Order Form CancerEssential®

General Information

Patient

Surname: _____

First name: _____

Date of birth: _____

Sex: ☐ male ☑ female

External ID: _____

Declaration of consent

By signing this form, I declare that I have received comprehensive information about the genetic background related to the disease in question, as well as the possibilities and limitations of molecular genetic testing. I understand that I have the right to withdraw my consent to genetic analyses.

I have been informed, and agree, that my personal data and the data obtained in the analysis will be recorded, evaluated or stored in an pseudonymised form in scientific databases, and further, in accordance with data protection and medical confidentiality, that the request, or parts thereof, may be transmitted to a specialized cooperating laboratory.

I consent to the re-evaluation of my test results within the data storage period. If significant alterations become apparent, my doctor will be informed by e-mail.

I have been informed, and agree, that all data collected by CeGaT GmbH is electronically stored, processed, used and transmitted.

For more detailed information on data privacy as well as your rights please refer to www.cegat.de/en/privacy-policy

Please Note

Our panels are regularly updated to reflect current scientific research. It should therefore be recognized that there is the possibility that the list of genes on the order form may have changed slightly (genes added or removed) by the time the sample is analyzed in the laboratory. By signing this form, the physican accepts that the list of genes actually analyzed may be slightly different from what is currently listed. When NGS is utilized more than the requested genes are sequenced for each sample.

This consent includes the permission to request tumor sample materials and reports from external sources.

This declaration of consent can be completely or partially withdrawn at any time. I have had sufficient time to consider giving my consent.

I, the referring physician, confirm that I am qualified to request genetic testing for the above-mentioned patient. For minors, I declare that I have the consent of all legal guardians.

If the patient did not sign this order form: I, the referring physician, confirm that the patient received genetic counseling and agrees with the genetic testing. The patient's consent has been obtained in writing.

Patient / Legal Guardian
(Block letters)

Doctor
(Surname, First name)

X _____
Patient / Legal Guardian
(Date, Signature)

X _____
Doctor
(Date, Signature)

Doctor's stamp / Barcode

Sender / Clinic

Surname: _____

First name: _____

Institution: _____

Street: _____

Postcode/City: _____

Country: _____

Phone: _____

Email: _____

VAT: _____

If applicable, please include a VAT number or a copy of your business registration certificate.

Invoice
☐ to sender / clinic
☐ to patient / other (KVA-No.: _____)

Surname: _____

First name: _____

Street: _____

Postcode/City: _____

Country: _____

Email: _____

If you do not check these boxes, your answer will be recorded as "No".

I consent to the storage of my genetic material for additional tests and/or quality control (for max. 10 years). ☐ Yes ☐ No

I consent to the storage of my test results beyond the timespan of 10 years (as required by German law). ☐ Yes ☐ No

I consent to the pseudonymous storage and use of surplus genetic material and/or test results for scientific research and in scientific literature. ☐ Yes ☐ No

With regard to secondary findings I would like to be informed: ☐ Yes ☐ No

Genetic variation may sometimes be identified, which does not fit within the scope of the requested genetic analysis (so-called secondary findings). The reporting of these variants is limited to pathogenic alterations (ACMG classes 4 and 5) within selected genes, for which a treatment or course of action exists for you or your family (according to the current guidelines of the American College of Medical Genetics and Genomics; details on genes and associated diseases can be found at https://www.cegat.com/acmg-genes/). There is no claim of a comprehensive analysis of this gene set. An absence of secondary findings cannot be used to indicate a reduced disease risk.

As part of this analysis we also examine germline changes present in leukocyte DNA. Even there is no known family history, it is possible that a clinically relevant germline variant is detected. This may be of relevance for the therapy, but possibly also for tumor follow-up, prevention or for at-risk family members. Therefore, we generally report clinically relevant germline variants (variants with therapeutic relevance or pathogenic/likely pathogenic variants only) in selected genes, unless explicitly contradicted. The results should be discussed as part of a genetic counseling.

