

College of Physicians & Surgeons of Columbia University | New York, N.Y. 10032

DEPARTMENT OF PATHOLOGY MOLECULAR PATHOLOGY LABORATORY  
ROOM: VC14-236; PHONE: 212-305-9706 FAX: 212-305-2301

630 West 168th Street

**REQUEST FOR MOLECULAR GENETIC TESTING FOR FACTOR V LEIDEN AND FACTOR II G20210A (Must be completely filled out; informed consent MUST be signed by patient, parent/legal guardian or legal next of kin).**

PATIENT NAME: \_\_\_\_\_ CPMC UNIT NO. \_\_\_\_\_ Date Collected: \_\_\_\_\_

REASON FOR TESTING (REQUIRED): \_\_\_\_\_

Type of Specimen: (Whole blood collected in EDTA/Citrate delivered within 24-48 hours to Molecular Pathology Laboratory preferred. Please contact lab directly for other specimens).

REQUESTING PHYSICIAN: \_\_\_\_\_ PHYSICIAN ADDRESS: \_\_\_\_\_

DATE: \_\_\_\_\_ PHYSICIAN TEL NO: \_\_\_\_\_

In accordance with New York State Law, the following has been discussed with the patient/legal guardian and informed consent obtained. The following was signed in my presence.

Name of Person Obtaining Consent \_\_\_\_\_ Title: \_\_\_\_\_  
Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Informed Consent/Advance Beneficiary Notice: Please read the following carefully and discuss with your ordering physician/person obtaining consent before signing consent.**

1. The tests ordered above are genetic (DNA-based) tests for mutations in two clotting factors, Factor V (Factor V Leiden mutation) and Factor II (Factor II G20210A variant).
2. These tests are performed to detect an inherited susceptibility to increased clotting.
3. Since these tests are for an inherited susceptibility to clotting, the patient and/or legal guardian might wish to obtain genetic counseling prior to signing this consent form. If so, please discuss this with the ordering physician.
4. A positive result for each of the above tests signifies an increased risk for developing blood clots in the circulation, either spontaneously, or in high-risk settings such as surgery, prolonged rest, pregnancy, contraceptive use etc. For each of the above tests, a mutation in one of the two copies of the gene carries a 3-5 fold increase in risk, while a mutation of both copies of the gene, carry a much higher risk for clotting.
5. Although a negative test for each of the above mutations means that the specific inherited condition associated with an increased tendency to clotting is not present, a number of other inherited and acquired conditions are associated with an increased risk for clotting, and are not tested-for by the above tests. These and other issues may be discussed with the ordering physician and/or genetic counselor.
6. The results of the above tests 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.
7. No tests other than the tests specifically authorized above will be performed on this sample, unless specifically authorized by the patient by signing another informed consent within sixty days of this test request. After 60 days, the sample will either be destroyed, or unlinked from all patient information and used as a laboratory control.
8. Because the above tests are considered investigational by New York State, Medicare/Insurance Carriers may not pay for the testing, in which case, the patient/responsible party will be billed for the test.
9. I have read and fully understood the above.

Name: \_\_\_\_\_ Relationship to Patient: \_\_\_\_\_  
Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Insurance Co: \_\_\_\_\_ Plan No. \_\_\_\_\_

Member I.D./Beneficiary #: \_\_\_\_\_ Address: \_\_\_\_\_

**To be filled in by Lab only.** MG Number: \_\_\_\_\_ Date/Time Received: \_\_\_\_\_  
Preliminary interpretation. Factor V: \_\_\_\_\_ Factor II: \_\_\_\_\_ PCR#: \_\_\_\_\_  
Discard date: \_\_\_\_\_