MEDICOVER GENETICS

SOLID TUMOR TESTS HISTOPATHOLOGY & GENETICS DETECT&ACT ORDER FORM

BARCODE

Person Completing Form / [Add translation in local language]

Contact (phone or e-mail) / [Add translation in local language]

Date (DD/MM/YYYY) / [Add translation in local language]

PHYSICIAN INFORMATION / [ADD TRANSLATION IN LOCAL LANGUAGE]

Institution/Practice / [Add translation in local language]

Address (street name, no., city, postal code, country) / [Add translation in local language]

First Name / [Add translation in local language]

Stamp (if necessary) / [Add translation in local language]

Last Name / [Add translation in local language]

Telephone Number (country code & number) / [Add translation in local language]

E-mail Address (for report access) / [Add translation in local language]

PATIENT INFORMATION / [ADD TRANSLATION IN LOCAL LANGUAGE]

First Name / [Add translation in local language]

Address (street name, no., city, postal code, country) / [Add translation in local language]

Last Name / [Add translation in local language]

Telephone Number (country code & number) / [Add translation in local language]

Date of Birth (DD/MM/YYYY) / [Add translation in local language]

Personal Identification No. / [Add translation in local language]

Reason for Test (diagnosis, predictive, carrier) / [Add translation in local language]

Gender (male/female/other - specify karyotype) / [Add translation in local language]

Sample Collection Date (DD/MM/YYYY) / [Add translation in local language]

DECLARATION OF CONSENT (ACCORDING TO GERMAN GENETIC DIAGNOSTICS ACT, GenDG)

APPLICABLE only for the determination of genetic (hereditary) characteristics

The GenDG requires provision of detailed information and a written consent for all genetic investigations as well as genetic counselling prior to both predictive (applies to healthy individuals) and prenatal testing (with restrictions: prenatal testing is not performed for late manifesting disorders, including Hereditary Cancer Panels). The German Society of Human Genetics (GfH) and the Association of German Human Geneticists (BVDH) recommend clarifying the issues listed below during the information process. Please read the declaration of consent carefully and tick the boxes, in accordance with your consent.

By signing the form below I confirm that I:

- Have been fully informed by my physician about the significance and consequences of the genetic investigation, in compliance with GenDG.
- Have read/have been read the Informed Consent which is attached to this form and which I fully understand.
- Have been given sufficient opportunity to discuss open questions.
- Authorize [insert legal entity here] to collect the necessary samples for investigation (blood, tissue, chorionic villus cells or amniotic fluid for prenatal diagnosis) and to send this form to MVZ Martinsried GmbH, Lochhamer Str. 29, 82152 Martinsried, Germany, in order to perform the tests requested through this form.
- Consent to the genetic test being carried out in order to clarify the disease/dysfunction/suspected diagnosis below.

In addition,

- I agree that a copy of the results of the analysis may be sent to the following physician(s), in accordance with my express requests and according to [insert legal entity here] internal procedures. ☐ YES ☐ NO

Dr(s) Name

Street

Postcode/City

Country

Place

Signature of Parent or Legal Guardian

- I agree that the investigation or parts of the investigation may be forwarded to collaborating medical laboratories, if necessary. ☐ YES ☐ NO
- I agree with the evaluation of additional genes in the same indication group as part of the research. ☐ YES ☐ NO
- I agree that the remaining specimens may be stored for further investigations after the examination is completed, yet not claiming storage. ☐ YES ☐ NO
- I agree that the specimens, and if applicable DNA sequence information, may be made available anonymously for quality management and scientific purposes. ☐ YES ☐ NO
- I agree that the results of the analysis may be stored for a longer period than the statutory period of 10 years, yet not claiming storage of results. ☐ YES ☐ NO
- I agree to the storage and use of my test results under the protection of anonymity in a statistical database used for scientific purposes and to help diagnose genetic diseases. I understand that I will remain under the protection of anonymity and I cannot be identified during the analysis of the data and that any personal information will be transformed into information of a non-personal nature. ☐ YES ☐ NO

By signing the form below I confirm that:

- I may stop the investigation at any time and ask for the results available until that time to be destroyed.
- I may withdraw any of my consents given through this form entirely or in part at any time without giving reasons.
- I will be charged for the costs incurred until the time of withdrawal of consent.
- I may choose not to be informed about the test results (right not to know).
- The genetic investigation and evaluation is limited to the requested indication and no statements will be made about other diseases.
- All information I have provided is true and correct.

Communication of additional findings found during the course of the research

☐ Yes, I wish to be informed about additional findings.

☐ No, I do not wish to be informed about additional findings.

