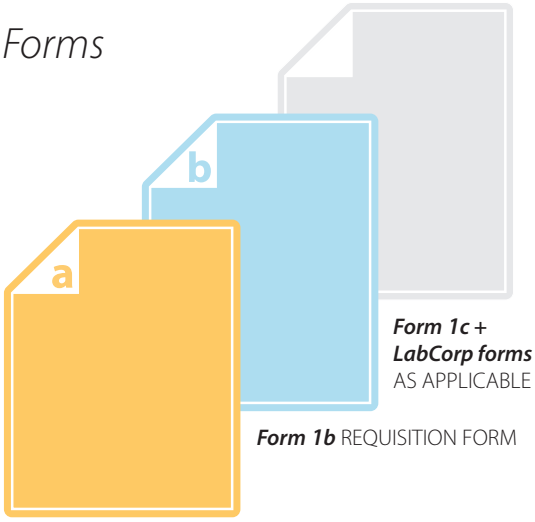
impact genetics

MLH1/MSH2/MSH6/PMS2/EPCAM Somatic Tumor MMR

Sequencing and Deletion/Duplication Test

1 Forms



Form 1c* + *LabCorp forms AS APPLICABLE

Form 1b REQUISITION FORM

Form 1a INFORMED CONSENT

2 Samples

LABEL WITH **AT LEAST 2** PATIENT IDENTIFIERS
(e.g. name and DOB)

3 Ship

Impact Genetics
115 Midair Court
Brampton, ON L6T 5M3
1-877-624-9769

Results

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

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 tumor testing shows a mutation(s) or alteration in any one or more of the following genes, *MLH1, MSH2, MSH6, PMS2* and *EPCAM*, the normal sample is analyzed for the same mutation(s). If the mutation 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 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 10 below, no information will be printed or released that discloses the patient's identity, or other confidential information.
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 tumor 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 below.
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. 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).
11. 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.

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: _____

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LAB USE ONLY DO NOT FILL OUT
Date received: Y M D
Specimen type:
Condition:
MRN: Tech:

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

Patient
Last name:
First name:
Date of birth: Y M D
Gender: ☐ Male ☐ Female

Test Submission Requirements
1. ☐ MSI and/or IHC report
2. ☐ Normal Sample
   ☐ Blood 5-10 ml
   Date Collected: Y M D
3. ☐ Tumor sample:
   ☐ Formalin fixed paraffin embedded (FFPE) block (preferred)
   Date Collected: Y M D

or ☐ 19 serial unstained unbaked slides (5-10 microns thick) with 1 adjacent unstained unbaked slide (4 microns 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 code: Country:
Facility contact:
Telephone: Fax:
Email:
☐ *Patient is aware that the specimen is to be sent to Impact Genetics*

Previous Test Results
For MLH1 abnormal tumors:
Methylation analysis complete? ☐ Yes ☐ No
Result:
BRAF V600 analysis complete? ☐ Yes ☐ No
Result:
Germline analysis complete? ☐ Yes ☐ No
Result:
Please provide report. Include coding (c.) and protein (p.) nomenclature for germline variant and genome build used.

Patient History
Colon cancer: ☐ Yes ☐ No
Diagnosis date: Y M D
Other clinical information:

Family History
☐ Isolated Case ☐ Positive Family History
Please complete pedigree.

Pedigree

Referring Specialist
Name:
Specialty:
Contact:
Telephone: Fax:
Email:

Signature:

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

Billing
Impact Genetics tests ordered through LabCorp test menu.
USA only.
☐ a) Client Bill
Provide details:

☐ b) Patient Pay
*Complete **LabCorp Financial Responsibility Form**.*

☐ c) Third party insurance (USA only)
*Complete **Form 1c:** U.S. Insurance Information and to expedite testing, complete **LabCorp Financial Responsibility Form**.*

115 Midair Court, Brampton, ON LT6 5M3
t: 647-478-4902 or 1-877-624-9769 f: 905-697-9786
e: info@impactgenetics.com *Please use secure email*

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Form 1c: *U.S. Insurance Information*

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, completing coverage checks and pre-authorization.

It is important for patients to understand that insurance rarely covers 100% of the cost of genetic testing and that they will be financially responsible for some or 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. Send ***Form 1d:*** *Credit Card Authorization for Non-Covered Services* to initiate testing immediately.
3. Insurance coverage will be investigated and patient/specialist will be contacted to provide coverage estimate if the patient's out of pocket costs are over $300.00.
4. Insurance claim will be submitted upon completion of testing.
5. 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 Tumor MMR Sequencing and Deletion/Duplication Test*

Disease/Genetic Test

☐ Somatic Tumor MMR
Sequencing and Deletion/Duplication

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: _____

_____

Telephone: _____

Fax: _____

Testing process will be initiated when
Form Id: *Credit Card Authorization for Non-Covered Services*
is received or confirmation is received from insurance provider.

