

REQUEST FOR CHROMOSOMAL ANALYSIS OF UVEAL MELANOMA

Please provide the following information. We cannot perform your test without ALL of this information. PLEASE PRINT ALL ANSWERS

PATIENT INFORMATION*

FIRST NAME _____ MI _____ LAST NAME _____ BIRTH DATE (MM/DD/YYYY) _____ GENDER _____

ANCESTRY Western/Northern European Central/Eastern European Latin American/Caribbean African

Asian Jewish (Ashkenazi) American Indian Near East/Middle Eastern Native Hawaiian or Pacific Islander

Specify countries: _____ Other: _____

CLINICAL INFORMATION

Location of tumor (select all that apply)? Iris Choroid Ciliary body

Which eye is affected: Left Right

What color is the iris? Black Brown Blue Green Hazel Other: _____

Personal history of dermal nevi (i.e. moles on skin) No Yes; if yes, approximately how many: _____

Personal history of cancer? No Yes; if yes, describe type and age of diagnosis: _____

Family history of cancer? No Yes

RELATIONSHIP

CANCER DIAGNOSIS

AGE DIAGNOSED

What is your occupation (if retired, what was your previous occupation)? _____

What prescription medications are you taking? _____

Personal history of smoking? No Yes; if yes, how long did you smoke? _____

Personal history of autoimmune conditions (i.e. Lupus, Hashimoto's, Addison's)? No Yes; if yes, describe: _____

Personal history of eye injury? No Yes; if yes, describe event and which eye: _____

TEST REQUESTED*

Chromosomal analysis (3, 6, and 8) of uveal melanoma tissue

PATIENT REGISTRATION FORM

Please provide the following information. We cannot perform your test without ALL of this information. PLEASE PRINT ALL ANSWERS

PATIENT INFORMATION*

FIRST NAME MI LAST NAME BIRTH DATE (MM/DD/YYYY) GENDER

STREET ADDRESS

CITY STATE ZIP HOME PHONE

EMAIL CELL PHONE

PHYSICIAN INFORMATION

REFERRING PHYSICIAN PHONE FAX

INSTITUTION AND DEPARTMENT

STREET ADDRESS CITY STATE ZIP

PAYMENT OPTIONS* (must choose one) [a receipt will be mailed to the patient for self-pay options]

I have enclosed a check or money order payable to the "Genetic Diagnostic Laboratory" for \$ 1000.00

Please charge my credit card for the amount of \$ 1000.00

VISA Master Card Discover American Express

Card Number: _____ Exp date: _____

Name of cardholder as it appears on card: _____

I have Pennsylvania Medicaid. A copy of my Medicaid card is attached.

The Genetic Diagnostic Laboratory is not able to bill your insurance. We will send you an itemized receipt to submit a claim to your insurance for possible reimbursement. Reimbursement depends upon your specific insurance plan. If you call your insurance to determine if the genetic testing will be reimbursed, you will need the following information:

- University of Pennsylvania Health System tax id #: 23-135-2685
- CPT Code: (aka billing codes): 81406

Your packet of paperwork and payment can be mailed, faxed or emailed to:

Genetic Diagnostic Laboratory
University of Pennsylvania
Department of Genetics
415 Curie Boulevard, Suite 500
Philadelphia, PA 19104-6145
Fax: 215-573-5940
Email gdllab@penntest.upenn.edu

If you have any questions, please call the laboratory at 215-573-9161

INFORMED CONSENT FOR GENETIC TESTING FOR CHROMOSOMAL ANALYSIS (3, 6 AND 8) IN UVEAL MELANOMA TISSUE

Background: Chromosomal analysis of 3, 6 and 8 gives knowledge about the biology of the uveal melanoma tumor. Copy number and heterozygosity of chromosomes 3, 6, and 8 provides information about the prognosis and stratify the risk for the cancer in the eye to spread to another place in the body (i.e. metastasis).

Purpose: The diagnostic samples will be used for the purpose of attempting to determine the risk group I (or my child) is for the uveal melanoma tumor to metastasize or spread to another place in the body. I understand that the testing will take approximately 8-10 weeks. This information may help establish appropriate medical management.