Date

Physician's Signature

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HISTOPATHOLOGY / [ADD TRANSLATION IN LOCAL LANGUAGE]

SAMPLE DETAILS

Specimen:

Retrieved Date:

Specimen ID:

Collection Date:

Block ID:

Collection Time:

Fixative/Preservative:

Biopsy Details/Body Site:

Reason for Referral:

☐ New Diagnosis ☐ Relapse ☐ In Remission ☐ Monitoring ☐ Other

Relevant Clinical Information:

Comprehensive information regarding clinical history and diagnosis is essential for interpretation of genomic findings and drug therapy recommendations.
Please attach patient's pathology report (if available), clinical history, and other applicable report(s).

If histopathology was conducted, please fill in:

Stage: ☐ Primary ☐ Metastasis – If Metastasis, list Primary:

☐ 0 ☐ I ☐ II ☐ III ☐ IIIA ☐ IIIB ☐ IV **Note:**

☐ **Slides #** _____ **Unstained** _____ **Stained** _____ ☐ **H&E** _____

☐ **ICD-10 Code/Narrative:**

☐ **Percentage of Tumor Cells:**

Conclusion of the report, if any:

E.g., type of cancer, tumor grade, lymph node status, margin status, stage, whether the tumor has hormone receptors or other tumor markers

Our pathologists will recommend the most appropriate sequencing analysis, if necessary, and provide professional interpretation of the results.

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MOLECULAR ANALYSIS / [ADD TRANSLATION IN LOCAL LANGUAGE]

Please choose the appropriate panel below to make your selection.

TARGETED-THERAPY TESTS

1 Bladder Cancer
IHC markers: CD44, CK20, CK7, GATA3, Ki67, p53
Genes: *FGFR2*, *FGFR3*

2 Breast Cancer
IHC markers: E-CD, ER, GATA3, HER2, Ki67, PR
Genes: *BRCA1*, *BRCA2*, *PIK3CA*
Molecular markers: ☐ fusion genes ☐ MSI

3 Colorectal Cancer
IHC markers: CDX-2, CK20, MLH1, MSH2, MSH6, PMS6, villin
Genes: *BRAF*, *KRAS*, *NRAS*
Molecular markers: ☐ fusion genes ☐ MSI

4 Gastric Cancer
IHC markers: CDX-2, CG-A, CK20, CK7, HER-2, Ki67, SYN
Molecular markers: ☐ fusion genes ☐ MSI

5 Gastrointestinal Stromal Tumor
IHC markers: CD34, c-KIT (CD117), desmin, DOG1, Ki67, S100
Genes: *BRAF*, *KIT*, *NF1*, *PDGFRA*, *SDHA*
Molecular markers: ☐ fusion genes

6 Melanoma
IHC markers: HMB45, Ki67, Melan-A, p16, S100, SOX10
Genes: *BRAF*, *KIT*, *NRAS*
Molecular markers: ☐ fusion genes

7 Non-Small Cell Lung Carcinoma
IHC markers: ALK, CG-A, EGFR, p40, PD-L1, ROS, SYN, TFF1
Genes: *BRAF*, *EGFR*, *ERBB2*, *KRAS*, *MET*
Molecular markers: ☐ fusion genes

8 Ovarian Cancer
IHC markers: AFP, calretinin, EMA, ER, hCG, inhibin, napsin A, OCT3/4, p16, p53, PAX8, PR, SALL4, WT1
Genes: *BRCA1*, *BRCA2*
Molecular markers: ☐ fusion genes ☐ MSI

9 Pancreatic Cancer
IHC markers: CK19, CK20, CK7, MUC5AC
Genes: *BRAF*, *BRCA1*, *BRCA2*, *KRAS*, *PALB2*, *SMAD4*
Molecular markers: ☐ fusion genes ☐ MSI

10 Prostate Cancer
IHC markers: BCC-AMACR, CK34BE12, CK5/6, NKX3.1, p63, PSA, PSAP
Genes: *ATM*, *BRCA1*, *BRCA2*, *CDK12*, *CHEK2*, *FANCA*, *PALB2*, *PTEN*, *RAD51*
Molecular markers: ☐ MSI

Fusion genes: ALK, NTRK, RET, ROS; IHC, immunohistochemistry; MSI, microsatellite instability

SOLID TUMOR PANELS (AND FUSION GENES)

Bladder Cancer
11 Gene Panel
11 Fusion Genes

Breast Cancer
12 Gene Panel

Colorectal Cancer
13 Gene Panel

Gastric Cancer
14 Gene Panel

Gastrointestinal Stromal Tumor
15 Gene Panel

Glioblastoma
16 Gene Panel

Liver Cancer
17 Fusion Genes

Lung Cancer
18 Fusion Genes

Melanoma
19 Gene Panel

Non-Small Cell Lung Carcinoma
20 Gene Panel
20 Fusion Genes

Ovarian Cancer
21 Gene Panel

Pancreatic Cancer
22 Gene Panel
22 Fusion Genes

Prostate Cancer
23 Gene Panel
23 Fusion Genes

Salivary Gland Sarcoma
24 Fusion Genes

Soft Tissue Sarcoma
25 Fusion Genes

Thyroid Cancer
26 Gene Panel
26 Fusion Genes

27 COMPREHENSIVE SOLID TUMOR PANEL

Please note that other gene fusions in addition to those specified may be detected by this assay and will be reported if they are of potential clinical significance.

