WESTCHESTER MEDICAL CENTER
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Informed Consent for Thrombophilia Genetic Testing

IF NO LABEL, PRINT PATIENT'S LAST, FIRST NAME, MR NO., GENDER, ROOM, DOB

I hereby give my consent and authorize Westchester Medical Center to perform genetic testing to diagnose a genetic predisposition to Thromobphilia. A phlebotomist will take 1 vial of blood, which will be tested by a NY State approved laboratory.

1. I am consenting to genetic (DNA-based) tests for specific mutations in two genes: Factor V ("Factor V Leiden mutation") and Prothrombin ("20210G>A" mutation), using methods that can distinguish different DNA sequences.

2. I understand that the purpose of this analysis is to test for an inherited predisposition to increased clotting. I have been advised that I (or the person for whom I am signing) may want to obtain professional genetic counseling prior to signing this informed consent. I have obtained that counseling or have decided, after a reasonable opportunity to do so, to forgo genetic counseling.

3. I understand that I am consenting to a test for genetic susceptibility ("genetic predisposition") for Thrombophilia, however, the risk of actually having a clotting disorder depends upon other genetic factors, and on environmental conditions. If either test is positive, I understand that I (or the person for whom I am signing) may wish to have further independent testing, consult with a physician or have genetic counseling.

4. The condition I am consenting to being tested for is hereditary Thrombophilia. I understand that hereditary Thromobphilia could lead to formation of blood clots, and also a possible increase in pregnancy complications because of clotting in the placenta, umbilical cord or the fetus.

5. The following has been explained to me:

Each gene has two chromosomes. A mutation in one chromosome of Factor V gene is associated with a 3 to 7-fold increase in risk of developing a clotting disorder during one's lifetime; mutations in both chromosomes of Factor V gene is associated with a 18 to 80-fold increase in the risk of developing a clotting disorder. A mutation in one chromosome of Prothrombin gene is associated with 2 to 4-fold increase in risk of developing a clotting disorder; mutations in both chromosomes of Prothrombin gene are associated with even higher risk, although the magnitude is not well defined. If mutations in one chromosome of both genes are found ("double mutations"), there is a 20- to 60-fold increase in risk of developing a clotting disorder. If no mutation is found, there is no increased risk of clotting due to these two genetic mutations, but I (or the person for whom I am signing) may still have an increased risk of clotting due to mutations in other genes that control clotting. I (or the person for whom I am signing) may want to discuss these and other issues with a physician.

6. I understand that the results of the above test become a part of my (or the person for whom I am signing) medical record, and may be made available to individuals/organizations with legal access to the medical record, including, but not limited to the physicians and nursing staff directly involved in my (or the person from whom I am signing) care, my (or the person for whom I am signing) current and future insurance carriers for the purpose of claims administration, and others specifically authorized by me or the patient/authorized representative to gain access to the medical records.

7. No additional tests will be performed on this sample, without specific, signed authorization by the patient. After 60 days, unless consent is given the sample will be destroyed. However, additional genetic testing may be performed on a given sample without my additional Consent provided such testing is necessary and required to demonstrate the integrity of the sample tested or to resolve the analysis of a test with a previously indeterminate result.

8. Medicare/Insurance Carriers may not pay for the test, in which case, the patient/responsible party will be billed for the test.

Name of Person Obtaining Consent: _____ **Title:** _____

Signature: _____ **Date:** _____

YES: I have read and fully understood the above, and give my consent for testing.

Patient (parent or legally authorized representative) name:_____ **Relationship:** _____

Signature:_____ **Date:** _____ **Witnessed by:**_____

NO: I DECLINE to have above described tests performed. I understand and accept the consequences of this decision.

Signature:_____ **Date:** _____ **Witnessed by:**_____