Rev 12May2024 (CAN/INT'L/US/LabCorp)
LabCorp Test #481472

impact genetics

MLH1/MSH2/MSH6/PMS2/EPCAM

Somatic Tumour MMR

Sequencing and Deletion/Duplicaton Test

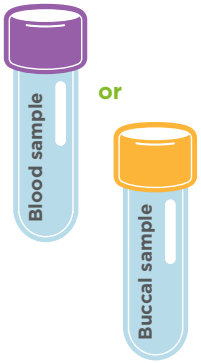
1. Forms

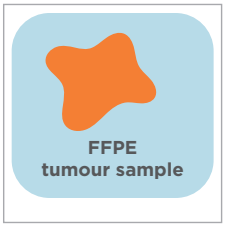
- **1a** Informed Consent
- **1b** Requisition
- **1c** U.S. Insurance Information **if applicable** (U.S. patients only) + Supporting insurance documents
- **1d** Credit Card Authorization **if applicable** (Canada and international patients only)

2. Samples

Name: _____
DOB: _____

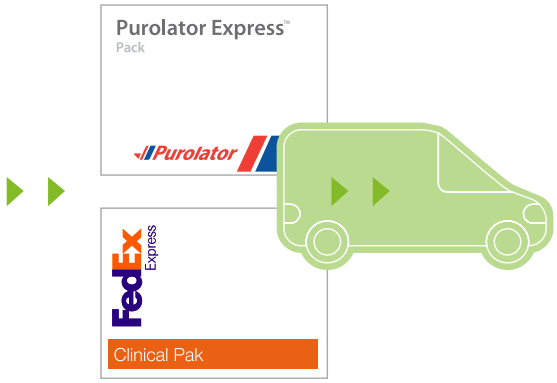
Ensure samples are labelled with at least 2 patient identifiers **(full name and DOB)**





If tumour procurement is required, provide sample details on **Form 1b** for Impact Genetics to obtain

3. Ship



Impact Genetics, Dynacare
115 Midair Court
Brampton, ON L6T 5M3
t 877.624.9769

Results

4 to **6** weeks
sample processing to report

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Form 1a: Informed Consent to Perform *MLH1/MSH2/MSH6/PMS2/EPCAM* Somatic Tumour MMR Sequencing and Deletion/Duplication Test

The purpose of my DNA test/or my child's DNA test is to look for variant(s) known to be associated with Lynch Syndrome.

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 variation cannot be identified.
4. When tumour testing shows oncogenic variant(s) in any one or more of the following genes, *MLH1*, *MSH2*, *MSH6*, *PMS2* and *EPCAM*, the normal sample is analyzed for the same variant(s). If the variant is present in the normal sample, this patient may be at risk for Lynch Syndrome which is 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. Impact Genetics will only collect, use, and disclose your personal health information as permitted/designated on the requisition/order form or required by applicable laws. For example, if necessary to obtain reimbursement of test fees, Impact Genetics, its agents and legal representatives, may disclose personal health information (including test results) for such purpose.
6. Impact Genetics is not a DNA banking facility and patient DNA samples may not be available for future testing.
7. Impact Genetics will return any unused tumour tissue to my treating physician or the pathology laboratory once testing is completed.
8. 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 on the requisition/order form.
9. 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.
10. 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 and limitations. I have had the opportunity to discuss the purposes and possible risks of this testing with my doctor or someone my doctor has designated.

Signature of patient: _____ Date: _____

Signature of witness: _____ Date: _____

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LabCorp Account #: _____
U.S patients only

Lab Use Only. Do not fill out.
Date received: Y ____ M ____ D ____
Specimen type: _____
Condition: _____
Lab #: _____ Tech: _____

Form 1b: *MLH1/MSH2/MSH6/PMS2/EPCAM* Somatic Tumour MMR Sequencing and Deletion/Duplication Test Requisition

LabCorp test #481472

Patient

Legal last name: _____
Legal first name: _____
Preferred first name (if applicable): _____
Date of birth: Y ____ M ____ D ____
Sex at birth: ☐ **Male** ☐ **Female** ☐ **Other** specify: _____
Gender identity: ☐ **Same as sex at birth**
☐ **Different than sex at birth** specify: _____
Address: _____
City: _____ Prov/State: _____
Postal/Zip code: _____ Country: _____
Phone: _____

Test Submission Requirements

1. ☐ MSI and/or IHC report
2. ☐ Normal Sample
   - ☐ **Blood 5-10 mL**
   - ☐ **Extracted DNA** extraction method: _____
   - ☐ **Buccal swab** ☐ **Buccal kit to be shipped to patient** Ensure the patient's address and phone # are provided.

