Order Form CancerDetect

General Information

Patient

Surname: _____

First name: _____

Date of birth: _____

Sex (assigned at birth): ❑ female ❑ male

Gender (if differs from sex assigned at birth):
❑ man ❑ non-binary ❑ woman ❑ self-described: _____

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.com/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This declaration of consent can be completely or partially withdrawn at any time.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 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.

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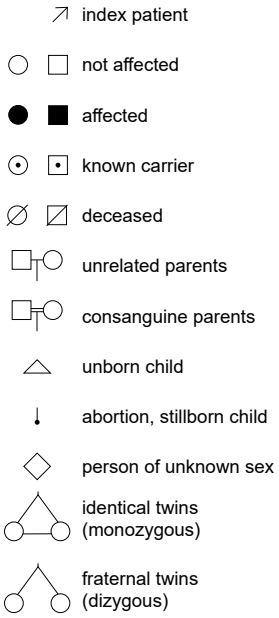
Indication

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 analyses

❑ **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 tumor@cegat.de to order the tubes.

❑ 3 x 10ml cfDNA tubes (If cerebrospinal fluid or fluid from cysts is to be used as starting material, please reduce the amount taken accordingly if necessary)

Type of primary sample for cfDNA isolation:

❑ Blood ❑ Ascites ❑ Liquor ❑ Pancreatic cyst fluid ❑ Other: _____

Inquiry

All relevant variants in a named exon are analysed. Exon numbers refer to coding exons (CDS) in a given transcript. Diagnostics is not necessarily limited to the example hotspot mutations listed. Exons not named and all variants within are not part of the analysis.

Gene	NM_Nr.	Enriched region (incl. example hotspot (HS)-variants)
AKT1	NM_005163.2	Exon 2 (incl. HS E17)
ALK	NM_004304.5	Exons 22-25 (incl. HS F1174 , G1202, F1245, R1275)
AR	NM_000044.6	Exons 4, 5, 8
BRAF	NM_004333.6	Exons 11, 15 (incl. HS V600)
CDKN2A	NM_000077.5	Entire coding region
CTNNB1	NM_001904.4	Exons 2, 6, 7 (incl. HS S37, S45, K335, N387)
EGFR	NM_005228.5	Exons 2, 3, 6, 7, 15, 18-21 (incl. HS A289, G598, E746_A750del, T790, L858)
ERBB2	NM_004448.4	Exons 8, 17, 19-21 (incl. HS S310, R678, V842)
ERBB3	NM_001982.4	Exons 3, 7-9, 23 (incl. HS V104, E928)
ESR1	NM_000125.4	Exons 4, 5, 7, 8 (incl. HS K303, Y537, D538, E380Q, L536H, Y537C/N/S, D538G)
FGFR1	NM_023110.3	Exons 11-13 (incl. HS N577, K687)
FGFR2	NM_000141.5	Exons 6, 8, 11-13 (incl. HS S252, N549)
FGFR3	NM_000142.5	Exons 6, 8, 13 (incl. HS R248, S249, Y375)
GNA11	NM_002067.5	Exons 4, 5 (incl. HS R183, Q209)
GNAQ	NM_002072.5	Exons 2, 4, 5 (incl. HS T96, R183, Q209)
GNAS	NM_000516.7	Exon 8 (incl. HS 201)
H3-3A	NM_002107.7	Exon 1 (incl. HS K27, G34)

Gene	NM_Nr.	Enriched region (incl. example hotspot (HS)-variants)
HRAS	NM_005343.4	Exons 1-3 (incl. HS G12, Q61)
IDH1	NM_005896.4	Exon 2 (incl. HS R132)
IDH2	NM_002168.4	Exon 4 (incl. HS R140, R172)
JAK2	NM_004972.4	Exon 12 (incl. HS V617)
KIT	NM_000222.3	Exons 9, 11, 13, 14, 17, (incl. HS W557_K558del, D816)
KRAS	NM_004985.5	Exons 1-3 (incl. HS G12, G13, Q61)
MET	NM_001127500.3	Exons 13, 15, 18 (incl. HS L982_D1028del, T1010, Y1248, Y1253), *MET* Exon 14 skipping
NRAS	NM_002524.5	Exons 1-3 (incl. HS G12, Q61)
PDGFRA	NM_006206.6	Exons 11, 13, 17 (incl. HS D842)
PIK3CA	NM_006218.4	Exons 1, 4, 7, 9, 13, 20 (incl. HS R93, E542, E545, H1047)
PTEN	NM_000314.8	Entire coding region
RET	NM_020975.6	Exons 10, 11, 13-16 (incl. HS C634)
TERT	NM_198253.3	Promotor HS c.-124 (C228), c.-146 (C250)
TP53	NM_000546.6	Entire coding region

DNA-based detection of selected structural variations in these genes:
ALK, RET, ROS1, FGFR2, FGFR3, NTRK1

Remarks:

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