ForeSENTIA®
tumor profile

AFFIX
BARCODE LABEL – SIF
HERE

SAMPLE INFORMATION FORM

Please complete sections below in English.

PATIENT INFORMATION

FIRST NAME	LAST NAME
DATE OF BIRTH	PATIENT GENETIC SEX
ETHNICITY	PHONE NUMBER
EMAIL	
DATE FFPE SECTIONS ARE SENT FOR TESTING	
ADDRESS	
CITY / POST CODE / COUNTRY	

ORDERING HEALTHCARE PROVIDER INFORMATION

CLINIC NAME	CLINIC ID
REFERRING HEALTHCARE PROVIDER	
PHONE NUMBER	FAX
EMAIL	
ADDRESS	
CITY / POST CODE / COUNTRY	

PATIENT HISTORY

PRIMARY DIAGNOSIS	PATIENT'S TUMOR SITE ☐ Primary ☐ Metastatic
STAGE	ICD-10 CODE
PATHOLOGY RESULT	Tumor content (as estimated by H&E staining) *Minimum acceptable 20%*
DATE OF BIOPSY TEST (DD/MM/YY)	

PATHOLOGY INFORMATION

CLINIC NAME	SUBMITTING PATHOLOGIST
PHONE	FAX
EMAIL	

ATTACHMENTS (IF APPLICABLE)

- ☐ PATHOLOGY OR CYTOLOGY REPORTS
- ☐ TEST RESULTS FROM MOLECULAR DIAGNOSTIC ASSAYS
- ☐ OTHER *Please specify*

FOR LABORATORY USE ONLY
F-OPR-01/04-V10-EN

ORDER NUMBER	LAB ID NUMBER	KIT LOT NUMBER
COMMENTS	DATE & TIME OF RECEIPT (DD/MM/YY HH:MM)	RECEIVED BY

MEDICOVER GENETICS
Neas Engomis 31, Nicosia, 2409 Cyprus
Phone: +357 22266888 Fax: +357 22266899
Web: www.medicover-genetics.com
Email: info.genetics@medicover.com

ForeSENTIA®
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REQUESTED TEST

Panel options are available below. Please select one.

EXTENDED TUMOR PROFILE PANELS

☐ **PAN-CANCER PLUS** *MSI and TMB testing is included.* *222 genes*	ABL1, ABL2, AKT1, AKT2, ALK, ANKRD26, APC, AR, ARAF, ASXL1, ATM, ATRX, B2M, BAP1, BARD1, BCL2, BCL6, BCOR, BCORL1, BCR, BMPR1A, BRAF, BRCA1, BRCA2, BRIP1, CALR, CBFB, CBL, CBLB, CBLC, CCND1, CCND2, CCND3, CCNE1, CD274, CD74, CDC25C, CDH1, CDK12, CDK4, CDK6, CDKN2A, CEBPA, CHEK2, CIC, CSF1R, CSF3R, CTLA4, CTNNB1, CUX1, CXCR4, DCK, DDR2, DDX41, DEK, DHX15, DICER1, DNMT3A, DUSP22, EGFR, EIF1AX, EPCAM, ERBB2, ERBB3, ERBB4, ERCC4, ERG, ESR1, ETNK1, ETV1, ETV4, ETV6, EWSR1, EZH2, FANCA, FBXW7, FGF13, FGF19, FGF2, FGF3, FGFR1, FGFR2, FGFR3, FGFR4, FLT1, FLT3, FLT4, FOXA1, FOXL2, FOXO1, FRS2, FUBP1, GATA1, GATA2, GATA3, GNA11, GNAQ, GNAS, H3F3A, HDAC2, HOXB13, HRAS, IDH1, IDH2, IKZF1, IL3, INHA, INSRR, IRF4, JAK1, JAK2, JAK3, KDM6A, KDR, KEAP1, KIT, KMT2A, KMT2C, KMT2D, KRAS, LUC7L2, MALT1, MAP2K1, MAP2K2, MAP3K1, MDM2, MECOM, MET, MITF, MLH1, MLLT3, MPL, MRE11, MSH2, MSH6, MTOR, MUTYH, MYC, MYCN, MYD88, MYH11, MYOD1, NBN, NCOA3, NF1, NF2, NFE2L2, NOTCH1, NPM1, NRAS, NRG1, NTRK1, NTRK2, NTRK3, NUP214, NUTM1, PALB2, PARP1, PBX1, PDCD1, PDCD1LG2, PDGFRA, PDGFRB, PGR, PHF6, PIK3CA, PIK3CB, PIK3R1, PML, PMS2, POLD1, POLE, PPM1D, PPP2R1A, PTCH1, PTEN, PTPN11, RAD21, RAD51C, RAD51D, RAF1, RARA, RB1, RBBP6, RET, RNF43, ROS1, RPS14, RUNX1, RUNX1T1, SETBP1, SF3B1, SH2B3, SLC29A1, SMAD4, SMARCA4, SMARCB1, SMC1A, SMC3, SMO, SOX10, SPOP, SRSF2, STAG2, STAT3, STAT5B, STK11, SUZ12, TCF3, TCL1A, TERT, TET2, TMPRSS2, TP53, TSC1, TSC2, U2AF1, VEGFA, VHL, WT1, XPO1, ZRSR2, 1p/19q codeletion
☐ **PAN-CANCER** *MSI testing is included.* *80 genes*	AKT1, ALK, APC, AR, ARAF, ATM, ATRX, BARD1, BRAF, BRCA1, BRCA2, BRIP1, CDH1, CDKN2A, CHEK2, CIC, CTNNB1, DDR2, DICER1, EGFR, ERBB2, ERBB3, ERBB4, ESR1, FBXW7, FGFR1, FGFR2, FGFR3, FLT3, FOXA1, FOXL2, FUBP1, GATA3, GNA11, GNAQ, GNAS, H3F3A, IDH1, IDH2, JAK2, KEAP1, KIT, KRAS, MAP2K1, MAP3K1, MET, MLH1, MRE11A, MSH2, MSH6, MTOR, MYC, MYCN, NBN, NF1, NPM1, NRAS, NTRK1, NTRK2, NTRK3, PALB2, PDGFRA, PIK3CA, PIK3CB, PMS2, POLE, PTEN, RAD51C, RAD51D, RAF1, RB1, RET, ROS1, RUNX1, SMAD4, SPOP, STK11, TERT, TMPRSS2, TP53, 1p/19q codeletion

