Molecular Hemostaseology Diagnostic Order

Patient Information (sticker or written)

_____
Last Name, First Name

_____
Street Address

_____
City, State, Postal Code, Country

Please send to:

Prof. Dr. med. J. Oldenburg
Email: johannes.oldenburg@ukb.uni-bonn.de
Inst. of Exper. Hematology & Transfusion Med.
University Clinic Bonn
Sigmund-Freud-Str. 25
53127 Bonn
Germany

Lab Tel.: **+49-228-287-19429**
Lab Fax: **+49-228-287-14783**
Email: **molhaem@ukb.uni-bonn.de**

The primary attending physician or clinic is required to obtain the patient's or responsible relative's informed, written consent according to the Declaration of Helsinki (4th Revision, 1996, recognized by the European Commision; 6th Revision, 2008) and is required to review the individual points of the permission for Genetic Testing (reverse side of this form) with the patient or responsible relative prior to signing this form and obtaining a blood specimen.

Ordered Tests (please check off) **Please attach relevant clinical data & laboratory results**

Procoagulation Factors
- ☐ Fibrinogen, FGA, FGB, FGG
- ☐ Factor II, F2
- ☐ Factor V, F5
- ☐ Factor VII, F7
- ☐ Factor VIII, F8 (Hemophilia A
- ☐ Factor IX, F9 (Hemophilia B)
- ☐ Factor X, F10
- ☐ Factor XI, F11
- ☐ Factor XII, F12
- ☐ Factor XIII, F13A, F13B
- ☐ von Willebrand Factor, vWF
- ☐ von Willebrand Factor – type Normandie, vWF2N

Further Genes
- ☐ VKORC1, GGCX (congenital deficiencies in FII, FVII, FIX, FX, PS, PC; VKCFD)
- ☐ LMAN1, MCFD2 (combined FV/FVIII deficiency)
- ☐ Kininogen, KNG
- ☐ Prekallikrein, KLKB1
- ☐ ADAMTS13
- ☐ other molecular genetic investigation (upon prior consultation only)

Thrombophilia
- ☐ Protein C, PROC
- ☐ Protein S, PROS
- ☐ Antithrombin, SERPINC1
- ☐ Protein C Receptor, PROCR (EPCR)
- ☐ F5 Leiden / HR2 haplotype
- ☐ Prothrombin gene G20210A mutation
- ☐ PAI1
- ☐ JAK2 / Calreticulin / Thrombopoetin receptor (MPN)
- ☐ MTHFR

Pharmacogenetics
- ☐ VKORC1, CYP2C9, CYP4F2; coumarin resistance
- ☐ VKORC1, CYP2C9, CYP4F, F9 exon 2; coumarin sensitivity

Blood specimen requirements: 3 mL EDTA-whole blood (lesser volume, citrate-blood or DNA upon prior consultation only). Transport at room temperature.

Detailed clinical information: Degree of severity, % activity, etc.; please attach additional sheets as required)

_____
Name of attending physician (please print)

_____
Email address, International Telphone number

_____
Signature of attending physician

_____
Date, City, Country

DAkkS Deutsche Akkreditierungsstelle

The Laboratory of Molecular Hemostaseology of the Institute of Experimental Hematology & Transfusion Medicine, University Clinic Bonn, is accredited according to ISO 15189 and certified according to ISO 9001

Permission for Genetic Testing

_____ _____ _____

Patient's Last Name First Name Date of Birth

Please indicate below how your blood sample and test results may be used. Your physician will read aloud and, if requested, expaln each of the points below, to which you should circle either "yes" or "no" to indicate your choice.

I agree to have a **blood sample taken** from me or from my child and **genetically tested** for mutations in the _____ gene. I have been duly and throroughly informed concerning the genetic basis of blood clotting diseases, about possibilities for preventing, avoiding or treating such diseases, as well as about the purpose, type, breadth and predicitve/diagnostic utility of the planned tests, together with the possible risks concerning drawing of blood samples. All of my questions have been answered by my attending physician/clinician.	YES	NO
I agree that my genetic test results will be communicated **to my local attending physician**: Dr. _____ _____	YES	NO
I request to be personally informed about the results of my genetic tests.	YES	NO
The tests will be carried out in a medical laboratory in Germany. German law currently requires that **patient samples and data** be destroyed at the latest after 10 years or earlier if requested by the patient. However, you may instead request the samples and data be kept for a longer or indefinite period of time – for example, stored samples can be used at a later time for comparisons in case further genetic testing of the patient's family members is desired. Also, anonymous patient samples can be used for ongoing basic scientific and medical research in order to better understand how genetic diseases arise and how to better prevent or treat them. Therefore, I agree to have **my blood sample and patient data** and kept beyond the period required to complete the presently ordered molecular genetic tests in order to repeat and verify my test results, as well as to serve as a control sample for any future genetic testing of my family members.	YES	NO
Blood samples for genetic anlysis are essential as **scientific quality controls** for tests performed in our diagnostic laboratory. Therefore, I agree that my blood sample be stored and used **for scientific quality control purposes**. I understand that my personal identifying information (name, address, etc.) will be removed from my blood sample for this purpose – in other words, my sample will be used anonymously for scientific quality control purposes.	YES	NO
I agree that if my test results do not result in positive identification of a genetic mutation that is responsible for my blood clotting deficiency, that additional test will be conducted in order to establish the cause and possible genetic basis of my blood clotting deficiency.	YES	NO
I agree to allowing my blood sample to be tested for new genetic factors affecting blood clotting that may be discovered in the future.	YES	NO
I request that I be directly contacted and informed of any future test results concerning new genetic factors affecting blood clotting that may be discovered in the future.	YES	NO
After completing the presently ordered medical diagnostic tests, I consent to having my results analyzed in anonymous form (pseudonymized form) by the Institute of Experimental Hematology & Transfusion Medicine, University Clinic Bonn, in Germany, for the purposes of scientific research concerning genotype/phenotype associatiions for patients with inheritable blood clotting disorders/diseases	YES	NO

Each of the above responses to my Permission for Genetic Testing can be changed by me without my having to give a reason. I am aware that I can call off and stop the testing procedure and have my samples, patient data and pending test results destroyed.

_____ _____

Signature of Patient or Responsible Relative Date, City, Country