MG2C551

Stony Brook Medicine

INFORMED CONSENT FACTOR V LEIDEN TESTING

1. **General description of the test and its purpose**
   This assay is a blood test that tells us if you have a change, or not, in a gene involved in blood clotting. Certain parts of DNA in the clotting Factor V gene (F5), such as Factor V Leiden, can cause an increased risk of venous thrombosis (clots forming in veins). One tube of blood (5-10 ml = 1-2 tsp) will be drawn for the test. DNA, the genetic material in your cells, will be prepared from the blood. The DNA will then be tested for the Factor V Leiden variant.

2. **Benefits of the test**
   If you have had a clot (thrombosis), this test may help your doctor be able to tell the cause. If you test positive for the Factor V Leiden variant, your doctor may be able to suggest steps to lower the risk of getting thrombosis (clot) in the future. This test is highly accurate; however, rare errors can occur due to testing problems. Your doctor will base their diagnosis on this and other tests. You may wish to obtain professional genetic counseling prior to signing the informed consent.

3. **Disclosure of results**
   The result of this test will be reported to your doctor. It will become part of your medical record. Under New York State Public Health Law the results from this test are confidential and may only be given to you or a person authorized or approved by law who consented to the test for you; to a person whom you have specifically authorized by signing a written release; to a health care facility (hospital or clinical laboratory) or a health care provider who needs the information to provide health care for you.

4. **Other tests**
   No other genetic test will be performed on your sample without separate written consent. The purified DNA will be stored in the laboratory until the test is completed, but no longer than 60 days. After that time, the leftover sample will be safely disposed of. If you have questions about confidentiality you may contact the New York Division of Human Rights at 1-888-392-3644.

Documentation of Interpreting Services and/or Special Assistance

An interpreter was used to obtain consent from this patient as follows:

☐ Qualified SBUH Medical Interpreter Name or Vendor Interpreter ID #: _____

☐ Special Assistance (Describe assistance provided): _____

☐ Patient Declined Interpreting Services

Reason why: _____

Qualified SBUH Medical Interpreter Name or Vendor Interpreter ID# Used to Obtain Declination: _____

Acknowledgment / Approval

If I have any questions regarding Factor V Leiden variant analysis, I will ask the doctor, medical geneticist or genetic counselor who referred me for this testing.

I have read the above information and have had the chance to have my questions answered. I consent to taking the test for Factor V Leiden variant.

Print Name of Patient	Patient Signature	Date	Time

If signed by someone other than patient,

Signature	Relationship to the Patient

Witness	Date	Time

I have read the above information to the patient, and am available to answer questions.

LIP Signature	ID#	Date	Time