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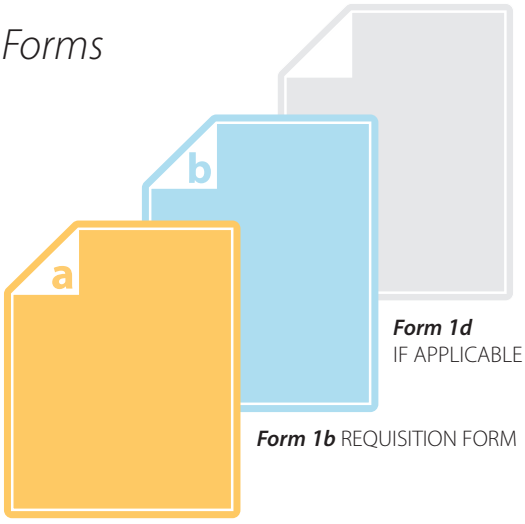
Uveal Melanoma

Prognostic Genetic Test Submission Guide

1 Forms

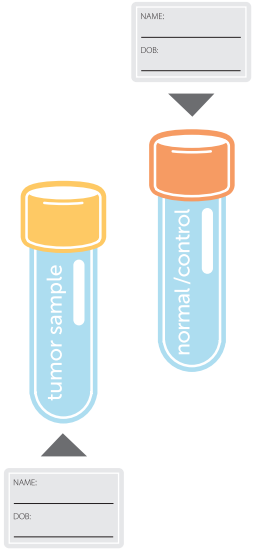


Form 1d IF APPLICABLE

Form 1b REQUISITION FORM

Form 1a INFORMED CONSENT

2 Samples



3 Ship

Impact Genetics
1100 Bennett Road - Unit 4
Bowmanville, ON L1C 0Y7
1-877-624-9769

Results

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Form 1a: *Informed Consent to Perform Genetic Testing for Uveal Melanoma*

The purpose of my DNA test is to look for mutation(s) or genetic alterations known to be associated with prognosis for survival in patients with uveal melanoma. I understand this test requires tumor and blood (or other normal) samples for use in prognostic testing.

By signing below, I acknowledge that:

1. My 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.
4. I understand that prognostic genetic tests for uveal melanoma are not entirely predictive. Patients with a good prognosis can develop metastatic disease (albeit rarely) and vice versa.
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 11 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. 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.
8. Until the results of this test are reported, the patient should still undergo examinations as prescribed by the referring specialist.
9. 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).
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.

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 in an **anonymous** fashion for research.

☐ YES ☐ NO

Consent to Contact Family:

I understand that information about my clinical health status will further improve the power of this prognostic uveal melanoma test for the benefit of future patients. I permit Impact Genetics (Dynacare) to contact me or members of my family for updated information about my health.

☐ YES ☐ NO

Contact Information:

Name: _____

Telephone: _____ Email: _____

Alternate Contact Information:

Name: _____

Telephone: _____ Email: _____

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: *Uveal Melanoma Prognostic Genetic Test Requisition*

Ordering Options

☐ Uveal Melanoma Prognostic Genetic Test

▸ *For BAP 1 Germline Analysis -Complete a BAP1 Test Requisition*

Patient

Last name:

First name:

Date of birth: Y M D

Gender: ☐ Male ☐ Female

Ethnicity:

Pigmentation:

Skin color: Hair color:

Eye color:

Specimen Information

Tumor collection method:

☐ FNAB ☐ Enucleation ☐ Surgical resection

☐ Other:

Tumor sample (required):

☐ Fresh tumor in cell lysis (Impact Genetics collection tube)

☐ Frozen tumor ☐ To follow (sending separately)

☐ DNA from tumor ☐ Other:

Date of collection: Y M D

Time of collection: HH:MM (24hr)

Normal/control sample (required):

☐ Buccal swab (UM Prognostic Test only)

☐ Blood (UM Prognostic Test and *BAP1* Germline Analysis)

