Dynacare®

Form 1a: Informed Consent to Perform Genetic Testing for Uveal Melanoma (NY)

The purpose of my DNA test is to look for variant(s) known to be associated with prognosis for survival in patients with uveal melanoma. I understand this test requires tumor and buccal (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. No tests other than those authorized shall be performed on this biological sample.
5. 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.
6. Impact Genetics will only collect, use, and disclose your personal health information as permitted/designated on the requisition/order form or required by applicable laws. For example, if necessary to obtain reimbursement of test fees, Impact Genetics, its agents and legal representatives, may disclose personal health information (including test results) for such purpose.
7. Impact Genetics is not a DNA banking facility and patient DNA samples may not be available for future testing.
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 on the requisition/order form.
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. 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 Storing a Sample

Impact Genetics is not a DNA banking facility and patient DNA samples may not always be available for future testing. However, Impact Genetics has my consent to store any surplus DNA samples indefinitely, for future clinical testing as requested by me. If "No" is checked or if neither box below is checked, the sample will be destroyed within 60 days after test completion.

☐ **Yes** ☐ **No**

Signature of Patient or Consenting Parent/Guardian: _____ Date: _____

Signature of Witness: _____ Date: _____

Statement of Referring Physician

I reviewed this form with my Patient. I offered to answer any questions.

Signature of Referring Physician: _____ Date: _____

CAP 7175554 CLIA 99D990947 IGADM-1100 Rev 23Jun2023

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Information About the Uveal Melanoma Prognostic Genetic Test

What is Uveal Melanoma?

Uveal melanoma (UM) is a melanoma (type of cancer) of the eye, involving the iris, ciliary body or choroid (collectively referred to as the uvea). These malignant (cancerous) tumors arise from the pigmented cells (melanocytes) within the uvea.

Purpose and Principle of the Test

Approximately 50% of patients diagnosed with UM will develop metastases within 10 years of treatment of the primary intraocular tumor. Multiple factors contribute to the survival prognosis of a patient with uveal melanoma including genetics of the tumor, histologic grade, size and clinical stage of the tumor [Damato, B. et al. Progress in Retinal and Eye Research, 2011].

One of the most important indicators of poor prognosis in UM is loss of chromosome 3 (monosomy 3). Metastatic disease develops almost exclusively in patients with this genetic abnormality. Other genetic factors contributing to the survival prognosis include copy number variation of chromosomes 1, 6 and 8 [Damato, B. and Coupland, S.E. Arch Ophthalmol. 2009]. The prevalence of monosomy 3 in small tumors (basal diameter <10 mm) is as high as 35% [Damato, B. and Coupland, S.E. Arch Ophthalmol. 2009]. For this reason, it is important to analyze the genetics of the tumor in addition to other factors such as size.

Cancer is often unpredictable and many patients find it difficult to come to terms with a diagnosis of cancer. Sharing this information with family members and friends can be very challenging. Some patients feel, however, that knowing their chance of survival is valuable. This knowledge empowers life planning and may initiate the development of support strategies. Many individuals diagnosed with this condition state that they have hope they will be considered to be at low risk for the cancer to spread; however, knowing either way can allow them to understand more clearly their risk for the future. If cancer spreads to the liver, there is limited treatment available to cure it at this time.

Some specialists will change treatment and/or surveillance for metastases depending upon the genetic make-up of cancer cells (determined through genetic prognostic testing).

Test Method: Impact Genetics' Mutation Identification Strategy

Fresh tumor sample is obtained from the affected eye either by a biopsy at the time of radiation plaque therapy or taken directly from the removed (enucleated) eye by a pathologist. Frozen tumor samples or banked tumor DNA can also be submitted for analysis. In addition, a blood or buccal sample is required and used for comparison analysis. Impact Genetics isolates DNA from the specimens provided (unless provided DNA directly) and performs molecular tests to identify the chromosomal alterations in the tumor DNA. The results from testing can be used to predict if these tumor cells have a high or low risk to metastasize and can be used in the design of appropriate surveillance and treatment plans and for life planning.

Impact Genetics is certified under the US Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing. Impact Genetics's tests were developed, and their performance characteristics determined, by Impact Genetics. They have not been cleared or approved by the US Food and Drug Administration, which has determined that such approval is not necessary. Impact Genetics does not perform linkage analysis.