Laboratory of Personalized Genomic
Department of Pathology and Cell Biology

COLUMBIA UNIVERSITY MEDICAL CENTER

630 West 168th Street
P&S 11th Floor, Room 453
New York, NY 10032
Tel: 212-305-9706
Fax: 212-342-0420

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. These are genetic (DNA-based) tests for specific mutations in one or more of the following genes: Factor V ("Factor V Leiden mutation") and Prothrombin ("20210G>A" mutation)

2. The purpose of this analysis is to test for an inherited risk to increased clots in veins, arteries, or the placenta.

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

4. 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.

5. 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.

6. If one copy of a Factor V Leiden mutation is found, you have a 2- to 7-fold increased risk of blood clots; if two copies are found this risk is 25 times higher than the general population. If one or two copies of the Factor II mutation are found, you have an (unquantified) increased risk of clotting. A mutation in both genes carries a greater risk (also unquantified). If no mutation is found, there is no increased risk of clotting due to these genes, but you may still have an increased risk of clotting due to mutations in other genes that control clotting. You may want to discuss these and other issues with your physician.
   A negative result means that you do not have these risk factors, but *you could have other risk factors.*

7. 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 others specifically authorized by the patient/authorized representative to gain access to the patient's medical records. Columbia University, NewYork-Presbyterian and Weill Cornell Medicine and their related entities participate in an Organized Health Care Arrangement (OHCA). This allows us to share health information to carry out treatment, payment and our joint health care operations, including integrated information system management, health information exchange, financial and billing services, insurance services, insurance, quality improvement, and risk management activities. Organizations that will follow this Notice include Columbia University, NewYork-Presbyterian sites, Weill Cornell Medicine and their related entities.

8. 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.

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

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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: _____

☐ _____ I allow my specimen to be de-identified and kept longer than 60 days for laboratory use.

Person obtaining consent:

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