CANCER-SPECIFIC TUMOR PROFILE PANELS

☐ **BREAST / GYNECOLOGICAL** *48 genes*	AKT1, ATM, BARD1, BRAF, BRCA1, BRCA2, BRIP1, CHEK2, CTNNB1, DICER1, EGFR, ERBB2, ERBB3, ESR1, FBXW7, FGFR1, FGFR2, FGFR3, FOXA1, FOXL2, GATA3, KIT, KRAS, MAP3K1, MET, MLH1, MRE11A, MSH2, MSH6, MTOR, NBN, NRAS, NTRK1, NTRK2, NTRK3, PALB2, PIK3CA, PIK3CB, PMS2, POLE, PTEN, RAD51C, RAD51D, RAF1, RET, RUNX1, SMAD4, TP53
☐ **COLORECTAL** *34 genes*	AKT1, APC, ATM, BRAF, BRCA1, BRCA2, CTNNB1, EGFR, ERBB2, FBXW7, FGFR1, FGFR2, FGFR3, GNAS, KRAS, MET, MLH1, MSH2, MSH6, MTOR, NRAS, NTRK1, NTRK2, NTRK3, PALB2, PDGFRA, PIK3CA, PIK3CB, PMS2, POLE, PTEN, RAF1, SMAD4, TP53
☐ **GLIOMA** *22 genes*	ATRX, BRAF, CDKN2A, CIC, CTNNB1, EGFR, FGFR3, FUBP1, H3F3A, IDH1, IDH2, MET, MYC, MYCN, NF1, NTRK1, NTRK2, NTRK3, POLE, PTEN, TERT, TP53, 1p/19q codeletion
☐ **LUNG (NSCLC)** *36 genes*	AKT1, ALK, APC, ARAF, ATM, BRAF, BRCA2, CTNNB1, DDR2, EGFR, ERBB2, ERBB3, ERBB4, FBXW7, FGFR1, FGFR2, FGFR3, JAK2, KEAP1, KRAS, MAP2K1, MET, NRAS, NTRK1, NTRK2, NTRK3, PDGFRA, PIK3CA, POLE, PTEN, RAF1, RET, ROS1, SMAD4, STK11, TP53
☐ **MELANOMA** *22 genes*	AKT1, ALK, BRAF, CTNNB1, ERBB2, GNA11, GNAQ, KIT, KRAS, MAP2K1, MYC, NF1, NRAS, NTRK1, NTRK2, NTRK3, PIK3CA, POLE, PTEN, RET, ROS1, TP53
☐ **PROSTATE** *36 genes*	AKT1, APC, AR, ATM, BARD1, BRAF, BRCA1, BRCA2, CHEK2, CTNNB1, ERBB2, FGFR1, FGFR2, FGFR3, FOXA1, MLH1, MSH2, MSH6, MYC, MYCN, NRAS, NTRK1, NTRK2, NTRK3, PALB2, PIK3CA, PIK3CB, PMS2, POLE, PTEN, RAD51C, RAD51D, RB1, SPOP, TMPRSS2, TP53
☐ **OPTIONAL ADD-ON TESTING**	Microsatellite Instability (MSI) testing *Can be included as part of the cancer-specific tumor profile panels*

