Order Form CancerPrecision®

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This declaration of consent can be completely or partially withdrawn at any time.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 CancerPrecision®

Indication

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

Indication / Suspected diagnosis / Course of disease / Pedigree

Already initiated / carried out somatic genetic analyzes

❑ **Clinical report(s) added**

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

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

Sample material: Liquid biopsy (cfDNA)

Liquid Biopsy samples are specimens that can only be withdrawn using special collection tubes that stabilize the cell-free DNA. If you are planning a diagnostic examination based on cfDNA, please use such collection tubes. We gladly provide such special collection tubes. Please contact us in time at sales@cegat.de to order the tubes.

Please note: In case the tumor DNA in cfDNA is lower as 20%, the analysis might not be able to provide meaningful results.

❑ 3x 10ml cfDNA Tubes

Material (tumor tissue) – minimum 20% tumor content needed!

❑ FFPE (Formalin-Fixed, Paraffin-Embedded)

Block number (FFPE): _____

❑ Tissue slides (minimum 10 slides)

❑ Tumor DNA (> 200 ng DNA)

❑ Frozen tissue

❑ Tumor sample in RNAlater

❑ EDTA bone marrow, proportion of neoplastic cells: _____

❑ Tumor sample from _____

Request from _____

Details of the tumor tissue

❑ Primary tumor

❑ Metastasis; Information on the primary tumor:

_____

Tissue: _____

Tumorstage/Cytogenetics. _____

Date of tumor resection: _____

Tumor content _____ %

Material (normal tissue)

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

DNA ____ µg (> 2 µg DNA): _____

DNA-No: _____

❑ Saliva sample

❑ Skin biopsy

❑ Buccal mucosa

❑ Fibroblast culture

❑ Others: _____

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Inquiry

❑ **CancerPrecision® (Somatic Tumor Diagnostics, TUM01)**

- Tumor to normal tissue comparative deep panel sequencing
- Validated list of variants with potential therapeutic relevance
- Treatment options based on identified somatic variants
- TMB determination/MSI prediction/HRD calculation
- HPV and EBV integration events
- Comprehensive depiction of cancer-relevant pathwayWWs and graphical overview
- Detection of copy number variants (CNV analysis)
- Detailed listing of relevant drugs incl. FDA/EMA approval requirements
- Detection of selected pharmacogenetically relevant germline variants

❑ **CancerFusionRx® (RNA-based identification of fusion transcripts, STR01)**

Targeted enrichment of relevant regions on RNA-basis allowing detection of fusions and translocations. Detected structural variants are included into the medical report.

Requested Analysis:

If multiple tumor tissue samples have been shipped (FFPE and liquid biopsy / multiple FFPE samples from different tumors, metastasis, reoccurance), please specify if you would like to receive a medical report for:

❑ **more than one tumor tissue sample TUM01DB ("double best"). Requested samples: _____**

❑ **FFPE tissue sample _____ primarily and use other samples as backup**

❑ **Liquid Biopsy sample primarily and use other samples as backup.**

Immunohistochemical (IHC) analyses (additional fees apply)

IHC analyses are performed externally.
Please note: IHC staining requires additional tumor slides. Not necessary, if an FFPE block has been sent.

❑ **PD-L1**

IHC staining for: PD-L1 (1 additional slide)

Additional analyses (additional fees apply)

❑ **HLA-Typing from normal tissue (HLA01)**

I would like to receive an additional report stating the HLA alleles (HLA class I (Gene A, B, C) and HLA class II (Gene *DPA1, DPB1, DQA1, DQB1, DRB1, DRB3, DRB4, DRB5*)).

❑ **MGMT promotor methylation** (3-5 additional slides)

❑ **Pharmacogenetics (PGX) (22 genes)**

ABCG2, CACNA1S, CYP2B6, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, CYP4F2, DPYD, G6PD, HLA-A, HLA-B, IFNL3, MT-RNR1, NUDT15, POR, RYR1, SLCO1B1, TPMT, UGT1A1, VKORC1

I would like to receive an additional report analyzing known variants in 22 genes that are involved in the metabolism of pharmaceutical products.