According to German Genetic Diagnostic Act (GenDG) we will issue the medical report to the counselling physician. Please indicate here the contact email of the counselling physician:

Email: _____

DAkkS Deutsche Akkreditierungsstelle D-ML-13206-01-00

CAP ACCREDITED COLLEGE of AMERICAN PATHOLOGISTS CLIA CERTIFIED ID: 99D2130225

CeGaT is accredited by DAkkS according to DIN EN ISO 15189:2014, the College of American Pathologists (CAP) and CLIA.

Order Form CancerEssential®

Indication & Material

For targeted and effective processing, please complete the medical history form with as much detail as possible and include a copy of relevant medical reports.

Indication / Suspected diagnosis / Course of disease / Pedigree

❑ **Clinical report(s) added**

❑ **Laboratory report(s) of Pathology / Cytology / Cytogenetics / Flow Cytometry added**

Transplants (bone marrow, tissue, stem cells) ☐ No ☐ Yes, (please specify) _____

Tumor tissue (minimal tumor content 20%)

❑ FFPE (Formalin-Fixed, Paraffin-Embedded)

FFPE block number: _____

❑ Tissue slides (minimum 10 slides)

❑ If possible: H&E-stained slides (in case of MSI ordering, please make sure tumor and normal tissue area are distinctly labeled)

❑ Tumor sample from: _____

Request from: _____

❑ DNA ____ µg (>200 ng DNA)
In case of MSI ordering, please also provide DNA from normal tissue

Normal tissue required for germline BRCA1/BRCA2 analysis

❑ Blood ____ ml (min. 1-2 ml EDTA-blood)

❑ DNA ____ µg (> 2 µg DNA): _____

DNA-No: _____

Normal tissue in addition to tumor tissue for MSI analysis

❑ Blood ____ ml (min. 1-2 ml EDTA-blood)

❑ DNA ____ µg (> 2 µg DNA): _____

❑ FFPE block with normal tissue (Formalin-Fixed, Paraffin-Embedded)

FFPE block number: _____

❑ FFPE tumor block with normal tissue area (incl. H&E-stained slide with distinctly labeled tumor and normal tissue area)

FFPE block number: _____

Information on tumor material

Details of the tumor tissue:

❑ Primary tumor

❑ Metastasis; Information regarding the primary tumor:

_____

Tissue: _____

Tumor stage/Cytogenetics: _____

Date of tumor resection: _____

Tumor content _____ %

Further remarks:

For further information and advice please do not hesitate to contact our Diagnostic Support team.