   Date Collected: Y ____ M ____ D ____
3. ☐ Tumour sample
   - ☐ **Formalin fixed paraffin embedded (FFPE) block (preferred)**

   or ☐ **19 serial unstained unbaked slides (5-10 µm thick) with 1 adjacent unstained unbaked slide (4 µm thick)**

   Date Collected: Y ____ M ____ D ____

or ☐ **Impact Genetics to procure block as detailed below**

Request for Impact Genetics to procure the FFPE sample on your behalf ⬇

Facility name: _____
Address: _____
City: _____ Prov/State: _____
Postal/Zip code: _____ Country: _____
Facility contact: _____
Phone: _____ Fax: _____
Email: _____

Previous Test Results

If '**Yes**' checked, please provide report.

Germline analysis complete? ☐ **Yes** ☐ **No** ☐ **N/A**
IHC/MSI ☐ **Yes** ☐ **No**
Result: _____

For *MLH1* abnormal tumours:
Methylation analysis complete? ☐ **Yes** ☐ **No** ☐ **N/A**
BRAF V600 analysis complete? ☐ **Yes** ☐ **No** ☐ **N/A**

Patient History

Cancer type: _____
Age of diagnosis: _____
Other clinical information: _____

Family History

☐ **Isolated case** ☐ **Positive family history**
⬇ Please complete pedigree.

Pedigree

Referring Specialist

Name: _____
Specialty: _____
Contact: _____
Phone: _____ Fax: _____
Email: _____

Signature: _____

Institution: _____
Address: _____
City: _____ Prov/State: _____
Postal/Zip code: _____ Country: _____
Additional copies to: _____
Email: _____
Fax: _____

Billing

☐ **Institution**
Provide details: _____

☐ **Patient pay**
Complete **Form 1d:** Credit Card Authorization for Non-Covered Services **(Canada and international patients only)**.

☐ **Third party insurance (U.S. patients only)**
Complete **Form 1c:** U.S. Insurance Information.

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115 Midair Court, Brampton, ON L6T 5M3
t 647.478.4902 or 877.624.9769 **f** 905.697.9786
e impactgenetics@dynacare.ca
Please ensure to use secure email.

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Form 1c: U.S. Insurance Information **(U.S. patients only)**

Impact Genetics is committed to providing the highest quality genetic testing to all patients.
In many situations, genetic testing improves outcomes and quality of life and decreases total costs to the patient and healthcare system.

Processing medical insurance claims is usually challenging and time consuming. Many insurance companies require pre-authorization prior to testing. Impact Genetics supports insurance billing via LabCorp, completing coverage checks and pre-authorization.

It is important for patients to understand that insurance may not cover 100% of the cost of genetic testing and they may be financially responsible for some of all of the cost of testing. The patient is responsible for any portion of the test fee not covered by insurance for any reason, including but not limited to, co-payments, unmet deductibles, co-insurance and non-covered services. Prior determinations do not guarantee payment and the amount paid by insurance when the claim is submitted may be different from the coverage indicated during the pre-verification or pre-authorization process.

Pre-authorizations can take time to obtain depending on each individual insurance plan's policy and documentation requirements. Turnaround time for test results begins after the pre-authorization has been processed and approved.

Insurance process

1. Send **Form 1c**: *U.S. Insurance Information* as soon as possible.
2. Insurance coverage will be investigated and the patient will be contacted to provide coverage estimate if the patient's out-of-pocket costs are over $300.00.
3. Insurance claim will be submitted upon completion of testing.
4. After insurance payment is received patient will be billed for non-covered services.

Note: Timely and complete submissions will enable faster insurance checks.

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Send this form to Impact Genetics
by fax to 905.697.9786

Form 1c: U.S. Insurance Information

***MLH1/MSH2/MSH6/PMS2/EPCAM* Somatic Tumour MMR Sequencing and Deletion/Duplication Test**

Disease/Genetic Test

☐ **Somatic Tumour MMR Sequencing and Deletion/Duplication Test (LabCorp test #481472)**

ICD-10 Code • provide code here ▸ _____

CPT Codes: 81445

Insurance Information

☐ **Primary insurance** ☐ **Secondary insurance**

If patient has secondary insurance, include the information on an additional copy of this form with the secondary insurance box checked.