Remarks / Additional analyses:

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

www.cegat.com/diagnostic-support · diagnostic-support@cegat.com · Phone +49 7071 565 44-55

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Gene lists

Gene list for DNA-based analysis (749 genes, CancerPrecision®, TUM01)

AAK1, ABCB1, ABCG2, ABL1, ABL2, ABRAXAS1, ACD, ACVR1, ADGRA2, ADRB1, ADRB2, AIP, AIRE, AJUBA, AKT1, AKT2, AKT3, ALK, ALOX12B, AMER1, ANKRD26, APC, APLNR, APOBEC3A, APOBEC3B, AR, ARAF, ARHGAP35, ARID1A, ARID1B, ARID2, ARID5B, ASXL1, ASXL2, ATM, ATR, ATRX, AURKA, AURKB, AURKC, AXIN1, AXIN2, AXL, B2M, BAP1, BARD1, BAX, BCHE, BCL10, BCL11A, BCL11B, BCL2, BCL3, BCL6, BCL9, BCL9L, BCOR, BCORL1, BCR, BIRC2, BIRC3, BIRC5, BLM, BMI1, BMPR1A, BRAF, BRCA1, BRCA2, BRD3, BRD4, BRD7, BRIP1, BTK, BUB1B, CALR, CAMK2G, CARD11, CASP8, CBFB, CBL, CBLB, CBLC, CCDC6, CCND1, CCND2, CCND3, CCNE1, CD274, CD79A, CD79B, CD82, CDC73, CDH1, CDH11, CDH2, CDH5, CDK1, CDK12, CDK4, CDK5, CDK6, CDK8, CDKN1A, CDKN1B, CDKN1C, CDKN2A, CDKN2B, CDKN2C, CEBPA, CENPA, CEP57, CFTR, CHD1, CHD2, CHD4, CHEK1, CHEK2, CIC, CIITA, CKS1B, CNKSR1, COL1A1, COMT, COQ2, CREB1, CREBBP, CRKL, CRLF2, CRTC1, CSF1R, CSF3R, CSMD1, CSNK1A1, CTCF, CTLA4, CTNNA1, CTNNB1, CTR9, CTRC, CUX1, CXCR4, CYLD, CYP1A2, CYP2A7, CYP2B6, CYP2C19, CYP2C8, CYP2C9, CYP2D6, CYP3A4, CYP3A5, CYP4F2, DAXX, DCC, DDB2, DDR1, DDR2, DDX11, DDX3X, DDX41, DEK, DHFR, DICER1, DIS3L2, DNMT1, DNMT3A, DOT1L, DPYD, E2F3, EBP, EED, EFL1, EGFR, EGLN1, EGLN2, EIF1AX, ELAC2, ELF3, EME1, EML4, EMSY, EP300, EPAS1, EPCAM, EPHA2, EPHA3, EPHB4, EPHB6, ERBB2, ERBB3, ERBB4, ERCC1, ERCC2, ERCC3, ERCC4, ERCC5, ERG, ERRFI1, ESR1, ESR2, ETNK1, ETV1, ETV4, ETV5, ETV6, EWSR1, EXO1, EXT1, EXT2, EZH1, EZH2, FAN1, FANCA, FANCB, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