Date of collection: Y M D

Time of collection: HH:MM (24hr)

Histology

Tumor thickness* (by ultrasound, mm):

Largest basal tumor diameter** (LBD, mm):

Anatomic sub-classification:

☐ Choroid ☐ Iris ☐ Ciliary body involvement

☐ Other:

Extraocular extension (spread) present: ☐ Yes ☐ No

Mitotic count: _____ per _____ HPF

Closed loops: ☐ Yes ☐ No

Predominant cellular classification:

☐ Pure spindle ☐ Predominantly spindle ☐ Epitheloid

☐ Predominantly epitheloid ☐ Unknown

Necrosis: ☐ Yes ☐ No

AJCC TNM stage:

*** These values are required for TNM survivorship prediction.*

Patient History

Diagnosis date: Y M D

Type of primary management:

☐ None ☐ Proton beam radiotherapy ☐ Enucleation

☐ Plaque therapy ☐ Other:

Date: Y M D

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.*

☐ c) Third party insurance (USA only)

Complete ***Form 1c:*** *U.S. Insurance Information and to expedite testing, complete* ***Form 1d:*** *Credit Card Authorization for Non-Covered Services.*

Ordering Specialist: By submitting this form, I confirm that this test is being ordered for the purpose of prognosis as per the **Laboratory and Specimen Collection Centre Licensing Act** (Ontario, Canada).

1100 Bennett Road - Unit 4, Bowmanville, ON L1C 0Y7
t: 647-478-4902 or 1-877-624-9769 f: 905-697-9786
e: info@impactgenetics.com *Please ensure to 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
☐ NeuroSURE℠: Epilepsy Gene Panel Test
☐ HHT 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
☐ *MLH1/MSH2/MSH6/PMS2/EPCAM* Somatic Tumor MMR 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: _____

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

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: *Uveal Melanoma Prognostic Genetic Test Sample Requirements*

U.S. insurance patients: a completed ***Form 1c****: U.S. Insurance Information* must be provided.

Kit includes:

- One tube with cell lysis for tumor sample
- One tube with cell lysis for buccal swab sample
- One sterile cytology brush for buccal swab collection
- Plastic bag to place samples in
- Absorbent pad for shipping
- Rigid box for shipping
- Patient lables

Samples required (both required):

- **Normal sample:** buccal swab or blood sample
- **Tumor sample:** tumor biopsy (FNAB or other)

Sample Preparation Instructions

Normal sample:

- **Blood samples for DNA:** 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.

Or

- **Buccal swab:**
  - Do a gentle mouth rinse with water to clear the mouth of debris.
  - Scrape the inside of the patient's mouth using ten strokes with the collection brush (provided). Either cheek is fine.
  - Eject the tip by firmly pressing the plunger at the end of the handle into the provided tube labelled **Buccal** (provided).
- Label the tube with one of the stickers (provided), complete with the patient name and date of birth.
- Once the buccal sample is in the tube, seal tube with twist top cap, it can be stored at room temperature or refridgerated (4˚C or 39˚F) until shipping.
- Place the tube in the plastic bag and rigid container (provided).

Tumor sample:

- **FNAB**: Place the FNAB sample in the collection tube (provided). Two or more FNAB passes are preferred and all passes can be combined in one tube.

Or

- **Biopsy**: If possible, larger tumor tissue samples from a biopsy are preferred. Place the fresh tumor sample in the collection tube (provided). **DO NOT FIX** the tissue.
- Label the tube with one of the stickers (provided), complete with the patient name and date of birth.
- Once the tumor sample is in the tube, seal tube with twist top cap. Tube can be regridgerated stored (4˚C or 39˚F) until shipping.
- Place the tube in the plastic bag and rigid container (provided). Leave the absorbent pad in the plastic bag.

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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 Uveal Melanoma 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.

Send to Impact Genetics

mail: Impact Genetics
1100 Bennett Road - Unit 4
Bowmanville, ON L1C 0Y7

tel: 1-877-624-9769

fax: 905-697-9786