisition? How do I know when it was collected?
9. The referral laboratory does not have a requisition OR the requisition does not request information about the ordering physician and/or billing information. Now what?
10. Does the ordering physician have to sign the referral laboratory requisition?

ABOUT THE "CONSENT TO RELEASE INFORMATION" FORM

11. When and why is this form required?
12. I have a signed consent form, but it is not the most current version, can I use this?
13. Do I need to provide the complete Lab/Institution address?
14. Can I sign it for my patient?
15. Can I modify this consent after the patient has signed, as long as I have verbal consent?
16. My patient does not want to sign it; now what?

ABOUT SAMPLES BEING SENT OUT

17. The patient has previously had blood drawn for testing in your lab; do you still have blood or DNA you can send?

ABOUT SELECTING AN EXTERNAL LABORATORY

1. **There are many referral labs listed on www.genetests.org (or <http://www.ncbi.nlm.nih.gov/gtr/>) that offer this genetic test. Which should I choose?**

In general, MGL prefers not to recommend specific referral laboratories for specific tests. That being said, we would have confidence in recommending any of the publically funded Canadian laboratories and suggest them as a first choice, if the particular test is available; this is in keeping with Ministry guidelines.

We send many cases to Prevention Genetics, GeneDx, and the Molecular Genetics Laboratory at Baylor College of Medicine, all in the United States. We particularly favour Prevention Genetics because their testing and customer service are of very high quality.

For FSHD, MGL historically referred out testing to University of Iowa Diagnostic Laboratories (UIDL) (<http://www.medicine.uiowa.edu/uidl/>), who offer excellent service at competitive pricing. MSP funding approval is now required to coordinate FSHD testing.

If you need further assistance in choosing a referral laboratory -- after reviewing (1) the options on www.genetests.org / <http://www.ncbi.nlm.nih.gov/gtr/>, (2) the aforementioned recommendations, and (3) the details provided by each testing laboratory on their respective websites – contact the MGL Molecular Geneticist on service at MGLOnService@phsa.ca.

FAQs: Out-of-Province Genetic Testing

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ABOUT MSP FUNDING APPROVAL

2. Do I need to provide a copy of the MSP funding approval letter in the package of paperwork faxed to MGL?

Yes. The completed paperwork, including the MSP funding letter, must be received by MGL prior to sample collection, unless specific exception has been preapproved by the Molecular Geneticist On Service. Furthermore, most laboratories will not proceed with testing without written confirmation of funding. MGL includes the copy of the MSP funding approval letter with the paperwork sent to the referral laboratory.

For rare tests where clinical testing is being performed in a research laboratory, and thus MSP funding is not applicable, please contact the Molecular Geneticist On Service (MGLOnService@phsa.ca), for preapproval and instructions on how to proceed.

3. The dollar amount for the test that MSP approved has changed, do I need to request an updated letter?

Contact MSP Out of Country claims to discuss. **Note:** Some referral laboratories will not proceed with testing unless the amount on the MSP funding approval letter is exactly the same as their current charge for the test. These labs may require that you provide them written assurance that the full cost of testing will be covered, even for small differences.

4. What information do I include to ensure that the referral laboratory bills MSP?

Under the "institutional billing" section of the referral laboratory requisition/billing form, provide the following information:

Bill at your institutional rate to: Ms. Kelly Braithwaite Authorization Coordinator HIBC Out of Country Claims P.O. Box 9480 Stn Prov Govt Victoria, BC V8W 9E7 CANADA Include the patient name, PHN, referring physician name and report with the invoice.

*** Do **NOT** indicate "insurance billing" for tests being covered by MSP. In the US, MSP is considered an institution ***

5. The referral laboratory does not offer the option of institutional billing; they are requesting prepayment.

Most laboratories will provide institutional billing, especially when the MSP approval letter is included with the send out paperwork. Upon receipt of the paperwork, a laboratory that does not accept institutional billing will contact you. This scenario has only rarely been encountered by MGL.

6. What do I do if the patient wants to pay for his/her own testing?

MGL does not coordinate out-of-province genetic testing for self-pay patients. Patients can contact the referral laboratory to explore options for collection and shipment.

