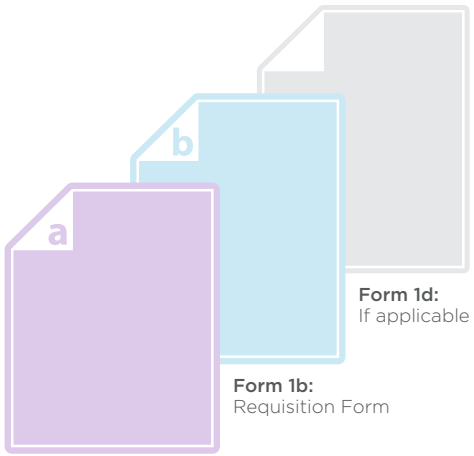
Rev 11Feb2018 (CAN)

Epilepsy
Genetic Test Submission Guide

1. Forms



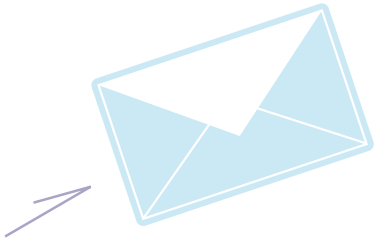
Form 1d:
If applicable

Form 1b:
Requisition Form

Form 1a:
Informed Consent

2. Samples

3. Ship



Impact Genetics, Dynacare
4-1100 Bennett Rd.
Bowmanville, ON LIC 3K5
T 877. 624. 9769

RESULTS

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Form 1a: Informed Consent to Perform Genetic Testing

The purpose of my DNA test/or my child's DNA test is to look for mutation(s) or genetic alterations known to be associated with the following genetic condition or disease: _____.

By signing below, I acknowledge that:

1. My participation or, as applicable, my child's participation in this DNA testing is voluntary. The decision to consent to, or to refuse the above testing is entirely mine.
2. This testing is done on small biological samples.
3. It is possible that the quantity or quality of sample submitted may be inadequate for testing or that a mutation cannot be identified.
4. When DNA testing shows a mutation or alteration, then the person is a carrier or is affected with that condition or disease, or, in the case of cancer genetic testing, the person is a carrier of a mutation or alteration that may be associated with an increased risk for certain cancer(s) compared to the general population. Consulting a doctor or genetic counsellor is recommended to learn the full meaning of the results and to learn if additional testing might be necessary.
5. When the DNA testing does not show a known mutation or alteration, the chance that the person is a carrier or is affected is reduced, or, in the case of cancer genetic testing, the person's risk for certain cancer(s) compared to the general population will depend on additional personal factors. There is still a chance to be a carrier or to be affected because the current testing cannot find all the possible changes within a gene.
6. Impact Genetics will disclose the test results ONLY to the specialist designated on the Requisition Form (**Form 1b**), or to his/her agent, unless otherwise authorized by the patient or required by law, except as described in point 11 below, no information will be printed or released that discloses the patient's identity, or other confidential information.
7. Impact Genetics is not a DNA banking facility and patient DNA samples may not be available for future testing.
8. An error in diagnosis may occur if the true biological relationships of the family members are not as stated in the pedigree submitted with the Requisition Form (**Form 1b**). It is possible that the test may disclose non-paternity (someone who is not the biological father), or some other previously unknown information about family relationships, such as adoption, and I consent that this finding be reported to the referring specialist designated below.
9. There is a chance that the test may reveal unexpected abnormalities that may be of medical value in the patient's care. Impact Genetics will inform the referring specialist designated below.
10. Until the results of this test are reported, the patient and members of the patient's family should still undergo examinations as prescribed by the referring specialist.
11. If necessary to obtain reimbursement of test fees, Impact Genetics, its agents and legal representatives may disclose information that identifies the patient or other confidential information (including test results).
12. I have read or have had read to me, the above information and I understand it. I have also read or had explained to me the specific disease or condition tested for, and the specific test(s) I am having, including the test descriptions, principles andlimitations. I have had the opportunity to discuss the purposes and possible risks of this testing with my doctor or someone my doctor has designated.

Consent for Future Research:

After all analysis required to reach a genetic diagnosis is complete, Impact Genetics has my consent to use any surplus DNA or RNA in an **anonymous** fashion for research. No tests(s) will be performed and reported on my sample other than the one(s) authorized by my doctor.

