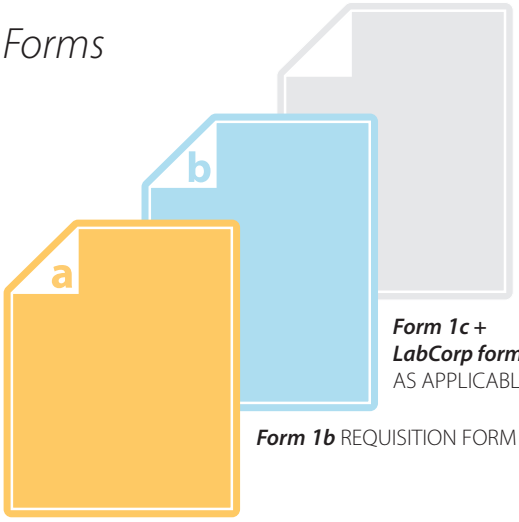
impact genetics

HHT Hereditary Hemorrhagic Telangiectasia

Genetic Test Submission Guide

1 *Forms*



Form 1c +
LabCorp forms
AS APPLICABLE

Form 1b REQUISITION FORM

Form 1a INFORMED CONSENT

2 *Samples*

3 *Ship*

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

Results

Rev 19Feb2020 (US/LABCORP)

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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 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: HHT Genetic Test Requisition

Patient

Last name:

First name:

Date of birth: Y M D

Gender: ☐ Male ☐ Female

Pregnant: ☐ Yes ☐ No

Expected delivery date: Y M D

Patient History

☐ Confirmed clinical diagnosis

☐ Suspected clinical diagnosis ☐ Unaffected

Symptoms:

☐ PAVM ☐ Rare nose bleeds ☐ Liver shunts

☐ CAVM ☐ Frequent nose bleeds ☐ Stroke

☐ Telangiectasia ☐ Other:

Family History

☐ Isolated case ☐ Positive family history

Family previously tested: ☐ Yes ☐ No

Mutation identified: ☐ Yes ☐ No

If mutation identified at lab other then Impact Genetics please provide report.

Proband name (first person in a family to be studied):

Mutation:

Relationship To Proband

☐ Proband ☐ Parent of proband

☐ Brother or sister of proband ☐ Child of proband

☐ Other:

Specimen Information

Sample:

☐ Blood sample for DNA

☐ Blood sample for RNA (at Impact Genetics' request)

☐ DNA from blood ☐ DNA from tumor

☐ Fresh tumor ☐ Frozen tumor

☐ Buccal swab (only for preapproved familial mutation confirmation, contact lab directly before submitting)

☐ Other:

Pre-natal:

☐ Cord blood ☐ CVS ☐ Cultured amniocytes

☐ Direct amniotic fluid ☐ DNA extracted from CVS

☐ DNA extracted from amniocytes

Date of collection: Y M D

Time of collection: HH:MM (24hr)

☐ Sample to test maternal cell contamination

Referring Specialist

Name:

Specialty:

Contact:

Telephone: Fax:

Email:

Signature:

Institution:

Address:

City: Prov/State:

Postal code: Country:

Additional copies to:

Email: Fax:

Pedigree

Please complete the following page for detailed family history information if available.

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 L6T 5M3
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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HHT Genetic Test Requisition: Family History Information

Proband name: ______________________ **Date of birth:** Y ____ M ____ D ____

Enter family members starting with the proband's parents and then brothers/sisters and biological children.
Use additional sheets as needed to provide information on additional affected family members.

Name of Family Member Relationship to Proband	Symptoms *Please check all applicable boxes* ☑		
Name: ____ Relationship: ____ Date of birth: Y ____ M ____ D ____ Carries HHT mutation? ☐ Yes ☐ No ☐ Unknown	☐ PAVM ☐ CAVM ☐ Rare nose bleeds ☐ Frequent nose bleeds	☐ GI bleeding ☐ Telangiacteses ☐ Liver shunts ☐ Stroke	☐ Unaffected ☐ Other (list below): ____ ____
Name: ____ Relationship: ____ Date of birth: Y ____ M ____ D ____ Carries HHT mutation? ☐ Yes ☐ No ☐ Unknown	☐ PAVM ☐ CAVM ☐ Rare nose bleeds ☐ Frequent nose bleeds	☐ GI bleeding ☐ Telangiacteses ☐ Liver shunts ☐ Stroke	☐ Unaffected ☐ Other (list below): ____ ____
Name: ____ Relationship: ____ Date of birth: Y ____ M ____ D ____ Carries HHT mutation? ☐ Yes ☐ No ☐ Unknown	☐ PAVM ☐ CAVM ☐ Rare nose bleeds ☐ Frequent nose bleeds	☐ GI bleeding ☐ Telangiacteses ☐ Liver shunts ☐ Stroke	☐ Unaffected ☐ Other (list below): ____ ____
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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.

