

**AUTHORIZATION FOR  
FACTOR V (LEIDEN, R506Q)  
AND/OR PROTHROMBIN (G20210A)  
GENETIC TESTING**

Patient Name: \_\_\_\_\_ MR#: \_\_\_\_\_

Account #: \_\_\_\_\_ DOB: \_\_\_\_\_ Date: \_\_\_\_\_

**Venous thrombosis** is the presence of abnormal blood clotting within the veins of the body. Normal clotting occurs when blood coagulation factors are activated to stop bleeding. When sufficient clotting has occurred, the coagulation factors must be deactivated. Too much clotting leads to venous thrombosis that blocks blood flow resulting in an increased risk of stroke or heart attack. Two coagulation factors that regulate normal blood clotting are Factor V (FV) and Prothrombin (F2). There are two copies each of the Factor V and Prothrombin genes in an individual. Genetic mutations occurring in the FV and F2 genes increase the risk for over clotting. At present, one genetic mutation in the **Factor V Leiden R506Q** (also known as p.Arg534Gln) and one in the Prothrombin gene **G20210A (also known as c.\*97G>A)** have been identified. These abnormal variants can fail to function normally to stop the blood from clotting, and result in an increased risk of venous thrombosis.

Approximately 1 in 10 people have one normal copy of the Factor V gene and one copy of the **Factor V Leiden** mutation (R506Q). Some people have two copies of the abnormal Factor V Leiden mutation. **Prothrombin G20210A** is less common, being found 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 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 are found, 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 only reason for determining risk.** Rare errors may occur, for example due to sample mix-ups, or technical errors such as 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 R506Q and Prothrombin G20210A mutations are the only genetic variations that will be tested. 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, the risk of developing venous thrombosis is reduced but not eliminated. Venous thrombosis due to non-hereditary causes will not be detected with this testing.

**Test Results** Results will be provided to the ordering health care provider. Genetic counseling may also be appropriate as follow up. To the extent permitted by law, all of the records, findings, and results of these tests are confidential and shall not be disclosed without your written consent authorizing to whom such records, findings, and results are to be released. In accordance with NYS Civil Rights Law (section 79-L), any remaining sample will be discarded after the testing process or 60 days after study in the lab.

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.

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Patient's Name: \_\_\_\_\_ Account #: \_\_\_\_\_ MR#: \_\_\_\_\_

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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 Leiden R506Q/Prothrombin G20120A 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 Molecular 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: \_\_\_\_\_