

## SAMPLE INFORMATION FORM

Please complete sections below in English.

### PATIENT INFORMATION

FIRST NAME	LAST NAME	
DATE OF BIRTH	PATIENT GENETIC SEX	
PHONE NUMBER	ETHNICITY	
EMAIL		
SAMPLE COLLECTION DATE		
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	<b>DISEASE STATUS:</b> <i>(select all that apply)</i> <input type="checkbox"/> Primary <input type="checkbox"/> Metastatic <input type="checkbox"/> Refractory <input type="checkbox"/> Recurrent <input type="checkbox"/> Relapse <input type="checkbox"/> Progression
<b>DISEASE STAGE:</b> <input type="checkbox"/> Stage I-II <input type="checkbox"/> Stage III <input type="checkbox"/> Stage IV	ICD-10 CODE:
<b>TREATMENT STATUS:</b> <input type="checkbox"/> Pre-Treatment <input type="checkbox"/> Post-Treatment	<b>TREATMENT RECEIVED:</b> <input type="checkbox"/> Chemotherapy <input type="checkbox"/> Hormone Therapy <input type="checkbox"/> Immunotherapy <input type="checkbox"/> Radiotherapy
<b>SURGERY:</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	Targeted therapy <i>(Please specify):</i> ..... <input type="checkbox"/>
DATE OF COLLECTION (DD/MM/YY):	Other <i>(Please specify):</i> ..... <input type="checkbox"/>

### ATTACHMENTS (IF APPLICABLE)

PATHOLOGY OR CYTOLOGY REPORTS

TEST RESULTS FROM MOLECULAR DIAGNOSTIC ASSAYS

CLINICAL HISTORY

### FOR LABORATORY USE ONLY

F-OPR-01/08-V8-EN	ORDER NUMBER	LAB ID NUMBER	KIT LOT NUMBER
COMMENTS	DATE & TIME OF RECEIPT (DD/MM/YY HH:MM)		RECEIVED BY

## REQUESTED TEST

Panel options are available below. Please select one.

### EXTENDED

<input type="checkbox"/> <b>NeoThetis PAN-CANCER PLUS</b> 222 genes	<p>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, INSR, 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, TMPPSS2, TP53, TSC1, TSC2, U2AF1, VEGFA, VHL, WT1, XPO1, ZRSR2</p> <p><i>MSI and bTMB assessment included</i></p>
<input type="checkbox"/> <b>NeoThetis PAN-CANCER</b> 80 genes	<p>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, MRE11, 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, TMPPSS2, TP53</p> <p><i>MSI assessment included</i></p>

### CANCER-SPECIFIC

<input type="checkbox"/> <b>NeoThetis BREAST / GYNECOLOGICAL</b> 48 genes	<p>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, MRE11, MSH2, MSH6, MTOR, NBN, NRAS, NTRK1, NTRK2, NTRK3, PALB2, PIK3CA, PIK3CB, PMS2, POLE, PTEN, RAD51C, RAD51D, RAF1, RET, RUNX1, SMAD4, TP53</p> <p><i>MSI assessment included</i></p>
<input type="checkbox"/> <b>NeoThetis COLORECTAL</b> 34 genes	<p>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</p> <p><i>MSI assessment included</i></p>
<input type="checkbox"/> <b>NeoThetis GASTRIC</b> 23 genes	<p>APC, CDH1, EGFR, ERBB2, FGFR1, FGFR2, FGFR3, KIT, KRAS, MET, MLH1, MSH2, MSH6, NF1, NTRK1, NTRK2, NTRK3, PDGFRA, PIK3CA, PMS2, SMAD4, STK11, TP53</p> <p><i>MSI assessment included</i></p>
<input type="checkbox"/> <b>NeoThetis MELANOMA</b> 28 genes	<p>AKT1, ALK, BRAF, CTNNB1, ERBB2, FGFR1, FGFR2, FGFR3, GNA11, GNAQ, KIT, KRAS, MAP2K1, MET, MYC, NF1, NRAS, NTRK1, NTRK2, NTRK3, PDGFRA, PIK3CA, POLE, PTEN, RET, ROS1, STK11, TP53</p> <p><i>MSI assessment included</i></p>
<input type="checkbox"/> <b>NeoThetis NSCLC</b> 36 genes	<p>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</p> <p><i>MSI assessment included</i></p>
<input type="checkbox"/> <b>NeoThetis PANCREATIC</b> 26 genes	<p>ALK, ATM, BRAF, BRCA1, BRCA2, CDKN2A, CHEK2, ERBB2, FBXW7, FGFR1, FGFR2, FGFR3, KRAS, MLH1, MSH2, MSH6, MYC, NTRK1, NTRK2, NTRK3, PALB2, PMS2, ROS1, SMAD4, STK11, TP53</p> <p><i>MSI assessment included</i></p>
<input type="checkbox"/> <b>NeoThetis PROSTATE</b> 35 genes	<p>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, SPOP, TMPPSS2, TP53</p> <p><i>MSI assessment included</i></p>

For full information related to the type of alterations targeted in each gene, please visit [www.medicover-genetics.com](http://www.medicover-genetics.com)

**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 counseling from my referring healthcare provider on the NeoThetis test and to discuss with the healthcare provider all aspects of the NeoThetis test and this form including the benefits, risks and limitations of the NeoThetis 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 blood 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 any part of 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 diagnosis 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 NeoThetis test.
5. I have answered all the patient's queries about the NeoThetis 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.

#### NeoThetis

NeoThetis is a blood-based test offering comprehensive genomic profiling of solid tumors and determination of microsatellite instability (MSI) status and blood tumor mutational burden (bTMB) score. MSI is an important biomarker in predicting response to immunotherapy treatment, as indicated by immune checkpoint inhibitor FDA/EMA approvals for MSI-H tumors. bTMB is an emerging biomarker that may help predict response to immunotherapy. NeoThetis is based on a novel target capture enrichment technology that has been validated for its accuracy and precision.

#### SAMPLE COLLECTION

The test requires the collection of 20ml of blood. 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 shipping delay, 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 6-9 working days 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 variant of strong clinical significance or a variant of potential clinical significance (as classified based on international guidelines) has been reported to be associated with the patient's cancer type. It is possible that the test identifies more than one clinically significant variant and/or structural alteration. 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 variant or structural alteration has been identified for the test performed. A 'no clinically significant variant detected' result does not rule out any pathogenic variants or chromosomal 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 change has been detected, but it is currently unknown whether that specific change is associated with cancer. More scientific research and data are needed to clarify VUS and their role in cancer.

**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).

**Blood Tumor Mutational Burden (bTMB):** bTMB is a biomarker that indicates the number of somatic mutations present in the circulating tumor DNA (ctDNA) and is quantified as mutations per megabase (mut/Mb). TMB is considered as an independent, tumor agnostic biomarker, that indicates patients who are eligible for specific immunotherapy treatment. Tissue TMB-high, predicts the response to immunotherapy treatment, as indicated by selected immunotherapy FDA approvals for TMB-high tumors. bTMB is an emerging biomarker with no consensus harmonization cut-off. Therefore, bTMB is not yet approved by the FDA.

*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. NeoThetis 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.

Blood-based 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 NeoThetis.

*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](http://www.medicover-genetics.com).*

## 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](http://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](mailto: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 different kinds of personal data about you as follows:

- Identity Data.
- Contact Data.
- Sensitive data (ethnicity, patient genetic sex, 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 which include 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.
- To contact you or your results or for consultation purposes.
- 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 notify the results of your test to them.

We may also share your personal data with cloud service providers, as we store certain information online.

### 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.