For tests ordered through LabCorp, LabCorp administers billing. The LabCorp prior-authorization team will file a pre-verification/prior-authorization on behalf of the patient with any commercial insurance company. State managed Medicare plans cannot be billed.

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 LabCorp
BY FAX TO 1-888-598-7568

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

Disease/Genetic Test

☐ **Test # 480074** - HHT Proband
ICD-10 Code •• *provide code here* ••▸ _____
CPT Codes: 81405, 81406, 81479

☐ **Test # 480192** - HHT Familial Mutation Analysis
ICD-10 Code •• *provide code here* ••▸ _____
CPT Codes:
- ☐ ENG del/dup mutation - 81405
- ☐ ENG point mutation - 81403
- ☐ ACVRL1/SMAD4 del/dup or point mutation - 81403

☐ **Test # 480216** - Prenatal HHT Test
ICD-10 Code •• *provide code here* ••▸ _____
CPT Codes:
- ☐ ENG del/dup mutation - 81405, 81265
- ☐ ENG point mutation - 81403, 81265
- ☐ ACVRL1/SMAD4 del/dup or point mutation - 81403, 81265

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: _____

LabCorp account #: _____

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 HHT 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

Testing process will be initiated when ***LabCorp Financial Responsibility Form*** *is received or confirmation is received from insurance provider.*

Performing Lab - Impact Genetics
115 Midair Court
Brampton, ON L6T 5M3 CANADA
t: 1-877-998-7837 **f:** 1-888-598-7568
e: preverification@labcorp.com *<u>Please ensure to use secure email</u>*

Rev 19Feb2020 (US/LABCORP)

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: *HHT Genetic Test Sample Requirements*

Sample Requirements

Proband:

• Blood or DNA from blood.

Pre/peri-natal sample options:

• Cultured amniocytes • Direct amniotic fluid • DNA extracted from amniocytes

• CVS tissue • DNA extracted from CVS • Cord blood

Maternal blood or DNA from blood (required for <u>all</u> pre/perinatal samples, to be submitted at same time or prior to procedure).

Genetically related family member for known mutation:

• Blood or DNA from blood;

• <u>Or</u> buccal swab (select cases only, contact lab directly to confirm if appropriate sample).

If genetic testing has been performed at a lab other than Impact Genetics, please provide copy of report.

Sample Preparation Instructions

Blood samples for DNA:

• 10 mls in yellow-topped ACD tubes **or** lavender-topped EDTA tubes (for infants 2-5 mls in pediatric or small tubes) at room temperature, to be received within 5 days after draw.

DNA from blood:

• DNA concentration—100 nanograms/microliter.

• DNA quantity—150 microliters.

Blood samples for RNA (only if requested):

• 10 mls in lavender-topped EDTA tubes *(*for infants 2-5 mls in pediatric or small tubes) on 4°C cool packs, to be received within 48 hours after draw.

Buccal swab:

• Kit available (select cases only contact lab directly to request); follow included instructions.

Amniocytes:

• Two T25 flasks of cultured amniotic cells ***or*** DNA extracted from amniotic cells at room temperature (100 nanograms/microliter: minimum 20 microliters).

Direct amnio:

• As much volume as possible in conical tube at room temperature, to be received within 48 hours after draw.

CVS:

• Send CVS tissue in sterile tissue-culture medium at room temperature **or** DNA extracted from CVS tissue at room temperature (100 nanograms/microliter: minimum 20 microliters).

Sample Identification

• Label each sample **with at least two** patient identifiers (e.g. name 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 HHT 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
115 Midair Court
Brampton, ON L6T 5M3

tel: 1-877-624-9769

fax: 905-697-9786