GENE-FOCUSED PANELS

☐ EGFR	☐ KRAS + NRAS	☐ PIK3CA + AKT1	☐ BRAF	☐ IDH1 + IDH2

A detailed list on the exonic coverage of the genes tested in the ForeSENTIA panels can be found in the following link: www.medicover-genetics.com

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PATIENT CONSENT

By placing my signature below I hereby:

1. Confirm that I have read, or have had read to me, the attached Patient Informed Consent and that I understand it.
2. Declare that I have had the opportunity to receive counselling from referring healthcare provider on the ForeSENTIA test and to discuss with the healthcare provider all aspects of the ForeSENTIA test and this form including the benefits, risks and limitations of the ForeSENTIA test, as well as the reasons for performing the test and availability of alternative testing options to my satisfaction.
3. Authorize my referring healthcare provider to collect the necessary biological sample, and to submit this form and transport the samples to Medicover Genetics laboratories for the purposes of conducting the tests requested with this form.
4. Authorize Medicover Genetics to use part or the entirety of the biological sample for the purposes of conducting the tests requested with this form.
5. Authorize Medicover Genetics to communicate the results of the test to my referring healthcare provider.
6. Confirm that all the information on this form is true to the best of my knowledge.

Your test results and any unused biological material can help Medicover Genetics improve and further develop the quality, accuracy and effectiveness of the analysis and help us expand the scope of genetic testing. For this reason, Medicover Genetics would like to use your anonymized, de-identified (i.e. after removing all the personal information from which you can be identified) test results and unused biological material.

☐ For the above scope, I consent to the inclusion of my test results in Medicover Genetics' database, the coding, storing and using of biological material.

PATIENT/GUARDIAN SIGNATURE	DATE

HEALTHCARE PROVIDER ATTESTATION

I hereby certify and undertake that:

1. I am the referring healthcare professional ordering this test.
2. The test results will determine my patient's medical management and treatment options.
3. The patient has been informed about the nature and purpose of the testing.
4. The patient has been duly and thoroughly counseled about the test and has received all the advice necessary to provide their informed consent, including the benefits, risks, and limitations of the ForeSENTIA test.
5. I have answered all the patient's queries about the ForeSENTIA test.
6. This form has been completed according to the wishes and instructions of the patients.
7. I have obtained the patient's informed consent and have attested their signature.

HEALTHCARE PROVIDER SIGNATURE	DATE

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PATIENT INFORMED CONSENT

GENERAL INFORMATION

GENETIC TESTING

The purpose of this test is to understand the genetic characteristics of your tumor by identifying changes in DNA sequences or alterations in the structure of chromosomes.

ForeSENTIA

ForeSENTIA is based on a novel target capture enrichment technology that has been validated for its accuracy and precision. ForeSENTIA is a genetic test for tumor profiling that can identify genetic alterations (changes) implicated in cancer. Identifying these changes can guide towards a more accurate prognosis and improved clinical management.

SAMPLE COLLECTION

The test requires the collection of a tumor tissue removed during biopsy or surgery. Your healthcare provider will send the sample to Medicover Genetics laboratories for analysis by following the provided sample collection instructions. Occasionally, additional sample may be needed if there is a breakage of the sample collection device, sample degradation, sample contamination, inadequate sample quantity or if the sample has been submitted incorrectly.

RESULT INTERPRETATION

The results are communicated within 2-3 weeks directly to your healthcare provider. The healthcare provider ordering this test is responsible to understand the specific uses and limitations of the test, communicate this information to you and answer any questions you may have.

THE FOLLOWING DESCRIBES THE POSSIBLE RESULTS FROM THE TEST:

Clinically significant variant detected: A Clinically significant variant detected indicates that a pathogenic genetic alteration that has been reported to be associated with a specific cancer has been identified. It is possible that the test identifies more than one clinically significant variant. The results should be interpreted in the context of all clinical findings and patient history.

No clinically significant variant detected: No clinically significant variant detected indicates that no cancer-causing genetic alteration has been identified for the test performed. A 'no clinically significant variant detected' result does not rule out any pathogenic variants or chromosome alterations in areas not assessed by the test or in regions that were covered at a level too low to assess.