Testing procedure: Genetic testing requires a sample of the related tumor in addition to a blood sample. I understand that there is a minimal amount of risk involved in obtaining a tissue and blood sample which have been discussed with my doctor.

Results: I understand that there are multiple possible results to this testing:

- 1) Low risk (<10% chance for metastasis)
- 2) Increased risk (Between 20-30% chance for metastasis)
- 3) Significantly increased risk (~50%) chance for metastasis)

Disclosure Policy: Results will be reported to me only through the physician or genetic counselor who requested the testing due to the complexity of DNA based testing. The results of genetic testing are protected by the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (Public Law 104-191). Release of test results is limited to authorized personnel as required by law. Additionally, results can be released to other medical professionals or other parties with my written consent.

Limitations: While genetic testing is highly accurate, a small fraction of alterations may be missed by the current technology. Due to the nature of the testing, there is a small possibility that the test will not work properly or that an error will occur. My signature below acknowledges my voluntary participation in this test, but in no way releases the laboratory and staff from their professional and ethical responsibility to me. Furthermore, the DNA analysis performed at the University of Pennsylvania Genetic Diagnostic Laboratory is specific only for analysis of copy number and heterozygosity of chromosomes 3, 6, and 8 and in no way guarantees my health.

There are federal laws in place that prohibit health insurers and employers from discriminating based on genetic information (i.e. Genetic Information Nondiscrimination Act (GINA) of 2008 (Public Law 110-233). There are currently no laws specific to discrimination based on genetic information for life insurance, long term care, or disability insurance companies. Additional information about GINA can be found on the Genetics Public & Policy Center's website at www.dnapolicy.org.

Use of Specimens:

I understand my blood or tissue specimen will not be returned to me or the ordering healthcare provider, and becomes the property of the lab upon receipt. The laboratory is not a DNA banking facility; therefore this is no guarantee that samples will be available or usable for additional or future testing.

After the laboratory completes the ordered clinical test, the lab may retain and preserve the specimen to validate the development of future genetic tests or for future research or education purposes. The laboratory is committed to continuous improvement and therefore I understand my coded sample may be used to validate a new assay. If testing reveals a clinically significant result during the validation process of a new assay related to the original indication for testing, my health provider may be contacted. If the lab uses the specimen for future research or education purposes, the specimen will be de-identified by removing my personally identifying information. My name, address and other personal identifying information will not be linked to the samples, or the results of the research, and I will not be identified in any research results or publications. I will not receive a copy of the research results. I can decline for my sample to be retained at the lab by filling out "Research Opt Out" form found on the following website: <http://www.med.upenn.edu/genetics/gdl/>.

I understand the lab may wish to contact me, or my ordering healthcare provider, for additional information. The additional information may include, but would not be limited to, information about health and family history that might be relevant to the research. I understand I can decline future contact from the lab by filling out "Research Opt Out" form found on the following website: <http://www.med.upenn.edu/genetics/gdl/>.

Genetic Counseling provided by a qualified specialist (i.e. genetic counselor/medical geneticist) is a recommendation for individuals proceeding with genetic testing. This service is available before and after genetic testing. Additionally, other testing or further physician consults may be warranted.

The Genetic Diagnostic Laboratory is also an available resource to ask more questions about this testing. The laboratory genetic counselor can be reached at 215-573-9161 and Arupa Ganguly, PhD, FACMG can be reached at 215-898-3122. I will be given a copy of this consent form to keep.

HEALTHCARE PROVIDER STATEMENT:

I have explained to _____ the purpose of this genetic testing, the procedures required and the possible risks and benefits to the best of my ability.

Printed Name of Professional Obtaining Consent

Signature of Professional Obtaining Consent

Date

CONSENT OF PATIENT: I have read and received a copy of this consent form. I agree to have genetic testing performed for myself, and accept the risks. I understand the information provided in this document and I have had the opportunity to ask questions I have about the testing, the procedure and the associate risks and alternatives.

Patient's Printed Name: _____

DOB: _____

Patient's Signature: _____
(Or parent/Guardian if patient is a minor)

Date: _____

Name and Relationship: _____
(Parent/Guardian if patient is a minor)