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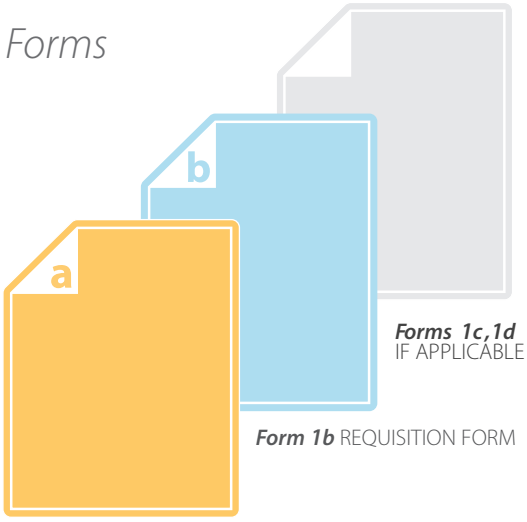
BAP1-TPDS (*BAP1* Tumor Predisposition Syndrome)

Genetic Test Submission Guide

1 Forms



Forms 1c,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 3K5
1-877-624-9769

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 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 that 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: *BAP1-TPDS Genetic Test Requisition* *(BAP1 Tumor Predisposition Syndrome)*

Patient

Last name:

First name:

Date of birth: Y M D

Gender: ☐ Male ☐ Female

Ordering Options

☐ **Proband** - *BAP1* full sequencing and copy number

☐ **Known familial mutation** - *BAP1* targetted sequencing

Has the Patient had uveal melanoma prognostic testing done at Impact Genetics?

☐ Yes ☐ No

Sample

☐ **Blood** – 10ml EDTA

☐ **DNA from blood stored at Impact Genetics**
Please call to ensure sufficient volume is available.

Clinical History *– Check all that apply*

☐ Uveal melanoma

☐ Mesothelioma

☐ Melanocytic skin tumors

☐ Renal cell carcinoma

☐ Other (specify type):

Family History

Relationship to Patient:
Type of cancer:
Age at diagnosis:

Relationship to Patient:
Type of cancer:
Age at diagnosis:

Relationship to Patient:
Type of cancer:
Age at diagnosis:

Relationship to Patient:
Type of cancer:
Age at diagnosis:

Relationship to Patient:
Type of cancer:
Age at diagnosis:

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.*

How to arrange genetic counselling

Patient is required to login to genetic counseling services portal: **http://impactgenetics.com/genetic_counseling/**

Or call, **855 GC CALLS (855-422-2557).**

Telegenetics appointment will be scheduled at which time genetic counseling will be provided by a board certified genetic counselor.

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 ensure to 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.
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 – BAP1-TPDS* *(BAP1 Tumor Predisposition Syndrome)*

Disease/Genetic Test

☐ *BAP1*-TPDS Genetic Test

ICD-10 Code •• *provide code here* ••▸ _____

CPT Codes: 81479

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 BAP1-TPDS 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
1100 Bennett Road - Unit 4
Bowmanville, ON L1C 3K5 CANADA
t: 1-877-998-7837 **f:** 1-888-598-7568
e: info@impactgenetics.com *<u>Please ensure to use secure email</u>*

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
☐ 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: *BAP1-TPDS (BAP1 Tumor Predisposition Syndrome) Genetic Test Sample Requirements*

U.S. insurance patients: a completed ***Form 1c****: U.S. Insurance Information* must be provided.
All submitted samples must be labeled with at least two patient identifiers (ie. name and date of birth)

Sample Requirements

Blood sample:

• 10 mls in lavender-topped EDTA tubes at room temperature, to be received within 5 days after draw.

Sample Identification:

• Label each sample with **at least two** patient identifiers (e.g. named and date of birth).

Step 3: *Shipping Requirements*

Multiple separated samples may be shipped in one package. 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 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 3K5

tel: 1-877-624-9769

fax: 905-697-9786