FANCM, FAS, FAT1, FBXO11, FBXW7, FEN1, FES, FGF10, FGF14, FGF19, FGF2, FGF23, FGF3, FGF4, FGF5, FGF6, FGF9, FGFBP1, FGFR1, FGFR2, FGFR3, FGFR4, FH, FLCN, FLI1, FLT1, FLT3, FLT4, FOXA1, FOXE1, FOXL2, FOXO1, FOXP1, FOXQ1, FRK, FRS2, FUBP1, FUS, FYN, G6PD, GALNT12, GATA1, GATA2, GATA3, GATA4, GATA6, GGT1, GLI1, GLI2, GLI3, GNA11, GNA13, GNAQ, GNAS, GNB3, GPC3, GPER1, GREM1, GRIN2A, GRM3, GSK3A, GSK3B, GSTP1, H3-3A, H3-3B, H3C2, HABP2, HCK, HDAC1, HDAC2, HDAC6, HGF, HIF1A, HLA-A, HLA-B, HLA-C, HLA-DPA1, HLA-DPB1, HLA-DQA1, HLA-DQB1, HLA-DRA, HLA-DRB1, HMGA2, HMGCR, HMGN1, HNF1A, HNF1B, HOXB13, HRAS, HSD3B1, HSP90AA1, HSP90AB1, HTR2A, ID2, ID3, IDH1, IDH2, IDO1, IFNGR1, IFNGR2, IGF1R, IGF2, IGF2R, IKBKB, IKBKE, IKZF1, IKZF3, IL1B, IL1RN, ING4, INPP4A, INPP4B, INPPL1, INSR, IRF1, IRF2, IRS1, IRS2, ITPA, JAK1, JAK2, JAK3, JUN, KAT6A, KDM5A, KDM5C, KDM6A, KDR, KEAP1, KIAA1549, KIF1B, KIT, KLF2, KLF4, KLHL6, KLLN, KMT2A, KMT2B, KMT2C, KMT2D, KRAS, KSR1, LATS1, LATS2, LCK, LIG4, LIMK2, LRP1B, LRRK2, LTK, LYN, LZTR1, MAD2L2, MAF, MAGI1, MAGI2, MAML1, MAP2K1, MAP2K2, MAP2K3, MAP2K4, MAP2K5, MAP2K6, MAP2K7, MAP3K1, MAP3K13, MAP3K14, MAP3K3, MAP3K4, MAP3K6, MAP3K8, MAPK1, MAPK11, MAPK12, MAPK14, MAPK3, MAX, MBD1, MBD4, MC1R, MCL1, MDC1, MDH2, MDM2, MDM4, MECOM, MED12, MEF2B, MEN1, MERTK, MET, MGA, MGMT, MITF, MLH1, MLH3, MLLT10, MLLT3, MN1, MPL, MRE11, MS4A1, MSH2, MSH3, MSH4, MSH5, MSH6, MSR1, MST1R, MTAP, MTHFR, MTOR, MT-RNR1, MTRR, MUC1, MUTYH, MXI1, MYB, MYC, MYCL, MYCN, MYD88, MYH11, MYH9, NAT2, NBN, NCOA1, NCOA3, NCOR1, NF1, NF2, NFE2L2, NFKB1, NFKB2, NFKBIA, NFKBIE, NIN, NKX2-1, NLRC5, NOTCH1, NOTCH2, NOTCH3, NOTCH4, NPM1, NQO1, NR1I3, NRAS, NRG1, NSD1, NSD2, NSD3, NT5C2, NTHL1, NTRK1, NTRK2, NTRK3, NUMA1, NUP98, NUTM1, OBSCN, OPRM1, PAK1, PAK3, PAK4, PALB2, PALLD, PARP1, PARP2, PARP4, PAX3, PAX5, PAX7, PBK, PBRM1, PBX1, PDCD1, PDCD1LG2, PDGFA, PDGFB, PDGFC, PDGFD, PDGFRA, PDGFRB, PDK1, PDPK1, PGR, PHF6, PHOX2B, PIAS4, PIGA, PIK3C2A, PIK3C2B, PIK3C2G, PIK3CA, PIK3CB, PIK3CD, PIK3CG, PIK3R1, PIK3R2, PIK3R3, PIM1, PLCG1, PLCG2, PLK1, PML, PMS1, PMS2, POLD1, POLE, POLH, POLQ, POT1, PPM1D, PPP2R1A, PPP2R2A, PREX2, PRKAR1A, PRKCA, PRKCI, PRKDC, PRKN, PRMT5, PRSS1, PSMB1, PSMB10, PSMB2, PSMB5, PSMB8, PSMB9, PSMC3IP, PSME1, PSME2, PSME3, PSPH, PTCH1, PTCH2, PTEN, PTGS2, PTK2, PTK7, PTPN11, PTPN12, PTPRC, PTPRD, PTPRS, PTPRT, RABL3, RAC1, RAC2, RAD21, RAD50, RAD51, RAD51B, RAD51C, RAD51D, RAD54B, RAD54L, RAF1, RALGDS, RARA, RASA1, RASAL1, RB1, RBM10, RECQL4, REST, RET, RFC2, RFWD3, RFX5, RFXANK, RFXAP, RHBDF2, RHEB, RHOA, RICTOR, RINT1, RIPK1, RIT1, RNASEH2B, RNASEL, RNF43, ROS1, RPS20, RPS6KB1, RPS6KB2, RPTOR, RSF1, RUNX1, RYR1, SAMHD1, SAV1, SBDS, SCG5, SDHA, SDHAF2, SDHB, SDHC, SDHD, SEC23B, SERPINB9, SETBP1, SETD2, SETDB1, SF3B1, SGK1, SH2B1, SH2B3, SHH, SIK2, SIN3A, SKP2, SLC19A1, SLC26A3, SLCO1B1, SLIT2, SLX4, SMAD3, SMAD4, SMARCA4, SMARCB1, SMARCE1, SMC1A, SMC3, SMO, SOCS1, SOS1, SOX11, SOX2, SOX9, SPEN, SPINK1, SPOP, SPRED1, SRC, SRD5A2, SRGAP1, SRSF2, SSTR2, SSX1, STAG1, STAG2, STAT1, STAT3, STAT5A, STAT5B, STK11, SUFU, SUZ12, SYK, TAF1, TAF15, TAP1, TAP2, TAPBP, TBK1, TBL1XR1, TBX3, TCF3, TCF4, TCL1A, TEK, TERC, TERF2IP, TERT, TET1, TET2, TFE3, TGFB1, TGFBR2, TMEM127, TMPRSS2, TNFAIP3, TNFRSF13B, TNFRSF14, TNFRSF8, TNFSF11, TNK2, TOP1, TOP2A, TP53, TP53BP1, TP63, TPMT, TPX2, TRAF2, TRAF3, TRAF5, TRAF6, TRAF7, TRIM28, TRRAP, TSC1, TSC2, TSHR, TTK, TYMS, U2AF1, UBE2T, UBR5, UGT1A1, UGT2B15, UGT2B7, UIMC1, UNG, USP9X, VEGFA, VEGFB, VHL, VKORC1, WRN, WT1, XIAP, XPA, XPC, XPO1, XRCC1, XRCC2, XRCC3, XRCC5, XRCC6, YAP1, YES1, ZFHX3, ZNF217, ZNF703, ZNRF3, ZRSR2