FAQs: Out-of-Province Genetic Testing

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ABOUT REQUISITIONS AND BILLING FORMS

7. Why do I have to complete an MGL requisition AND the referral laboratory's requisition?

While MGL is not funded to assist in the coordination of out-of-province testing (see the MSP approval letter), we recognize that good patient care would be impeded if this service was not available. Therefore, currently we will ship samples to referral laboratories for MSP funded testing. In order for the sample to arrive in our laboratory, you must complete the MGL requisition. MGL has neither the resources nor the knowledge of the patient's clinical history to complete the referral laboratory requisition. Therefore, the physician requesting the test from the referral laboratory is responsible for completing all associated paperwork.

8. Do I need to provide the sample collection date on the referral lab requisition? How do I know when it was collected?

No. When MGL packages your patient's sample for shipment, a label indicating the sample collection date will be placed on the referral lab requisition.

9. The referral laboratory does not have a requisition OR the requisition does not request information about the ordering physician and/or billing information. Now what?

Full and complete contact information should be provided for ALL testing requested, regardless of whether the information is requested on the forms from the external laboratory. This includes: ordering physician name, address, phone and fax numbers; cc Physician name and address; Health records name and address; billing information. Additional information can be provided in a letter that includes patient demographics (Name, PHN, DoB) attached to or in place of a referral laboratory requisition.

10. Does the ordering physician have to sign the referral laboratory requisition?

Yes. Physicians are required to sign all test orders. Many laboratories will not proceed with testing without this signature. MGL cannot comment on whether a designee would be accepted.

ABOUT THE "CONSENT TO RELEASE INFORMATION" FORM

11. When and why is the "Consent to Release Information" form required?

BC Privacy laws prohibit the release of personal information outside of Canada without full disclosure and signed consent; Canada is not able to protect a patient's personal information once it is sent outside of the country. Both personal and institutional penalties apply, should laws be contravened.

http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/00_03063_01

http://www.bclaws.ca/Recon/document/ID/freeside/96165_00

Consent must be obtained each and every time any time a sample is being sent to a lab outside of Canada, and for each and every laboratory/institution to which a sample is sent.

The PHSA also has policy which applies to all employees:

<http://www.phsa.ca/Documents/PrivacyandConfidentiality.pdf>

MGL is, therefore, required to have on file, evidence of signed consent to release information outside of Canada. This form must be signed any time a sample is being sent to a lab outside of Canada, and for each and every laboratory/institution to which a sample is sent. Please fax the relevant signed consent form with each request for shipment.

FAQs: Out-of-Province Genetic Testing

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A consent form is required for EACH patient for whom we are shipping a sample. If the patient cannot sign the form themselves (e.g. children), their parent or legal guardian can sign on their behalf.

12. I have a signed consent form, but it is not the most current version, can I use this?

No. The most current version of the consent form reflects current privacy law requirements; previous versions become invalid when a new version is created.

13. Do I need to provide the complete Lab/Institution address on this form?

No; but, jurisdiction is required. Through conversation, and on the consent form as a record of this conversation, you need to inform the patient of the laboratory/institution to which the sample is being sent (i.e. who will receive the personal information) as well as the jurisdiction to which it is being sent. Thus, an exact address is not required, but the jurisdiction is. For example, if sending to the USA, state and country are sufficient.

14. Can I sign the "Consent to Release Information" form for my patient?

No. By law, the form must be signed by the patient or legal guardian.

15. Can I modify this consent after the patient has signed, as long as I have verbal consent?

No. Modification of the consent *cannot be made after the patient has signed*. The patient must sign a new copy of the consent.

16. My patient does not want to sign the "Consent to Release Information" form; now what?

MGL cannot ship de-identified samples, due to the patient safety risks this creates. Assess whether testing is available within Canada.

ABOUT SAMPLES BEING SENT OUT

17. The patient has previously had blood drawn for testing in your lab; do you still have blood or DNA you can send?

Generally, no.

Blood is not stored by MGL.

Only a sufficient amount of DNA to complete the requested clinical testing is extracted. MGL will not ship residual DNA to another laboratory unless there are exceptional circumstances; this requires preapproval by the Molecular Geneticist On Service (MGLOnService@phsa.ca). DNA samples may not be available as they are disposed of according to our DNA Extraction and Retention Policy.