Name of insured (if not patient):

_____

Insurance company: _____

Claims address: _____

_____

City: _____

State: _____ Zip code: _____

Country: _____

Group #: _____

Subscriber/member #: _____

Physician Information

Physician's name: _____

NPI: _____

Practice name: _____

Practice address: _____

_____

Phone: _____

Fax: _____

Patient Information

Last name: _____

First name: _____

Date of birth: Y _____ M _____ D _____

Address: _____

_____

City: _____

State: _____ Zip code: _____

Country: _____

Phone: _____

Contact Information

Details of insurance coverage will be communicated directly to patient. Please provide patient contact info:

Phone: _____

Alternate phone: _____

Email: _____

☐ **In the event Patient cannot be reached a voice message related to somatic tumour MMR genetic testing may be left at the above phone number(s).**

Please Attach **All** of the Following

- Copies of both the front and back of insurance membership card(s)
- Letter of Medical Necessity, signed by Referring Specialist (contact Impact Genetics for template if needed)
- Clinic notes demonstrating the Patient's need for testing and confirmation of diagnosis
- Insurance approval details **if** prior authorization already completed

Performing lab:

impact genetics
115 Midair Court, Brampton, ON L6T 5M3
t 647.478.4902 or 877.624.9769 **f** 905.697.9786
e impactgenetics@dynacare.ca
Please ensure to use secure email.

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Please do not send form with sample:
Send this form to Impact Genetics
by fax to 905.697.9786
or call 647.478.4902/1.877.624.9769
For patient pay, testing will be held pending receipt of this completed form.

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

(Canada and international patients only)

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

Laboratory Test

- ☐ **Retinoblastoma Genetic Test**
- ☐ **Uveal Melanoma Prognostic Genetic Test**
- ☐ **HHT Genetic Test**
- ☐ ***MLH1/MSH2/MSH6/PMS2/EPCAM* Somatic Tumour MMR Sequencing and Deletion/Duplication Test**

Billing Information

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: _____

CVC # (3-digit Card Verification Code on back of card): _____

Contact Information

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 health coverage 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: Sample Preparation Instructions

***MLH1/MSH2/MSH6/PMS2/EPCAM* Somatic Tumour MMR Sequencing and Deletion/Duplication Test**

Germline/Normal Sample Requirements

Blood:

- 5-10 mL venous blood in yellow-topped ACD tubes or lavender-topped EDTA tubes at room temperature, to be received within 5 days after draw.

Buccal:

- Collection kits can be provided to a clinic or the patient's home.
  Please contact Impact Genetics to arrange for shipment.

Extracted DNA:

- Please provide DNA extraction method.

Tumour Sample Requirements

Fomalin fixed paraffin embedded (FFPE) block (preferred),
or Slides:

- 19 serial sections that are 8-10 µm thick **and** 1 adjacent section that is 4 µm thick.
  All sections must be mounted on uncharged slides. **Do not bake sections in oven**.

Impact Genetics will assist in obtaining FFPE tumour blocks/slides from pathology storage.
Please provide detailed information on the requisition form (**Form 1b**) with details of tumour location and pathology contact information.

Sample Identification

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

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Buccal Swab Collection Instructions

1. The person providing the buccal cell samples should **not** eat, drink, smoke, clean their teeth or use mouthwash 1 hour before sample collection.
2. The person taking the samples should thoroughly wash their hands prior to collecting the sample.
3. Open the OmniSwab packaging at the handle end and carefully remove the swab. **Do not touch** the collection pad (soft side) of the swab.
4. Holding the handle end of the OmniSwab, scrape the collection pad (soft side) firmly against the inside of the cheek 5–6 times (for around 10 seconds). Be careful not to eject the tip. *See Figure 1.*

Figure 1

Scan QR code to view a short video demonstrating the OmniSwab collection method.

