

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		
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

TEST INDICATIONS

- DIAGNOSTIC
- FAMILY HISTORY
- FAMILY VARIANT
- PRESYMPTOMATIC
- OTHER

CLINICAL DIAGNOSIS

CLINICAL DIAGNOSIS:

ICD-10 CODE:

AGE AT DIAGNOSIS:

FOR LABORATORY USE ONLY

F-OPR-01/03-V9-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.

<input type="checkbox"/> PAN-CANCER 62 genes	APC, ATM, BAP1, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A ^{p16(INK4A)} , CDKN2A ^{p14(ARF)} , CHEK2, DDB2, DICER1, EPCAM, ERCC1, ERCC2, ERCC3, ERCC4, ERCC5, FANCA, FANCB, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FANCM, GREM1, HOXB13, MEN1, MLH1, MRE11, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, POLD1, POLE, POLH, PTEN, RAD50, RAD51C, RAD51D, RB1, RET, SDHAF2, SDHB, SDHC, SDHD, SLX4, SMAD4, SMARCA4, STK11, TP53, VHL, XPA, XPC
<input type="checkbox"/> BREAST & GYNECOLOGICAL 26 genes	ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, DICER1, EPCAM, MLH1, MRE11, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, POLD1, POLE, PTEN, RAD50, RAD51C, RAD51D, SMARCA4, STK11, TP53
<input type="checkbox"/> BREAST / GYNECOLOGICAL GUIDELINES-BASED 19 genes	ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH6, NBN, PALB2, PMS2, PTEN, RAD51C, RAD51D, STK11, TP53
<input type="checkbox"/> BREAST HIGH-RISK 7 genes	BRCA1, BRCA2, CDH1, PALB2, PTEN, STK11, TP53
<input type="checkbox"/> BRCA1 / BRCA2 2 genes	BRCA1, BRCA2
<input type="checkbox"/> COLORECTAL 17 genes	APC, BMPR1A, CDH1, CHEK2, EPCAM, GREM1, MLH1, MSH2, MSH6, MUTYH, PMS2, POLD1, POLE, PTEN, SMAD4, STK11, TP53
<input type="checkbox"/> COLORECTAL HIGH-RISK 10 genes	APC, BMPR1A, EPCAM, MLH1, MSH2, MSH6, MUTYH, PMS2, SMAD4, STK11
<input type="checkbox"/> COLORECTAL NON-POLYPOSIS 5 genes	EPCAM, MLH1, MSH2, MSH6, PMS2
<input type="checkbox"/> COLORECTAL POLYPOSIS SYNDROME 7 genes	APC, BMPR1A, MUTYH, POLD1, POLE, SMAD4, STK11
<input type="checkbox"/> FAMILIAL MELANOMA 7 genes	BAP1, BRCA2, CDK4, CDKN2A ^{p16(INK4A)} , CDKN2A ^{p14(ARF)} , PTEN, RB1, TP53
<input type="checkbox"/> GASTRIC 14 genes	APC, BMPR1A, CDH1, EPCAM, MLH1, MSH2, MSH6, PMS2, SDHB, SDHC, SDHD, SMAD4, STK11, TP53,
<input type="checkbox"/> MYELODYSPLASTIC SYNDROME / LEUKEMIA 24 genes	ATM, BRCA1, BRCA2, BRIP1, EPCAM, ERCC4, FANCA, FANCB, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FANCM, MLH1, MSH2, MSH6, PALB2, PMS2, RAD51C, SLX4, TP53
<input type="checkbox"/> PANCREATIC 17 genes	APC, ATM, BMPR1A, BRCA1, BRCA2, CDK4, CDKN2A ^{p16(INK4A)} , CDKN2A ^{p14(ARF)} , EPCAM, MEN1, MLH1, MSH2, MSH6, PALB2, PMS2, SMAD4, STK11, TP53
<input type="checkbox"/> PARATHYROID 1 gene	MEN1
<input type="checkbox"/> PARAGANGLIOMA / PHEOCHROMOCYTOMA 6 genes	RET, SDHAF2, SDHB, SDHC, SDHD, VHL
<input type="checkbox"/> PROSTATE 15 genes	ATM, BRCA1, BRCA2, CHEK2, EPCAM, HOXB13, MLH1, MSH2, MSH6, NBN, PALB2, PMS2, PTEN, RAD51D, TP53
<input type="checkbox"/> RENAL 13 genes	BAP1, EPCAM, MLH1, MSH2, MSH6, PMS2, PTEN, SDHAF2, SDHB, SDHC, SDHD, TP53, VHL
<input type="checkbox"/> SKIN (XERODERMA PIGMENTOSUM ASSOCIATED) 9 genes	DDB2, ERCC1, ERCC2, ERCC3, ERCC4, ERCC5, POLH, XPA, XPC
<input type="checkbox"/> THYROID 1 gene	RET

CLINICAL INFORMATION

PATIENT PERSONAL HISTORY OF CANCER

If yes, please fill in accordingly:

YES

NO

CANCER / TUMOR PATHOLOGY

<input type="checkbox"/> BREAST	TYPE: <input type="checkbox"/> ER	<input type="checkbox"/> PR	<input type="checkbox"/> HER2
	MULTIPLE PRIMARIES:	<input type="checkbox"/> YES	<input type="checkbox"/> NO
<input type="checkbox"/> OVARIAN	TYPE: <input type="checkbox"/> SEROUS	<input type="checkbox"/> MUCINOUS	<input type="checkbox"/> ENDOMETRIOID
	<input type="checkbox"/> CLEAR CELL	<input type="checkbox"/> MIXED HISTOLOGIES	<input type="checkbox"/> OTHER
<input type="checkbox"/> ENDOMETRIAL /UTERINE			
<input type="checkbox"/> PANCREATIC			
<input type="checkbox"/> PROSTATE	GLEASON SCORE:		
	METASTATIC:	<input type="checkbox"/> YES	<input type="checkbox"/> NO
<input type="checkbox"/> COLORECTAL	TYPE: <input type="checkbox"/> ADENOMATOUS	<input type="checkbox"/> OTHER	NUMBER OF POLYPS:
<input type="checkbox"/> MELANOMA			
<input type="checkbox"/> HEMATOLOGICAL	ALLOGENIC BONE MARROW TRANSPLANT OR STEM CELL TRANSPLANT:		
	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
<input type="checkbox"/> ENDOCRINE	TYPE: <input type="checkbox"/> THYROID	<input type="checkbox"/> PARATHYROID	<input type="checkbox"/> PARAGANGLIOMA
	<input type="checkbox"/> PHEOCHROMOCYTOMA	<input type="checkbox"/> OTHER:	
<input type="checkbox"/> RENAL			
<input type="checkbox"/> OTHER CANCER	Please specify:		

FAMILY CANCER HISTORY

FAMILY MEMBER 1	AGE OF ONSET	RELATION TO PATIENT
GENETIC SEX:	<input type="checkbox"/> FEMALE	<input type="checkbox"/> MALE <input type="checkbox"/> UNKNOWN
DIAGNOSIS		
FAMILY MEMBER 2	AGE OF ONSET	RELATION TO PATIENT
GENETIC SEX:	<input type="checkbox"/> FEMALE	<input type="checkbox"/> MALE <input type="checkbox"/> UNKNOWN
DIAGNOSIS		
FAMILY MEMBER 3	AGE OF ONSET	RELATION TO PATIENT
GENETIC SEX:	<input type="checkbox"/> FEMALE	<input type="checkbox"/> MALE <input type="checkbox"/> UNKNOWN
DIAGNOSIS		

ATTACHMENTS (IF APPLICABLE)

PEDIGREE IF AVAILABLE OTHER CLINICAL OR GENETIC TESTING REPORTS

PATIENT CONSENT

By placing my signature signing 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 PreSENTIA test and to discuss with the healthcare provider all aspects of the PreSENTIA test and this form including the benefits, risks and limitations of the PreSENTIA 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 buccal swab 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 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, and to the coding, storing and using of biological material.

PATIENT 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 PreSENTIA test.
5. I have answered all the patient's queries about the PreSENTIA 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

PATIENT INFORMED CONSENT

GENERAL INFORMATION

GENETIC TESTING

Genetic disorders are caused by certain small changes (mutations) in the sequence (order) of DNA, or from much bigger alterations in the structure or number of chromosomes (thread-like structures made up of DNA). Genetic testing tries to identify these changes in the DNA. The results of genetic testing may confirm or rule out a suspected genetic condition or help determine a person's chance of developing or passing on a genetic disorder.

PreSENTIA

PreSENTIA is based on a novel target capture enrichment technology that has been validated for its accuracy and precision. PreSENTIA examines genetic changes that are associated with an increased risk of hereditary cancer.

SAMPLE COLLECTION

Your healthcare provider will take a buccal swab sample following the provided sample collection instructions and send it to Medcover Genetics' laboratories for analysis. Occasionally, additional sample may be needed if there is a shipping delay, breakage of the sample collection device, sample degradation, sample contamination, inadequate sample, 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' result indicates that a pathogenic or likely pathogenic genetic variant or chromosome alteration has been identified in a gene associated with an increased risk of hereditary cancer. It is possible that the test identifies more than one clinically significant variant. The results should be interpreted in the context of the patient's clinical findings, biochemical profile or family history.

No clinically significant variant detected: A No clinically significant variant detected' indicates that no disease-causing genetic variant or chromosome 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. A 'no clinically significant variant detected' result does not guarantee that the individual will be healthy or free from genetic disorders or medical conditions.

Inconclusive / 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 change is associated with a genetic disorder either now or in the future. Further analysis may be recommended by your doctor. Detailed medical records or information from other family members may also be needed by your doctor in combination with clinical counseling to help clarify results.

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. It is recommended that you keep in contact with your referring healthcare professional to learn of any changes in your interpretation of your results or new developments in cancer genetics which may affect your cancer risk.

DISCLOSURE

Medcover Genetics is a fully accredited state-of-the-art genetic testing laboratory. All necessary measures are taken to perform the testing reliably and under strict standards. PreSENTIA 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 (mosaicism). The analysis is specific only for the tests ordered. This test will not detect all genetic alterations in the evaluated genes. Some undetected genetic changes could be disease-related and are not tested by PreSENTIA. Genetic testing is an important part of the diagnostic process. However, genetic tests may not always give a definitive answer. In some cases, testing may not identify a genetic variant even though one exists. This may be due to limitations in current medical knowledge or testing technology. Accurate interpretation of test results is dependent upon the patient's clinical diagnosis or family history, as well as the fact that any reported family relationships are true biological relationships. This test does not have the ability to detect all the long-term medical risks. Other diagnostic tests may still be necessary.

BENEFITS

Your genetic test results may help you and your doctor make informed decisions about your healthcare and management. The results of genetic testing may have implications on other blood relatives. It is recommended that you receive genetic counseling 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 PreSENTIA.

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.medcover-genetics.com.

PATIENT PRIVACY SUMMARY

This privacy notice provides a summary of how Medcover 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.medcover-genetics.com

1. Important information and who we are

Medcover 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: Medcover Genetics Limited (HE 418406)

Email address: dpo.cy@medcover.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 your 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.

Medcover 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.