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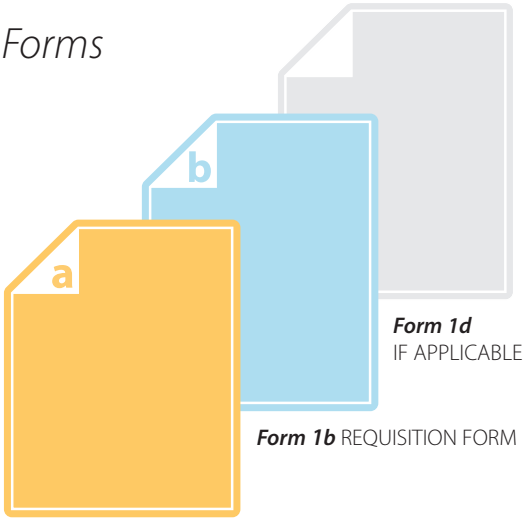
MLH1/MSH2/MSH6/PMS2/EPCAM Somatic Tumor MMR

Sequencing and Deletion/Duplication Test

1 *Forms*



Form 1d
IF 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
1100 Bennett Road - Unit 4
Bowmanville, ON LIC 3K5
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

☐ a) Institution

Provide details:

☐ b) Patient Pay

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

1100 Bennett Road - Unit 4, Bowmanville, ON L1C 3K5
t: 647-478-4902 or 1-877-624-9769 f: 905-697-9786
e: info@impactgenetics.com *Please use secure email*

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
☐ *MLH1/MSH2/MSH6/PMS2/EPCAM* Somatic Tumor MMR Genetic 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 U.S. PATIENTS ONLY

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: *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
1100 Bennett Road - Unit 4
Bowmanville, ON L1C 3K5

tel: 1-877-624-9769

fax: 905-697-9786