Consent for genetic testing using panel diagnostics

Patient details (use label):

Name _____ Given name _____

Date of birth _____ ☐ male ☐ female

Street _____

Post code _____ City _____

Please return to:

Zentrum Med. Genetik Würzburg
Biozentrum, Am Hubland
97074 Würzburg

Praxis für Humangenetik
PD Dr. med. Erdmute Kunstmann
Tel: 0931-3184435, Fax: 0931-45265859
E-Mail: kunstmann@biozentrum.uni-wuerzburg.de

Institut für Humangenetik, DNA-Labor
Tel: 0931-3184064, Fax: 0931-3184069
E-Mail: gmeng@biozentrum.uni-wuerzburg.de

The German gene testing act (GenDG) requires written informed consent to be obtained from every patient prior to genetic testing.

*Please read the following carefully, and tick **each** box, as appropriate*

I hereby consent to the analysis of my DNA or the DNA of my child by panel diagnostics for clarification of a putative **hereditary tumor disease**. I have been informed about its genetic basis, options for prevention and treatment and about the scope and aims of the planned genetic test, its predictive value and its limits. I have been further informed about the risk of the required blood / tissue sampling. All my questions have been answered to my satisfaction.	☐ yes
The application of such screening tests can result in incidental findings which are not associated with the above named disease. I wish to be informed of any such incidental findings.	☐ yes ☐ no
By German law, surplus genetic material (blood, DNA sample) must be destroyed after the completion of the genetic test. However, with my consent it may be stored and used for subsequent additional tests (if required) and/or as control for later testing of family members and relatives. I consent to storage and subsequent use of my genetic material for the above purposes.	☐ yes ☐ no
Internal quality control is an important tool to guarantee the accuracy and reliability of genetic testing methods. For this purpose, genetic material from patients with rare genetic variants is an indispensable control material. I consent to my DNA being stored and used for internal quality control in the laboratory. Before such use, my sample will be anonymised.	☐ yes ☐ no
Genetic material from patients is also important for studying biological mechanisms which contribute to the development of hereditary diseases. I consent to my DNA being stored and used for disease studies in the laboratory. Before such use, my sample will be anonymised.	☐ yes ☐ no
The German gene testing act requires genetic data to be stored for 10 years and then destroyed. With patient's consent they may be stored for longer. Often, genetic data are required for counselling of children and relatives even after 10 years' time . I consent to storage of my genetic data beyond the legal time-span and its use for my family only.	☐ yes ☐ no
As required the results may be used for the counselling / analysis of my relatives.	☐ yes ☐ no

Genetic data will be deposited in a database at the Institut für Humangenetik. All data will anonymised and only used for the purpose of quality control and data comparison.

I have been informed that I can withdraw my consent at any time without giving reason and without incurring any penalty. I have further been informed that I have the right not to know about my genetic test results and to terminate the testing procedure at any time. I can request my genetic material and my genetic data to be destroyed before result reporting, if I have changed my mind.

With my signature I consent to the genetic test(s) indicated above and the sampling of blood or tissue for this purpose.

_____ _____

City, date Signature of the patient or his/her legal representative

Source: http://www.humgen.biozentrum.uni-wuerzburg.de/diagnostik/formulare/

Order form for cancer panel sequencing

Zentrum Medizinische Genetik Würzburg, Biozentrum, Am Hubland, 97074 Würzburg

Patient details (use label):

Name

Given name

Date of birth

Relevant clinical patient and/or family data:

Information to anamnesis and other remarks:

Core genes (please tick boxes)

MATERIAL: 5-10 ml EDTA- blood. Please label tubes clearly, package in shatter-resistant packaging; ship at ambient temperature as soon as possible within one week

Cost coverage declaration (mandatory to fill in):

☐ **A signed agreement to cost coverage is enclosed**

Please send us a cost quote for an:

☐ **Invoice to patient (give details and address on reverse page)**

☐ **Invoice to referring institution**

☐ **Invoice by special agreement with Zentrum Medizinische Genetik Würzburg (to be obtained prior to testing)**

The invoicing process will be handled on our behalf by Ärztliche Verrechnungsstelle Büdingen e.V.

Information about the TruSight cancer panel:

The technology „Next generation sequencing" (NGS) allows the parallel analysis of numerous genes in a single approach permitting panel diagnostics.

The **TruSight cancer panel** (Illumina) targets **94 genes** which are associated with various hereditary tumor diseases.

According to the test order only the so called "core genes" diseases will be completely analyzed and reported. Further potentially cancer causing DNA variants will only be reported, if you have agreed to the reporting of incidental findings and their pathogenicity is well documented in the literature.

Please tick the boxes to specify the core genes.

The analysis will be performed by Illumina Nextera Capture and MiSeq technologies. Together with the report you will receive an overview of the analyzed genes and the achieved coverage.

The NGS technology covers only mutations, which are detectable by DNA sequencing. Other types of mutations like repeat expansions, large deletions and duplications and methylation deficiencies cannot be analyzed.

We are happy to answer further questions.

Contacts:
Dr. Gerhard Meng, tel: +49-931-31-84064 (cost information)
Dr. Andrea Gehrig, tel: +49-931-31-84090 (technical information)

☐ ***Hereditary breast and ovarian cancer (HBOC)***
ATM, BRCA1, BRCA2, CHEK2, PALB2, RAD51C, RAD51D, NBN, CDH1, TP53, PTEN

☐ ***Lynch syndrome (HNPCC)***
MLH1, MSH2, MSH6, PMS2

Further cancer panel genes:

AIP, ALK, APC, BAP1, BLM, BMPR1A, BRIP1, BUB1B, CDC73, CDK4, CDKN1C, CDKN2A, CEBPA, CEP57, CYLD, DDB2, DICER1, DIS3L2, EGFR, EPCAM, ERCC2, ERCC3, ERCC4, ERCC5, EXT1, EXT2, EZH2, FANCA, FANCB, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FANCM, FH, FLCN, GATA2, GPC3, HNF1A, HRAS, KIT, MAX, MEN1, MET, MUTYH, NF1, NF2, NSD1, PHOX2B, PMS1, PRF1, PRKAR1A, PTCH1, RB1, RECQL4, RET, RHBDF2, RUNX1, SBDS, SDHAF2, SDHB, SDHC, SDHD, SLX4, SMAD4, SMARCB1, STK11, SUFU, TMEM127,TSC1, TSC2, VHL,WRN, WT1, XPA, XPC

(Please mark the favored genes)

Samples taken (date): _____ by: _____

Physicians name (please print)

Date Physicians signature (Physicians stamp)

According to the German gene testing act written patient's consent is required for every genetic test (see overleaf)