Email: diagnostic-support@cegat.com

Phone: +49 7071 565 44-55

www.cegat.com/diagnostic-support

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Inquiry

Inquiry

- ❑ **Melanoma (7 Genes, PAT01)**
  BRAF, CDKN2A, GNA11, GNAQ, KIT, NRAS, TP53
- ❑ **Colorectal cancer (16 Genes, PAT02)**
  AKT1, BRAF, CTNNB1, EGFR, ERBB2, FBXW7, KRAS, MLH1, MSH2, MSH6, NRAS, PIK3CA, PMS2, PTEN, SMAD4, TP53
- ❑ **Lung cancer (19 Genes and 3 Translocations, PAT03)**
  AKT1, ALK, BRAF, EGFR, ERBB2, FBXW7, FGFR1, FGFR2, FGFR3, KRAS, MAP2K1, MET, NOTCH1, NRAS, PIK3CA, PTEN, RET, ROS1, TP53, ALK Translocation, RET Translocation, ROS1 Translocation
- ❑ **Gastrointestinal Stromal Tumors (4 Genes, PAT04)**
  BRAF, KIT, PDGFRA, TP53
- ❑ **Glioma (10 Genes, PAT05)**
  BRAF, EGFR, H3-3A, H3C2, IDH1, IDH2, PIK3CA, PTEN, TERT, TP53
- ❑ **Breast- and ovarian cancer (15 Genes, PAT06)**
  AKT1, ATM, BARD1, BRCA1, BRCA2, BRIP1, CHEK2, ERBB2, ESR1, PALB2, PIK3CA, PTEN, RAD51C, RAD51D, TP53
- ❑ **Thyroid cancer (7 Genes, PAT07)**
  BRAF, HRAS, KRAS, NRAS, PIK3CA, RET, TP53
- ❑ **Cholangiocellular carcinoma (5 Genes, PAT09)**
  IDH1, IDH2, KRAS, PIK3CA, TP53
- ❑ **Pancreatic cancer (8 Genes, PAT10)**
  BRCA1, BRCA2, CDKN2A, CHEK2, ERBB4, KRAS, SMAD4, TP53
- ❑ **BRCA1 and BRCA2 (2 Genes, PAT11)**
  - ❑ BRCA1 and BRCA2 analysis only in tumor tissue (BRC01)
  - ❑ BRCA1 and BRCA2 analysis only in normal tissue (incl. MLPA) (BRC02)
  - ❑ BRCA1 and BRCA2 analysis in tumor and normal tissue (BRC03) (incl. MLPA in germline)
- ❑ **Prostate cancer (20 Genes, PAT12)**
  ATM, BARD1, BRCA1, BRCA2, BRIP1, CDK12, CHEK1, CHEK2, FANCL, MLH1, MSH2, MSH6, PALB2, PMS2, RAD51B, RAD51C, RAD51D, RAD54L, SPOP, TP53
- ❑ **Gastric cancer (18 Genes, PAT13)**
  AKT1, ATM, BRAF, BRCA1, BRCA2, CHEK2, CTNNB1, ERBB2, KRAS, MLH1, MSH2, MSH6, NRAS, PIK3CA, PMS2, PTEN, SMAD4, TP53
- ■ **Structural variants (9 genes, PAT01-PAT13)**
  Selected therapy relevant fusions are evaluated additionally as part of PAT01-PAT10, PAT12, and PAT13 without further costs.
  NTRK1, FGFR1, FGFR2, FGFR3, BRAF, ALK, RET, MET, ROS1
- ❑ **MMR-Panel (4 Genes, PAT14)**
  MLH1, MSH2, MSH6, PMS2
- ❑ **Analysis for microsatellite instability (MSI) via PCR**
  (Marker: BAT25, BAT26, NR21, NR22, NR27)

❑ **Individual selection:** Please enter your selected genes here (any combinations from all gene sets on this form).
Available Genes: AKT1, ALK, ATM, BARD1, BRAF, BRCA1, BRCA2, BRIP1, CDK12, CDKN2A, CHEK1, CHEK2, CTNNB1, EGFR, ERBB2, ERBB4, ESR1, FANCL, FBXW7, FGFR1, FGFR2, FGFR3, GNA11, GNAQ, H3-3A, H3C2, HRAS, IDH1, IDH2, KIT, KRAS, MAP2K1, MET, MLH1, MSH2, MSH6, NOTCH1, NRAS, NTRK1, PALB2, PDGFRA, PIK3CA, PMS2, PTEN, RAD51B, RAD51C, RAD51D, RAD54L, RET, ROS1, SMAD4, SPOP, SRY, TERT, TP53

_____ , _____ , _____ , _____ , _____ , _____ , _____ ,

_____ , _____ , _____ , _____ , _____ , _____ , _____ ,

_____ , _____ , _____ , _____ , _____ , _____ , _____

Additional analyses (additional fees apply):

Please note: The analysis requires additional FFPE slides Not necessary, if an FFPE block has been sent.

- ❑ **PD-L1**
  IHC staining for: PD-L1 (1 additional slide)
- ❑ **MGMT promotor methylation** (3-5 additional FFPE slides)
- ❑ **MLH1 methylation**
  In tumor tissue (3-5 additional FFPE slides)

For further information and advice please do not hesitate to contact our Diagnostic Support team.

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Phone: +49 7071 565 44-55

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