UPSTATE
UNIVERSITY HOSPITAL

AUTHORIZATION FOR THE GENETIC TEST FOR HEREDITARY HEMOCHROMATOSIS

Patient Name: _____ MR#: _____

Account #: _____ DOB: _____ Date: _____

Hereditary Hemochromatosis (HH) is an inherited disease that results from the accumulation of iron in organs and eventually, if untreated, in serious illness (organ failure). If diagnosed early enough it can be treated. Everyone has two copies of the hemochromatosis gene (HFE). An individual may have two normal copies, two abnormal copies or one normal and one abnormal copy. Two abnormal copies have been found in the majority but not all individuals with HH. This tes will detect the presence of two specific mutations (changes) in the HFE gene that have been associated with a diagnosis of HH. These mutations are referred to as C282Y and H63D.

Molecular Test for Hereditary Hemochromatosis You will be required to donate 10 mL of blood, which is equal to abou two teaspoons. In addition, you may be asked to provide information regarding your medical history. A correct history is critical for proper interpretation of the data. This is a routine clinical laboratory test and the results from it may aid in diagnosis, so you or your health insurer will be billed for the procedure.

Significance of the Results If the HFE mutations tested for are found by the testing procedure, you may be predisposed to or may have, hereditary hemochromatosis. The significance of the results of this test will depend on which mutations are found and what other risk factors or symptoms are also present. For example, the finding of two mutations in an individual with symptoms is highly suggestive of HH, but the finding of only one mutation in an individual without symptoms if o uncertain significance. **A positive result by itself should not be used as the sole criteria for diagnosis.** Rare (less than 1% of the time) errors may occur, for example due to sample mix-ups, or due to technical errors such as rare genetic variants that mimic or mask mutations being tested. **To understand your results, you should consult your physician and may wish to consider further independent testing or pursue genetic counseling.**

Limitations The C282Y and H63D mutations of the HFE gene are the only genetic variations that will be tested for. If these mutations are not found by the testing procedure, it does not rule out the possibility that other mutations of the HFE gene could be present. Furthermore, the absence of these two mutations does not mean that the risk of carrying or developing HH is not present. It is also possible that you may have secondary hemochromatosis, due to non-hereditary causes, which would not be detected by this test.

Results from the test The test result will be provided to health care professionals directly involved with your care. Genetic counseling may also be appropriate as follow up. To the extent permitted by law, all of the records, findings, and results of this test are confidential and shall not be disclosed without your written consent specifically authorizing to whon such records, findings, and results are to be released. In accordance with NYS law, any remaining DNA will be discarded unless it is retained as a laboratory control, in which case all information identifying the DNA to you will be removed.

(continued on pg. 2)

I have read this entire document and understand its contents. In addition, I understand that I am free to withdraw any portion of my consent by crossing off and initialing unacceptable statements. Please note that crossing off the laboratory's option to bill for the testing will result in the testing being cancelled.

If you have any questions about the test to be performed, you may also wish to obtain genetic counseling prior to signing this form. You may also contact the Molecular Diagnostics Laboratory at (315) 464-6806.

Patient's Name (printed): _____ Patient's Medical Record Number: _____
(for office use only)

For the Patient:
Please print the name, phone number, and address (if known) of all health care professionals, physicians (other than the referring physician), or other individuals/organizations (such as a health insurer) to whom you authorize the release of the Hereditary Hemochromatosis test result. (Medical results cannot be sent to a patient, a patient's family member or guardian.) Please print legibly.

Name and Title	Address	Phone Number
_____	_____	_____
_____	_____	_____
_____	_____	_____

My signature below indicates that the above information has been explained to me and that I give consent for this Hereditary Hemochromatosis testing. **I hereby authorize SUNY Upstate Medical University to furnish my designated insurance carrier the information on this form if necessary for reimbursement. I also authorize benefits to be payable to SUNY Upstate Medical University. I understand that I am responsible for any amount not paid by insurance for reasons including, but not limited to, non-covered and non-authorized services. I permit a copy of this authorization to be used in place of the original.**

Date: _____ Signature of Patient: _____

Name of Parent/Guardian: _____

Signature of Parent/Guardian if patient is a minor: _____

As referring physician/health care professional, I understand the benefits and limitations of this clinical assay. I hereby attest to the fact that I have provided the patient or patient's guardian with the information contained above in compliance with the NYS Civil Rights Act, Section 79-l, have answered any questions fully, and have obtained a signed informed consent as appropriate.
I request that the above indicated genetic test be performed.

Signature of Physician/Health Care Professional: _____

Printed Name/Stamp/Title: _____ Date/Time: _____