

ASSOCIATION OF HLA MARKERS WITH NARCOLEPSY: Informed Consent

1. **What is Narcolepsy?** Narcolepsy is a neurological sleep disorder characterized by excessive daytime sleepiness. Patients may also have cataplexy, a brief episode of severe loss of tone of various muscles as well as weakness and dream-like hallucinations between sleeping and waking. Narcolepsy is a chronic, life-long condition. Narcolepsy is usually diagnosed by clinical evaluation, sleep studies, and genetic testing for the presence of certain DNA markers.
2. **What is the purpose of this test and what are its limitations?** This test assesses the presence or absence of a genetic marker that is found in high frequency in narcoleptic patients. However, this test alone is not sufficient for diagnosis, since many affected patients do not have this marker and about 25% of non-narcoleptic patients do have this marker. This test is most useful in atypical cases or in patients with suspected narcolepsy without cataplexy.
3. **What is required to perform this test?** You will be asked to provide 5 mL of blood, which is equal to about one teaspoon. DNA will be extracted from this blood sample and tested. The only discomfort that you may feel is the stick of the needle in your arm. You may also experience a small bruise at the site of the needle puncture. In the unlikely event that you should be injured in the course of being tested, your physician will provide any necessary medical care. However, you would be expected to bear the cost of such medical care. Compensation will not be provided in the event of any injury.
4. **Is there a cost for this test?** This is a routine clinical laboratory test and the results may aid in your diagnosis; thus, you or your health insurer will be billed for this procedure.
5. **What will happen to the DNA once the test is complete?** The only testing that will be performed on this sample is the test for 2 specific HLA alleles. In most cases, the original blood sample will be discarded at the end of the testing process or not more than 60 days. The DNA will be retained for a minimum of 6 months. In some circumstances, a patient DNA may be used as a control sample in future testing, but, in this event, all identifiers will be removed and your DNA sample will be anonymized.
6. **How will I obtain results from this test?** DNA testing and interpretation of results are complex. The information from this test will be provided in the form of a written report to your physician who will inform you of the results. The laboratory will not provide results directly to patients. Your physician may recommend follow up genetic counseling. To the extent permitted by law, all of your laboratory records and results are confidential and shall not be disclosed without your written authorization.

My signature below indicates that I have received information about this test and that I have read and understood the material in this document. I have been given a full opportunity to ask questions that I may have about the testing procedure and related issues. I agree to undergo this testing.

Date

Patient Signature

Name of Parent/Guardian

Signature of Parent/Guardian if Patient is a minor

For the Physician: As the referring physician, I understand the benefits and limitations of this study and have requested that the above named patient be tested. I attest to the fact that I have provided the patient with the information contained above and answered any questions fully. I believe that the patient understands the information and is signing this informed consent voluntarily.

Printed Name of Physician/
Health Care Professional

Signature of Physician/
Health Care Professional