Information and Consent

FB-PÄ 19

Labor für Leukämiediagnostik
Med. Klinik und Poliklinik III
Marchioninistr. 15
81377 München
Tel: 089 – 4400 7 4977
Fax: 089 – 4400 7 4978

To be sent enclosed with samples

Patient Information Routine Diagnostics for Immunophenotypical and Genetic Analyses

Your physician has informed you about a suspected blood or bone marrow (hematological) disease. To enable a reliable diagnosis, samples of your blood, bone marrow or other tissue have been taken and sent to the Laboratory for Leukemia diagnostics (see above). Depending on the suspected diagnosis and the findings obtained by additional analyses, it might be necessary to analyze proteins and nucleic acids to support the diagnosis. This material will be isolated from the samples taken from you and will be examined for disease-specific alterations.

Molecular genetic examinations are aimed at identifying or excluding alterations of the genetic material which in your case were presumably caused by a somatic disorder.

Cytogenetic investigations (chromosome analyses) are used to analyze of the number or structure of the chromosomes. Structural chromosome alterations are only identifiable to the extent the quality of the specimen so permits. This might limit the interpretation of the chromosome analyses.

Basically, all investigation techniques may produce results that are not directly related to the? malignant disease, but which may be of medical relevance for yourself or your family (so-called incidental findings). In this case, your treating physician shall offer you genetic counseling according to the German Genetic Diagnostics Act (GenDG).
You or your family members always have the option of obtaining human genetics counselling. We would be happy to assistance you in this respect.

Patient Information about Storage of Samples

Diagnostic examination frequently requires only part of the samples for the necessary investigations. To ensure the legally prescribed verifiability of results, residual material has to be stored for a period of at least 10 years.

The material may be an important research and development tool in the field of medical genetics and diagnostics. You are kindly requested therefore to give your consent to your sample material being used in current[1] and future scientific investigations. Please be informed that you will probably not be able to directly benefit from these studies.

In the case of medical-scientific investigations and analyses – possibly via transfer to or in collaboration with medical-scientific cooperation partners – your data and your samples will be exclusively used in pseudonymized form. This means that your data and samples will be encoded to prevent third parties from drawing conclusions as to your identity.

All research studies will be conducted in conformity with German confidentiality laws and data protection provisions in medical research. All your personal data and medical findings will be stored and passed on in encoded and pseudonymized form – which means that neither your name nor your initials or date of birth will appear in the encryption code. Only the following persons are allowed access to the original data and to the encryption code: the staff of Med. Klinik und Poliklinik III. The associated records will be kept in the Leukemia Diagnostics Laboratory, if necessary for a period exceeding the legally prescribed 10 years. The data will only be decoded in cases where this appears mandatory to warrant your personal safety ("medical reasons"). The confidentiality of your personal data will remain guaranteed whenever study results are published.

Should you withdraw your consent, the data already obtained from your samples may only be used in irreversibly anonymized form.

[1] Current studies: "MRD in acute and chronic Leukemias" (Dr. med. P. Greif, Prof. Dr. med. M. Subklewe, Prof Dr. med. K. Spiekermann); "Immunotherapy for acute Leukemias" (PD Dr. med. M. Subklewe); "Pathogenetic Mechanismen of acute Leukemias" (Prof. Dr. med. K. Spiekermann, PD Dr. med. I. Jeremias); "Identification and Evaluation of known and new markers in hematopoietic neoplasms" (Dr. hum biol. A. Dufour, Dr. P. Greif, Dr. rer. nat. S. Schneider, Prof. Dr. med. K. Spiekermann); "Targeted mutational analysis in acute Leukemias using new sequencing technologies" (Dr.med. K. Metzeler, Dr. med. T. Herold); „Molecular pathogenesis of malignant lymphomas" (Prof. Dr. med. M. Dreyling, PD Dr. med. O. Weigert) "Analyses of clonal heterogeneity and genetic evolution in AML" (Dr.med. K. Metzeler, M. Rothenberg-Thurley, PhD)

Declaration of Consent
To Immunophenotypical and Genetic Analyses

Patient : _____ _____ _____
Last Name First Name Date of birth

Please decide on how the samples taken from you may be used. After the questions mentioned below have been discussed with you in detail, please tick **and** sign this form. Your informing/treating doctor also needs to sign this form.

I wish to have the analyses conducted which my treating physician has recommended, if a clinical indication makes this necessary.	YES ☐
I agree that my personal data and material are sent to an external laboratory if an analysis is not possible at the Leukemia Diagnostics Laboratory of Med. Klinik III.	YES ☐
I give permission for **remaining sample material** to be utilized **in pseudonymized form** for research purposes after diagnostic testing is finished. This material will be used for laboratory-internal quality control and for **scientific investigations** intended to clarify the pathogenesis of your disease and/or to further develop diagnostic and therapeutic options in the future. I agree to storage of the sample material beyond the regulatory time period if this appears necessary. Following diagnostic examination, I consent to the results obtained being stored and evaluated in **pseudonymized** form for scientific purposes.	YES ☐

I am aware that, with effect for the future, I can withdraw my consent at any time and without giving any reason, and I understand that opting out will not affect my future medical care. In case of continued use of the samples taken from me I understand that confidentiality and anonymity will be maintained also in the future.

I am capable of voluntarily giving informed consent.

.....
Place and date

.....
Last name, first name of informing/treating doctor Signature

.....
Last name, first name of **patient**/ parent or legal guardian * Signature

* adolescents over 12 years are required to sign together with their parent or legal guardian