Patient Information

Last name: _____

First name: _____

Date of birth: Y _____ M _____ D _____

Address: _____

_____

City: _____

State: _____ Zip code: _____

Country: _____

Telephone: _____

Contact Information

Details of insurance coverage will be communicated. Please provide preferred telephone number(s):

☐ Patient ☐ Referring specialist

Telephone: _____

Alternate telephone: _____

Email: _____

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

Please Attach <u>All</u> 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 pre-approval completed

Performing Lab - Impact Genetics
115 Midair Court
Brampton, ON LT6 5M3 CANADA
t: 1-877-998-7837 **f:** 1-888-598-7568
e: info@impactgenetics.com *<u>Please ensure to use secure email</u>*

LabCorp **Statement of Financial Responsibility**

Section A: Member/Patient Information

Member/patient name: _____ / Date of birth: _____

Address: _____

City: _____ / ST: _____ / ZIP: _____

Specimen #: _____ / Client account #: _____ / Client phone #: _____

Subscriber #: _____

Section B: Requested procedure or service information

Based on information given to us by your insurance plan, your plan is **not expected to pay 100%** for the laboratory test(s) ordered by your physician/healthcare provider (marked below).

Test/CPT Description	Reason for Patient Out of Pocket	Estimated Cost*

Total Estimated Patient Responsibility*: _____

*This is only an estimate. Actual amount owed may be adjusted based on final coverage amount.

Next Steps:

- Read this notice and decide if you agree to be financially responsible for the estimated patient responsibility costs listed above.
- Choose an option below about whether to receive the items listed in Section B above.
- Sign below and return this form to us within 5 calendar days via email, fax, or mail to the addresses listed below. We will not proceed until we receive this signed consent form with an option checked.

Section C: Options — Check only one box. We cannot choose a box for you.

☐ Option 1 — **I want** the laboratory test(s) marked above to be performed. 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.

  ☐ I would like to set up a payment plan for $_____a month.**

☐ Option 2 — **I want** the services listed above, but **do not** bill my insurance. I understand I cannot appeal the coverage of these services with my insurance plan if they are not billed. Discounts may apply to the services listed above. Payment in full is required in order to proceed with the testing services.

☐ Option 3 — **I do not want** the laboratory test(s) marked above to be performed. I understand with this choice I am not responsible for payment. No test will be performed and my plan will not be billed.

Patient can contact the Billing department at 888-210-9264 to discuss payment options. For non-billing questions, call 855-488-8750.

**Your first invoice will include the full balance due. If your payment plan is approved, you will receive another invoice that reflects your requested payment amount.

Signature: _____ / Date: _____

Please print name: _____

LabCorp

www.LabCorp.com

Email this form to: / **Fax this form to:**

Mail this form to: LabCorp Prior Authorization
PO Box 2230 / Millstream Mailstop 285 / Burlington NC 27216-2230

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Step 2: *Sample Preparation Instructions*

Normal Sample Requirements

Blood samples for DNA:

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

Tumor Sample Requirements

Formalin Fixed paraffin embedded (FFPE) block (preferred),

or

Slides:

- 19 serial unstained unbaked slides (5-10 microns thick)
- 1 adjacent unstained unbaked slide (4 microns thick)

Impact Genetics will assist in obtaining FFPE tumor blocks from storage. Please provide detailed information on the Requisition Form (***1b***) for the storage facility and obtain authorization from the patient for the block to be released to us.

Sample Identification

- Label each sample with **at least two** patient identifiers (e.g. named 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 *MLH1/MSH2/MSH6/PMS2/EPCAM* Somatic Tumor MMR Sequencing and Deletion/Duplication Test Informed Consent 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, info@impactgenetics.com**.
- For emailed PDF FedEx waybills and customs forms, please contact us directly.

For samples from outside Canada:

- Complete all fields and sign 4 copies of the Pro-Forma Invoice (*available on our website; phone us if help is required*). Place the 4 Pro-Forma Invoice copies in the document pouch.
- Mark on the Air Waybill and Pro-Forma Invoice:
  EXEMPT HUMAN DIAGNOSTIC SPECIMEN – non-hazardous, non-toxic and non-infectious.
- To avoid Customs clearing delays, declare value at US $10 on the Air Waybill and Pro-Forma Invoice.

Send to Impact Genetics

mail: Impact Genetics
115 Midair Court
Brampton, ON L6T 5M3

tel: 1-877-624-9769

fax: 905-697-9786