☐ YES ☐ NO

Signature of Patient: _____ Date:_____

Signature of Witness: _____ Date:_____

LAB USE ONLY DO NOT FILL OUT

Date received: Y M D

Specimen type:

Condition:

MRN: Tech:

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Form 1b: Epilepsy Genetic Test Requisition

Test Panel

Use menu on page 2 to select test panel.

☐ Epilepsy: Comprehensive (69 genes)

☐ Epilepsy: Management Impact (16 genes)

Patient

Last name:

First name:

Date of birth: Y M D

Gender: ☐ Male ☐ Female

Pregnant: ☐ Yes ☐ No

Patient History

☐ Confirmed clinical diagnosis

Diagnosis Date: Y M D

☐ Suspected clinical diagnosis ☐ Unaffected

Clinical Diagnostics & Family History

☐ Isolated case ☐ Positive family history

Family previously tested: ☐ Yes ☐ No

Mutation identified: ☐ Yes ☐ No

If mutation identified at lab other then Impact Genetics please provide report.

Proband name (first person in a family to be studied):

Gene:

Mutation:

Relationship to Proband (Index Case)

☐ Proband ☐ Parent of proband

☐ Brother or sister of proband ☐ Child of proband

☐ Other:

Specimen Information

Sample:

☐ EDTA Blood sample for DNA

☐ DNA from blood (min. 500 ng)

☐ Buccal swab (only for preapproved familial mutation confirmation, contact lab directly before submitting)

Date of collection: Y M D

Time of collection: HH:MM (24hr)

Referring Specialist

Name:

Specialty:

Contact:

Telephone: Fax:

Email:

Signature:

Institution:

Address:

City: Prov/State:

Postal code: Country:

Additional copies to:

Email: Fax:

Billing

☐ a) Institution

Provide details:

☐ b) Patient Pay

Complete **Form 1d:** Credit Card Authorization for Non-Covered Services.

4-1100 Bennett Rd. Bowmanville, ON L1C 3K5
T 647. 478. 4902 or 877.624-9769
F 905-697-9786
impactgenetics@dynacare.ca
Please ensure to use secure email

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Form 1b: Epilepsy Genetic Test Requisition

Patient name:_____ Date of birth: Y ____ M ____ D ____

Epilepsy Test Panels

☐ **Epilepsy: Comprehensive** (69 genes)

Consider when the prognosis based on clinical and EEG findings is poor or the likelihood of lethal outcome is high, when clinical or EEG findings are not specific for a specific epilepsy syndrome.

ALDH7A1, AMT, ARX, ASAH1, ATP1A2, ATP1A3, CDKL5, CERS1, CHD2, CHRNA7, CNTNAP2, CSTB, DNM1, DOCK7, EPM2A, FOLR1, FOXG1, GAMT, GATM, GLDC, GOSR2, GRIN2A, GRIN2B, HCN1, KCNC1, KCNJ10, KCNJ11, KCNQ2, KCNQ3, KCNT1, KCTD7, LMNB2, MBD5, MECP2, MEF2C, MOCS1, NECAP1, NEU1, NHLRC1, NRXN1, PCDH19, PHGDH, PLCB1, PNKP, PNPO, POLG, PRICKLE2, PRRT2, PSAT1, PSPH, SCARB2, SCN1A, SCN1B, SCN2A, SCN8A, SCN9A, SLC2A1, SLC6A8, SLC9A6, SPTAN1, STXBP1, SUOX, SYNGAP1, TBC1D24, TCF4, TSC1, TSC2, UBE3A, ZEB2.

☐ **Epilepsy: Management Impact** (16 genes)

Consider this panel when epilepsy is associated with features suggestive of treatable inborn errors of metabolism. Clinical features strongly suggestive of an inborn error of metabolism:

- Family history of known condition
- Parental consanguinity
- Newborn or metabolic screening identifies a biochemical marker associated with “metabolic” epilepsy.