DNA-based detection of selected structural variations in these genes

ALK, BCL2, BCR, BRAF, BRD4, EGFR, ERG, ETV4, ETV6, EWSR1, FGFR1, FGFR2, FGFR3, FUS, MET, MYB, MYC, NOTCH2, NTRK1, NTRK2, NTRK3, PAX3, PDGFB, RAF1, RARA, RET, ROS1, SSX1, SUZ12, TAF15, TCF3, TFE3, TMPRSS2

Gene list for RNA-based identification of fusion transcripts (CancerFusionRx®, STR01)

Gene list for *de-novo* fusion detection

ABL1, ACTB, AFAP1, AGK, AKAP12, AKAP4, AKAP9, AKT2, AKT3, ALK, ASPSCR1, ATF1, ATP1B1, ATRX, BAG4, BCL2, BCOR, BCORL1, BCR, BICC1, BRAF, BRD3, BRD4, c11orf95, CAMTA1, CCAR2, CCDC6, CCDC88A, CCNB3, CCND1, CD74, CIC, CLTC, CNTRL, COL1A1, CREB1, CREB3L1, CREB3L2, CRTC1, DDIT3, DNAJB1, EGFR, EML4, EPC1, ERBB2, ERBB4, ERG, ESR1, ETV1, ETV4, ETV5, ETV6, EWSR1, EZR, FEV, FGFR1, FGFR2, FGFR3, FLI1, FN1, FOXO1, FOXO4, FUS, GLI1, GOPC, GPR128, HMGA2, JAZF1, KIAA1549, KIF5B, LMNA, LPP, MAGI3, MAML1, MAML2, MAML3, MET, MGA, MGMT, MITF, MKL2, MYB, MYC, NAB2, NCOA1, NCOA2, NCOA4, NFIB, NOTCH2, NPM1, NR4A3, NRG1, NRG2, NSD3, NTRK1, NTRK2, NTRK3, NUTM1, PAX3, PAX7, PAX8, PDGFB, PDGFRA, PDGFRB, PHF1, PIK3CA, PLAG1, PML, POU5F1, PPARGC1A, PPP1CB, PRKACA, PRKAR1A, PTPRZ1, QKI, RAF1, RANBP2, RARA, RELA, RELCH, RET, ROS1, RREB1, RSPO2, RSPO3, SDC1, SDC4, SHTN1, SLC34A2, SND1, SQSTM1, SS18, SSX1, SSX2, SSX4, STAT6, STRN, SUZ12, TACC1, TACC3, TAF15, TCF12, TERT, TFE3, TFG, THADA, TMPRSS2, TPM3, TPR, TRIM24, TRIM33, TRIO, VGLL2, WT1, WWTR1, YAP1, YWHAE, ZMYM2, ZNF703

Gene list for selected break points in these fusion genes

AFAP1-NTRK2, ATP1B1-NRG1, BCOR-CCNB3, BRD3-NUTM1, BRD4-NUTM1, CCDC6–RET, CCDC88A-ALK, CD74-NRG1, CD74-ROS1, CLTC-ALK, DNAJB1-PRKACA, EGFR-PPARGC1A, EML4-ALK, ETV6-NTRK2, ETV6-NTRK3, EWSR1-ATF1, EWSR1-ERG, EWSR1-FLI1, EWSR1-WT1, EZR-ROS1, FGFR2-BICC1, FGFR1-TACC1, FGFR2-TACC3, FGFR3-TACC3, KIAA1549-BRAF, KIF5B-ALK, KIF5B–RET, MGA-NUTM1, NAB2-STAT6, NCOA4–RET, NPM1-ALK, NSD3-NUTM1, PAX3-FOXO1, PAX7-FOXO1, PPP1CB-ALK, PRKAR1A-RET, QKI-NTRK2, SDC4-NRG1, SDC4-ROS1, SLC34A2-ROS1, SND1-BRAF, SS18-SSX1, SS18-SSX2, TMPRSS2-ERG, TPM3-ALK, TPM3-NTRK1, TPM3-ROS1, TPR-NTRK1, TRIM24-BRAF, TRIM24-NTRK2, TRIM33-RET, TRIO-TERT

List for specific transcript variants

EGFR del ex2-3, EGFR del ex2-4, EGFR del ex2-14, EGFR del ex2-22 (mLEEK), EGFR del ex5-6, EGFR del ex6-7, EGFR del ex9, EGFR del ex9-10, EGFR del ex10, EGFR del ex12, EGFR del ex25-26, EGFR del ex25-27, EGFR del ex26-27, EGFR VII, EGFR VIII, MET ex14 skipping