UPSTATE
UNIVERSITY HOSPITAL

AUTHORIZATION FOR THE GENETIC TEST FOR FACTOR V (LEIDEN AND D2194G) AND PROTHROMBIN 20210G>A

Patient Name: _____ MR#: _____

Account #: _____ DOB: _____ Date: _____

Thrombosis Venous thrombosis is abnormal clotting of blood within the veins of the body. Normal clotting of blood occurs when blood components, called coagulation factors, are "turned on." When adequate clotting has taken place, the coagulation factors must be "turned off." Too much clotting can lead to the formation of clots (thrombosis) and blockage of blood vessels, and this in turn results in an increased risk of stroke or heart attack. Two of the coagulation factors that play an important role in normal regulation of blood clotting are Factor V and Prothrombin (F2). There are two copies each of the Factor V gene and Prothrombin (F2) gene in an individual's cells. At present, two genetic variations (mutations) at Factor V (**Factor V Leiden** and **Factor V D2194G**) and one at Prothrombin (**Prothrombin (20210G>A)**) have been identified. These abnormal variants can fail to function normally to stop the blood from clotting, thus resulting in an increased risk of venous thrombosis (presence of a blood clot in the circulatory system). In the case of the Factor V D2194G mutation, an increased risk of thrombosis primarily occurs in people who also carry a Factor V Leiden mutation. For this reason, we will only test for the Factor V D2194G mutation in individuals that are heterozygous for Factor V Leiden.

Approximately 1 in 10 people have one normal copy of the Factor V gene and one copy of either of the **Factor V Leiden** or **Factor V D2194G** mutations. Some people have two copies of the abnormal Factor V Leiden mutation. **Prothrombin (20210G>A)** is less common, being found only in about 1% of the general population and 18% of patients with a family history of venous thrombosis.

Molecular Test for Thrombosis You will be required to donate 10 mL of blood, which is equal to about 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 may aid in diagnosis, so you or your health insurer will be billed for the procedure.

Significance of the Results If the Factor V and/or Prothrombin mutations tested for are found by the testing procedure, you may be predisposed to venous thrombosis. The significance of the results will depend on which mutations are found and what other inherited or acquired risk factors or symptoms are also present. **A positive result by itself should not be used as the sole criteria for determining risk.** 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 the mutation 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 Factor V Leiden, Factor V D2194G and Prothrombin (20210G>A) mutations are the only genetic variations that will be tested for. Other abnormalities of the Factor V gene, the Prothrombin gene, or other risk factors associated with developing a thrombosis will not be detected with this testing. If these mutations are not found, it does not mean that the risk of developing venous thrombosis is not present. Venous thrombosis due to non-hereditary causes will not be detected with this testing.

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 whom 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)

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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 Factor V/Prothrombin 20120G>A test results. (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 Factor V 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: _____