Laboratory of Personalized Genomic
Department of Pathology and Cell Biology

COLUMBIA UNIVERSITY MEDICAL CENTER

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Informed Consent for Thrombophilia Risk Panel Testing *Must be filled out completely.*

PATIENT INFO	LAST NAME	FIRST NAME	M.I.	DATE OF BIRTH (MM/DD/YY)	MRN	SEX
						□ MALE □ FEMALE

Please read the following form carefully and discuss with your ordering physician/genetic counselor before signing consent.

1. The genetic (DNA-based) tests for specific mutations in two genes: Factor V ("Factor V Leiden mutation") and Prothrombin ("20210G>A" mutation), using PCR-restriction fragment length polymorphisms.
2. The purpose of this analysis is to test for an inherited predisposition to increased clotting.

2a. You (or the person for whom you are signing) may want genetic counseling before signing consent.

3. This is a test for genetic susceptibility ("genetic predisposition"), the risk of actually having a clotting disorder depends upon other genetic factors, and on environmental conditions. If either test is positive, you may wish to have further independent testing, consult your physician or have genetic counseling.
4. The condition being tested for is hereditary thrombophilia, which could lead to formation of clots in veins, and also a possible increase in pregnancy complications because of clotting in the placenta.
5. For each of the above tests, a mutation in one copy of the gene is associated with a 3 to 7 –fold increase in risk of developing clotting disorder during one's lifetime; if both copies of either gene are mutated, there is a very high (unquantified) likelihood of developing a severe clotting disorder, without treatment. If a mutation f one copy of both genes is found, there is a greater (unquantified) risk of having a clotting disorder, than when only one gene is mutated. If no mutation is found, there is no increased risk of clotting due to these two genes, but may still have an increased risk of clotting due to mutations in other genes that control clotting. The patient may want to discuss these and other issues with his/her physician.
6. The results of the above test become a part of the patient's medical record, and may be made available to individuals/organizations with legal access to the patient's medical record, on a strict "need-to-know" basis, including but not limited to the physicians and nursing staff directly involved in the patient's care, the patient's current and future insurance carriers, and other specifically authorized by the patient/authorized representative to gain access to the patient's 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 – please see below.
8. Medicare/Insurance Carriers may not pay for the test, in which case, the patient/responsible party will be billed for the test.

Person obtaining consent:

_____ _____ **Date:** _____
Print Name of Person Obtaining Consent Signature of Person Obtaining Consent

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

Patient (person being tested):

_____ _____ **Date:** _____
Print Name of Patient/Authorized Representative Signature of Patient/Authorized Representative

Relationship to Patient: _____

☐ _____ My specimen may be used for routine laboratory use only. After 60 days, unless consent is given, the sample will be destroyed.