5. After taking the sample, eject the tip into the tube labelled "*Buccal*" (provided) by firmly pressing the plunger at the end of the handle. After ejecting the tip into the lysis tube, dispose of buccal swab handle according to local regulations.
6. Once the buccal sample is in the tube, place the twist top cap on the tube and firmly tighten to close.
7. Label the buccal tube with one of the stickers (provided) with full name (first and last) and date of birth of the patient from whom the buccal sample has been collected.
8. Place the tube inside the plastic biohazard bag and seal the bag.
9. Complete the *Buccal Swab Patient Information Form*. Fold and place in the external pouch of the plastic biohazard specimen bag. Then place specimen biohazard bag into rigid container (provided).
10. Once collected, the buccal sample tube is stable when stored at room temperature or refrigerated (2-8 °C) for several days. However we recommend sending the buccal sample as soon as possible to ensure specimen integrity and to expedite your test results.

Notes:

- To ensure a safe experience during buccal sample collection, follow instructions above.
- If the swab becomes contaminated through touch or contact with an unclean surface do **not** proceed to use the swab for sample collection. Contact us directly to request an additional buccal collection kit.
- If the contents of the tube are spilled prior to or after buccal collection continue with sample collection steps above and add this information to the *Buccal Swab Patient Information Form*.
- The tube provided for buccal collection contains "Cell Lysis Solution" provided by Qiagen GmbH. This cell lysis solution is considered non-hazardous. For more information, visit: **https://www.qiagen.com/de-us/knowledge-and-support/product-and-technical-support/quality-and-safety-data/sds-search**.

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Buccal Swab Patient Information Form

This form is to be completed by the person who has performed the buccal swab collection. Once completed, fold and place this form in the outside pouch of the biohazard plastic bag containing the buccal sample.

Patient Information

First name: _____ Last name: _____

Date of birth: Y M D _____ Date of collection: Y M D _____

Sample Collection Comments

1. Did the buccal swab collection pad (soft side) potentially come in contact with hands or other surfaces?

   ☐ **Yes** ☐ **No**

   If *Yes*, please describe: _____

2. Was any cell lysis solution lost from the specimen tube provided?

   ☐ **Yes** ☐ **No**

   If *Yes*, please describe: _____

Signature: _____ Date: _____

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Step 3: Shipping Instructions

For shipping inquiries and notifications, please contact:

impact genetics
email: info@impactgenetics.com
phone: 647.478.4902 or 877.624.9769
fax: 905.697.9786

General Shipping Instructions

- If you have more than one patient request to submit, multiple patients can be sent in the same shipment.
- Submit specimen(s) for each patient in a biohazard specimen bag, **only one patient's specimen(s) per bag**. Refer to **Step 2:** *Sample Preparation Instructions* for shipping conditions.
- Include informed consent and requisition forms (**Form 1a** and **1b**) as well as any required clinical documents along with the samples. Place documents in a separate pouch or bag. **Do not** place documents inside the biohazard bag with specimens.
- Samples coming from the U.S. must also include U.S. insurance information (**Form 1c**) if required and **not** provided previously.
- Provide us with the parcel tracking number by phone or email shortly after courier pickup.
- For emailed PDF FedEx waybills and customs forms, please contact us directly.

Instructions for Specimens from Outside of Canada

- DNA studies: select **FedEx International Priority**
- RNA studies for *RB1*, **or** prenatal studies on direct amniotic fluid or CVS sample,: select **FedEx International Priority Express** (contact Impact Genetics before sending)
  - Samples **must** be received within 48 hours of collection
- Samples coming from outside of Canada **must** submit a waybill and commercial invoice:
  - Print **one** copy of the waybill and **three** copies of the commercial invoice
  - Sign each commercial invoice and place with the waybill in the external document pouch
- When preparing documentation:
  - Declare a value of $10.00
  - Declare as "*Exempt Human Diagnostic Specimen(s)*"
  - Description of Goods: *Human (blood/tissue) specimen for testing in a clinical laboratory. The enclosed material(s) are not zoonotic, are not of tissue culture origin, and are not known or suspected to contain an etiological agent, host, or vector of human disease.*

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Step 3: Shipping Instructions (continued)

Instructions for Specimens from Within Canada

- DNA studies: select **Purolator Express** (next-day) or **FedEx Priority** (overnight)
- RNA studies for *RB1*, **or** prenatal studies on direct amniotic fluid or CVS sample: select **FedEx First Overnight** (contact Impact Genetics before sending)
  - Samples **must** be received within 48 hours of collection
- When preparing documentation:
  - Declare a value of $10.00
  - If required, declare as "*Exempt Human Diagnostic Specimen(s)*"