Health Insurance

Surname, First Name

Date of birth

Health Insurance ID No. | Personal Insurance ID No. | Status

Business No. | Doctor's ID | Date

Doctor's stamp / clinic or barcode

Put barcode here!

0051002701

laborkrone

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Hereditary tumor syndrome consent form according to GenDG

Submitter Physician _____ Phone _____

Cost Unit ☐ Statutory health insurance (Please attach referral!) ☐ Privately insured ☐ Self-payer

☐ **Fast Track** (Duration approx. 15 working days from sample entry[1]), Reason (e.g., surgery appointment): _____

Patient information

Gender ☐ Female ☐ Male ☐ Diverse Ethnic origin _____

Type of investigation ☐ **Affected/Diagnostic** ☐ **Predictive/Carrier-screening**

For primarily predictive, please state reasons, e.g., index patient ☐ Not tested ☐ Deceased ☐ Findings of an index not available

Family Anamnesis _____

Medical history/ Indication _____

Genetic findings available? (Patient/relatives) ☐ No ☐ Yes (Please attach a barcoded document)

Transplantation (bone marrow, tissue, stem cells, blood) ☐ No ☐ Yes (Please specify) _____

Information on the desired analysis/requirement

2 EDTA sample tubes required

Mamma and Ovarian carcinoma

☐ **MAMMA1 prior to PARP inhibitor therapy**
Advanced, HER2/neu neg. Mamma-CA or high-grade epithel. Ov-CA (BRCA1, BRCA2)

☐ **MAMMA2, hereditary[2]**
(ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, PALB2, PTEN, RAD51C, RAD51D, STK11, TP53)

Lynch-syndrome (HNPCC) and Polyposis-syndrome

☐ **LYNCH1[3]**
(EPCAM, MLH1, MSH2, MSH6, PMS2)

☐ **LYNCH2[3]**
(MLH1, PMS2)

☐ **LYNCH3[3]**
(EPCAM, MSH2, MSH6)

☐ **POLYP1**
(APC)

☐ **POLYP2**
(APC, BMPR1A, GREM1, MSH3, MUTYH, NTHL1, POLD1, POLE, PTEN, SMAD4, STK11, TP53)

Pancreas carcinoma prior to PARP inhibitor therapy
metastasized, platinum-sensitive

☐ **PANKC1** (BRCA1, BRCA2)

Pancreas carcinoma, hereditary

☐ **PANKC2**
(ATM, APC, BRCA1, BRCA2, CDKN2A, EPCAM, MLH1, MSH2, MSH6, PALB2, PMS2, STK11, TP53)

Prostate carcinoma prior to PARP inhibitor therapy
metastasized, castration-resistent

☐ **PROSC1** (BRCA1, BRCA2)

Prostate carcinoma, hereditary

☐ **PROSC2**
(ATM, BRCA1, BRCA2, CHEK2, EPCAM, HOXB13, MLH1, MSH2, MSH6, PALB2, PMS2, RAD51D)

Uterus carcinoma, hereditary

☐ **UTERCA**
(EPCAM, MLH1, MSH2, MSH6, MUTYH, NTHL1, PMS2, PTEN, POLD1, POLE, STK11)

Stomach carcinoma, hereditary

☐ **GASTCA**
(BMPR1A, CDH1, EPCAM, MLH1, MSH2, MSH6, PMS2, SMAD4, STK11, TP53)

Familial mutation

☐ **FAMMUT**

Confirmation of findings

☐ **MUTVER**

_____
(Please state/attach previous findings)

Pharmacogenetics

☐ **DPYD-Variants (prior to 5-FU-Therapy)**

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[1] regular test duration approx. 6 weeks

[2,3] Indication criteria, see back page

please turn over →

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Business No. | Doctor's ID | Date

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Consent according to the German Genetic Diagnostic Act (GenDG)

Herewith in agreement with this consent form and completed consultation, I confirm that I had sufficient time to reconsider my desire to have the requested genetic analyses performed and the sampling material to be taken as required per the German Genetic Diagnostic Act (www.gesetze-im-internet.de/gendg/). I was informed in detail about the purpose of this examination, the disease to be examined and its genetic basis, as well as the possibilities and limits of the diagnostics to be carried out in my specific case. I consent to the report being sent to the requesting physician and to the physicians specified by me. I agree to:

- The **forwarding of the request contract**, if necessary, to a specialized cooperating laboratory ☐ No
- The **storing of results** for and exceeding the statutory period of 10 years ☐ No
- The **storing of material** for possible testing at a later stage ☐ No
- The **use of testing material** for the purpose of quality assurance and research ☐ No
- The **use of test results** for the purpose of advising and testing of family members ☐ No

Information about additional findings: In rare cases, medical findings, which are not related to the initial question can be received, but which have a treatment consequence for me or my family (following the recommendations of the ACMG).

I would like to be informed about such findings (as far as no choice has been made below, "no" is assumed)

☐ **Yes** ☐ **No**

This declaration of consent in accordance with GenDG is valid for me and for my child on its behalf, and may be revoked in parts or fully at any time.

Surname and First Name of informing physician | Place, Date | Signature of informing physician* | Signature of patient/Legal guardian

*In case of **predictive genetic testing**, I confirm as the attending physician that I have the nessessary qualification according to GenDG.

Indication criteria for patients of the statutory health insurance

[2] Hereditary Mamma and Ovarian carcinoma

According to the quality assurance agreement "molecular genetics", the indication for testing the genes BRCA1 and BRCA2 is only given, if **one of the following criteria** is met. Please check the boxes, where applicable:

- ☐ ≥ 3 women from the same family lineage had breast cancer, independent of age
- ☐ ≥ 2 women from the same family lineage, one of them younger than 51 years, had breast cancer
- ☐ ≥ 1 woman had breast cancer, aged younger than 36 years
- ☐ ≥ 1 woman had bilateral breast cancer (first diagnosed younger than 51 years)
- ☐ ≥ 2 women from the same family lineage had ovarian cancer
- ☐ ≥ 1 woman had breast cancer and 1 other woman had ovarian cancer or 1 woman had both breast and ovarian cancer
- ☐ ≥ 1 man had breast cancer and 1 woman had breast or ovarian cancer
- ☐ ≥ 1 woman had a triple-negative breast cancer (younger than 51 years)

[3] Lynch-syndrome (HNPCC)

According to the quality assurance agreement "molecular genetics", the indication for direct testing of MMR-genes (MLH1, MSH2, MSH6 and PMS2) without prior analysis of tumor tissue, is bound to the fulfillment of the **Amsterdam-II-criteria**.

All the following criteria must be fulfilled. Please check the boxes, where applicable:

- ☐ ≥ 3 family members with HNPCC-associated carcinoma (colon/rectum, endometrium, small intestine, renal pelvis/ureter)
- ☐ 1 of the relatives concerned is a first-degree relative of affected persons
- ☐ Diseases in at least 2 subsequent generations
- ☐ At least 1 person with carcinoma diagnosis before the age of 50
- ☐ Exclusion of familial adenomatous polyposis coli (FAP)

Alternatively the testing of the microsatellite instability and, if necessary, testing of MMR-genes – dependent on immunhistological stainings (MLH1 and PMS2 or MSH2 and MSH6) – is bound to the fulfillment of the **revised Bethesda-criteria**.

One criterion must be met. Please check the boxes, where applicable:

- ☐ Colorectal carcinoma, inital diagnosis before the age of 50
- ☐ Synchronous/metachronous colon-/rectum carcinomas or HNPCC-associated cancer diseases (endometrium, renal pelvis/ureter, small intestine, stomach, pancreas, ovaries, hepatobiliary system, brain (commonly glioblastomas), sebaceous gland adenomas and keratoacanthomas, independent of age
- ☐ Colorectal carcinoma with MSI-H-typical morphology, diagnosed before the age of 60
- ☐ Patient with colorectal carcinoma and at least 1 direct relative with a HNPCC-associated tumor, who was initially diagnosed before the age of 50
- ☐ Patient with colorectal carcinoma and at least 2 first- or second-degree relatives with HNPCC-associated tumors (see above), independent of the age of disease onset

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