Variant of Uncertain Significance (VUS): A finding of a variant of uncertain significance indicates that a genetic alteration has been detected, but it is currently unknown whether that specific alteration is associated with cancer. More scientific research and data are needed to clarify VUS and their role in cancer.

Inconclusive result: An inconclusive result indicates either that the sample quality was severely compromised and does not meet quality control standards for further analysis, or that the quantity of the tissue provided was very limited, leading to low quality material available for sequencing. No conclusion can be drawn from such samples. Sample recollection is recommended.

Microsatellite Instability (MSI): MSI-High status indicates increased genomic instability and is associated with better response to immunotherapy treatment. MSI status determination is based on the specific microsatellite loci covered by the test and is only reported when determined to be High (MSI-H).

Tumor Mutational Burden (TMB): TMB is a biomarker that reflects the number of somatic mutations present in a patient's tumor and is quantified as mutations per megabase (mut/Mb). A patient's tumor with TMB score higher than 10mut/Mb is classified as TMB High, whereas a TMB score lower than 10mut/Mb is classified as TMB-Low. Patients harboring a TMB-High tumor are associated with better response to immunotherapy treatment.

Result interpretation is based on currently available information in the medical literature, research and scientific databases. Because the literature, medical and scientific knowledge are constantly changing, new information that becomes available in the future may change the interpretation of your test results.

DISCLOSURE

Medicover Genetics is a fully accredited state-of-the-art genetic testing laboratory. All necessary measures are taken to perform the testing reliably under strict standards. ForeSENTIA is highly accurate, however, there is a small possibility for false positive and false negative results due to technical and biological reasons. Although rare, these reasons include but are not limited to: mislabeled samples, inaccurate reporting of clinical/medical information, rare technical errors, or other rare events such as the presence of change(s) in such a small percentage of cells that the change(s) may not be detectable by the test. The analysis is specific only for the tests ordered. This test will not detect all variants or all structural alterations in the evaluated DNA. Some undetected events could be cancer-related.

Tumor profiling is an important part of the diagnostic process. However, genetic tests may not always give a definite answer. In some cases, testing may not identify genomic alterations even though one exists. This may be due to limitations in current medical knowledge or testing technology. Also, identification of the tumor genetic profile may not always identify potential treatment options.

BENEFITS

Your genetic test results may help you and your doctor make informed choices about your healthcare and management. It is recommended that you receive genetic counselling before and after having this genetic test.

QUALITY IMPROVEMENT

Please choose the relevant option on the consent form to grant us permission to anonymously use your remaining sample to improve the quality, accuracy and effectiveness of ForeSENTIA.

Please make sure you read and understand the information on this document before signing and complete all relevant information accurately as incorrect information can lead to inaccurate test results. Please discuss any questions you may have with your healthcare provider. For additional information please visit our website at ***www.medicover-genetics.com****.*

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PATIENT PRIVACY SUMMARY

This privacy notice provides a summary of how Medicover Genetics Limited collects and processes your personal data with this form. It is important that you read this privacy notice together with our full privacy policy which contains more detailed information about our data processing. A copy is available online at www.medicover-genetics.com.

1. Important information and who we are

Medicover Genetics is responsible for processing the personal data collected on this form.

We have appointed a data protection officer (DPO). If you have any questions about this privacy notice or our data protection practices, please contact the DPO.

CONTACT DETAILS

Full name of legal entity: Medicover Genetics Limited (HE 418406)

Email address: dpo.cy@medicover.com

Postal address: 31 Neas Engomis Street, 2409 Engomi, Nicosia, Cyprus

Telephone number: + (357) 22266888

2. The data we collect about you

We collect, use, store and transfer personal data about you as follows:

- Identity Data.
- Contact Data.
- Sensitive data (medical/clinical data).

3. How we use your personal data

We will only use your personal data for the purpose for which we collected it. This includes the following:

- To register you as a new customer.
- To conduct the selected test and to process and deliver your results.
- To manage your relationship with us and to provide customer support, where applicable.
- To contact you or your referring healthcare provider on your results or for consultation purposes, where applicable.
- To invoice the referring healthcare provider.

4. How we share your personal data

We share your personal data with your referring healthcare provider, so we can communicate the results of your test to them.

Medicover Genetics stores personal information on its database which is hosted by cloud service providers.

5. International transfers

We do not transfer, store or process your personal data outside the European Economic Area (EEA) unless you or your referring healthcare provider are located outside the EEA.

6. Your legal rights

Under certain circumstances, you have rights under data protection laws in relation to your personal data including the right to receive a copy of the personal data we hold about you, the right to erasure ('right to be forgotten'), the right to restriction of processing and the right to make a complaint at any time to the Office of the Commissioner for Personal Data Protection.

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