For our complete gene list, turnaround times, specimen requirements and more, please visit our website: www.medicover-genetics.com.

Medicover Genetics GmbH, Teltowkanalstr. 1b, 12247 Berlin, Germany
Accreditation: DIN EN ISO 15189
www.medicover-genetics.com

MVZ Martinsried GmbH
Lochhamer Str. 29
82152 Martinsried

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INFORMATION PART OF CONSENT FORM

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PATIENT INFORMATION / [ADD TRANSLATION IN LOCAL LANGUAGE]

First Name / [Add translation in local language]

Last Name / [Add translation in local language]

Date of Birth (DD/MM/YYYY) / [Add translation in local language]

Gender (male/female/other - specify karyotype) / [Add translation in local language]

Telephone Number (country code & number) / [Add translation in local language]

E-mail Address / [Add translation in local language]

Clinical Diagnosis / [Add translation in local language]

Genetic counselling or counselling by the ordering physician is necessary before ordering a test in order to inform the patient of all of the possible outcomes and the limitations of the genetic test.

I understand that I will be tested for:

(To be filled in by physician)

I understand that the biological sample will be used to determine if I, or members of my family, are carriers of a genetic variant causing the disease, or are carriers of the disease, or have an increased risk of developing a disease.

The role of genetic testing. In many cases, a genetic test can directly detect a genetic alteration. Molecular tests can identify structural changes in the DNA (variants). Cytogenetic tests identify the chromosomal changes (structural or numerical). The sensitivity and specificity of each test varies.
The tests offered are complex analyses and are performed using high-end equipment. The methods are externally validated, but there is a minimal possibility of errors.

The significance of the results. If the result is identified as being directly causative of the clinical manifestations, it is considered to be **conclusive**. If the test does not identify the causative mutations of the clinical manifestations, it is considered to be **inconclusive** and this does not preclude other genetic changes (or non-genetic factors) responsible for the disease (a genetic disease or susceptibility to a genetic condition is not excluded). Therefore, an inconclusive result (no causative mutation identified) does not exclude the existence of other pathogenic genetic changes (variants) not tested through the current analysis.
Interpretation of the genetic results relies on **a complete clinical picture of the patient**, including clinical manifestations, family medical history and previous diagnoses. An error in diagnosis could occur due to a clinical picture that is different from that declared. In addition, the test can identify a possible nonpaternity. The test results will be forwarded to the patient by the geneticist or ordering physician and are **confidential.**

Incidental findings. Genetic testing can provide information unrelated to the purpose of the test, but that may have medical importance for the patient or family (information correlated with an increased risk for incurable disorders).

Use of the sample/result. The sample provided will be used solely for the purpose of the test and for which I have given my written consent.
Test results can also be used for research and to improve the diagnosis and treatment of genetic diseases.

The genetic material can be used for other purposes only with my prior express written consent.

Post-testing genetic counselling. A conclusive result may offer the patient information on the susceptibility, diagnosis, possible prognosis and/or heritability of the disease. An inconclusive result may lead to confusion and anxiety or may suggest the need for further genetic testing. Therefore, post-testing genetic counselling is advised for the clinical interpretation of the results.

By my signature, I hereby certify that:

1. I have been informed of the nature and purpose of the genetic test.
2. I have been informed of the benefits and limitations of the genetic test by _____ (name of physician).
3. I have been informed that the genetic test can provide information/results which have no connection with the purpose of testing. I understand that only I decide if I want those additional results to be provided.
4. I have received clear answers to my questions in relation to the genetic test.
5. I have received a copy of this form.
6. I agree to provide a sample for the above mentioned genetic test.

Completed by: ☐ **Parent/Legal Guardian** ☐ **Patient**

First Name

Last Name

Date of Completion

Signature

I have explained the risks and benefits of the test as well as alternative test methods to the patient or parent/legal guardian. I have answered all the questions from the patient or parent/legal guardian.

Name of the ordering physician

First Name

Last Name

Signature of the Ordering Physician

Date of Signature