Examples of important treatable conditions include (list is not complete):

- Pyridoxine dependent epilepsy
- Folic acid responsive seizures
- Pyridoxal phosphate dependent epilepsy
- Creatine deficiency syndromes
- Glucose transporter (GLUT1) deficiency
- Cerebral Folate deficiency

ALDH7A1, AMT, FOLR1, GAMT, GATM, GLDC, MOCS1, PHGDH, PNPO, POLG, PSAT1, PSPH, SCN1A, SLC2A1, SLC6A8, SUOX.

PLEASE DO NOT SEND FORM WITH SAMPLE;
Send this form to Impact Genetics
BY FAX TO 905. 697. 9786
For patient pay, testing will be held pending receipt of this completed form.

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Form 1d: Credit Card Authorization for Non-Covered Services

To be completed by and returned to Impact Genetics directly by the cardholder.

Billing Information

Laboratory Test:

- ☐ Retinoblastoma Genetic Test
- ☐ HHT Genetic Test
- ☐ Epilepsy Gene Panel Test
- ☐ *MLH1/MSH2/MSH6/PMS2/EPCAM* Somatic Tumor MMR Sequencing and Deletion/Duplication Test
- ☐ Uveal Melanoma Prognostic Genetic Test
- ☐ Uveal Melanoma 5 Gene Panel *(SF3B1/ EIF1AX/GNAQ/GNA11/BAP1)*
- ☐ *BAP1*-TPDS (*BAP1* Tumor Predisposition Syndrome) Genetic Test

Patient name:_____ Date of birth: Y_____ M_____ D_____

☐ **VISA** ☐ **MASTERCARD**

Name on card:_____

Billing address:_____

City:_____

Province/State:_____ Postal/Zip code:_____

Country:_____

Card #:_____ Expiration date:_____

Contact Information

Impact Genetics will contact the cardholder prior to placing the credit card charge, to confirm the date and amount of the charge. **Please provide at least 2 contact methods** and check preferred:

☐ Phone:_____

☐ Email:_____

☐ Fax:_____

Statement of Financial Responsibility

Box below must be checked for testing to proceed.

☐ **I understand that my insurance plan is not expected to pay for these test(s) at 100% and I agree to be personally and fully responsible for payment**.

Cardholder's signature:_____ Date:_____

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Step 2: Epilepsy Genetic Test Sample Requirements

Sample Requirements

Proband:

- Blood or DNA from blood.

Genetically related family member for known mutation:

- Blood or DNA from blood;
- **Or** buccal swab (select cases only, contact lab directly to confirm if appropriate sample).

If genetic testing has been performed at a lab other than Impact Genetics, please provide an aliquot of proband DNA and/or a copy of proband's report.

Sample Preparation Instructions

Blood samples for DNA:

- 10mL in yellow-topped ACD tubes or lavender-topped EDTA tubes (for infants 2-5mL in pediatric or small tubes) at room temperature, to be received within 3-5 days after draw. Best results are achieved if received within 3 days.

DNA from blood:

- DNA quantity—minimum 500ng. Ship with cool packs.

Sample Identification

- Label each sample with at least two patient identifiers (e.g. name and date of birth).

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Step 3: Shipping Requirements

Multiple separated samples may be shipped in one box. Place multiple biohazard bags containing labeled samples into one box. Multiple boxes can be shipped in one courier envelope.

Shipping Instructions

- Ship samples to Impact Genetics at address shown on this page using a courier envelope.
- Include Informed Consent for Genetic Testing and Requisition Forms (**1a** and **1b**) with the samples. Patients in the U.S. must also include U.S. Insurance Information (**Form 1c**) if required and not provided previously.
- Complete appropriate Air Waybill. If you cannot use FedEx or Purolator, please contact us.
- Place Air Waybill in the document pouch.
- For samples from outside of Canada, complete and sign appropriate customs forms (provided and available on our website; phone us if help is required). Place the customs forms in the document pouch.
- Within Canada, use **Purolator Express** (next-day) or **FedEx Priority** service (next-day). Outside of Canada use FedEx Priority service (next-day) and **use a FedEx "Clinical Pak"**. If you cannot use Purolator or FedEx, please contact us.
- Provide us with the parcel tracking number soon after courier pick-up: **647. 478. 4902**, **impactgenetics@dynacare.ca**.
- For emailed PDF FedEx waybills and customs forms, please contact us directly.

Send to Impact Genetics

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