MEDICOVER GENETICS

AFFIX
BARCODE LABEL – SIF
HERE

DONOR-RECIPIENT GENETIC TESTING SAMPLE INFORMATION FORM

Please complete sections below in English.

ORDERING HEALTHCARE PROVIDER INFORMATION

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

TESTED INDIVIDUAL INFORMATION

Sections with an asterisk must always be completed. Sections without an asterisk can be left blank only in cases the sample is anonymized.

FULL NAME **OR** PATIENT IDENTIFIER FOR ANONYMIZED SAMPLES*	
DATE OF BIRTH	PATIENT GENETIC SEX*
ETHNICITY*	PHONE NUMBER
EMAIL	SAMPLE COLLECTION DATE*
ADDRESS	
CITY / POST CODE / COUNTRY	

FAMILY HISTORY OF GENETIC DISORDER*: ☐ YES (Please specify) ..... ☐ NO

REQUESTED TEST

Please select all that apply

☐ **SPERM DONOR CARRIER SCREENING**
Testing and reporting of a fixed number of genes, as per prespecified panel

☐ **OOCYTE DONOR CARRIER SCREENING**
Testing and reporting of a fixed number of genes, as per prespecified panel

☐ **RECIPIENT CARRIER SCREENING**
Testing and reporting of a fixed number of genes, as per prespecified panel

☐ **MATCHING REPORT FOR DONOR-RECIPIENT**
If you select this option, please complete the next section

DONOR RECIPIENT MATCHING

Please complete if matching is requested

RECIPIENT TESTING *Choose one from the options below*	**DONOR TESTING** *Choose one from the options below*
☐ RECIPIENT TESTING TO BE PERFORMED BY MEDICOVER GENETICS NOW	☐ DONOR(S) TESTING HAS BEEN PERFORMED AT MEDICOVER GENETICS. THE DONOR(S) MEDICOVER GENETICS ORDER NUMBER ARE ..... *Please indicate up to two donor IDs*
☐ RECIPIENT TESTING HAS ALREADY BEEN PERFORMED BY MEDICOVER GENETICS. THE RECIPIENT'S MEDICOVER GENETICS ORDER NUMBER IS	
☐ RECIPIENT TESTING HAS BEEN PERFORMED ELSEWHERE *Attaching the report results is **mandatory***	☐ DONOR TESTING HAS BEEN PERFORMED ELSEWHERE *Attaching the report results is **mandatory***

Please attach all relevant medical records and clinical information.

FOR LABORATORY USE ONLY
F-OPR-01/22-V4-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

MEDICOVER GENETICS

CONSENT OF TESTED INDIVIDUAL

By placing my signature signing below I hereby:

1. Confirm that I have read, or have had read to me, the attached 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 selected test and to discuss with the healthcare provider all aspects of the selected test and this form including the benefits, risks and limitations of the selected 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 sample (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.

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.

Please sign either the 'Tested individuals' section **or** the 'anonymized samples' section, as applicable:

TESTED INDIVIDUALS:

☐ *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.*

ANONYMIZED SAMPLES:

☐ *I, the healthcare provider of the anonymous individual undergoing testing, confirm that I have received the individual's written consent with respect to the aforementioned points 1-6.*

☐ *I, the healthcare provider of the anonymous individual undergoing testing, confirm that I have received the individual's written consent with respect to the storing of their results to the Medicover Genetics' database.*

SIGNATURE OF TESTED INDIVIDUAL	HEALTHCARE PROVIDER SIGNATURE
DATE	**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/or 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 selected test.
5. I have answered all the patient's queries about the selected test.
6. This form has been completed according to the wishes and instructions of the patient.
7. I have obtained the patient's informed consent and have attested their signature.

HEALTHCARE PROVIDER SIGNATURE	DATE

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TESTED INDIVIDUAL INFORMED CONSENT

GENETIC TESTING FOR DONORS-RECIPIENTS

Medicover Genetics Donor-Recipient Genetic Testing analyzes genetic changes in the tested individual's DNA. The test is designed to determine whether the tested individual carries genetic changes that could cause moderate to severe genetic conditions when transmitted to a child. For most conditions on the panel, both partners must carry the genetic change in the same gene for their children to be affected (autosomal recessive). However, there are certain conditions for which only the female needs to carry a genetic change for her children to be at risk of developing symptoms (X-linked). Different technologies are used to perform this test.

When selected, matching for donors and recipients is provided. The matching report specifies whether there are mutations between the donor and the recipient causing the same genetic disorder.

SAMPLE COLLECTION

Your healthcare provider will take two buccal swabs following the provided sample collection instructions, and send it to Medicover 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 approximately 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 patient's test:

DONOR & RECIPIENT TESTING

Clinically significant variant detected: A clinically significant variant (change) indicates that a pathogenic or likely pathogenic genetic variant has been identified in one of the tested genes, and that you are a carrier of the associated disorder. You may be identified as a carrier for more than one disorder. Carriers usually do not experience symptoms of the disease. A 'clinically significant variant detected' result may also indicate the presence of two disease-causing mutations in the same gene, which would typically indicate that you are affected now or may be affected in the future. However, some of the disorders in this panel may be moderate or may vary in severity, so you may not experience clinically significant symptoms.

No clinically significant variant detected: A 'no clinically significant variant detected' result indicates that no disease-causing genetic variant has been identified for the test performed. A 'no clinically significant variant detected' result does not rule out any pathogenic variants in areas not assessed by the test, or in regions that were covered at a level too low to be assessed. A result of 'no clinically significant variant' does not guarantee that the individual is not a carrier.

DONOR RECIPIENT MATCHING

The genetic matching evaluation is based on a prespecified panel. This evaluation takes into consideration pathogenic and likely pathogenic variants at the time of genetic testing of each individual. In certain cases re-evaluation of variants will be performed. The genetic matching evaluation does not review the genetic changes for which the disease risk association is unclear – these are classified as Variants of Uncertain Significance (VUS) or likely benign and benign variants. The genetic matching evaluation does not take into consideration digenic inheritance. A 'No match' result indicates that the individuals have a high risk of transmitting at least one of the diseases included in the panel. A 'Match' result indicates that the individuals have a low risk of transmitting one of the diseases tested in the panel. The two individuals do not share pathogenic and likely pathogenic variants in the same gene. Furthermore, the woman is not a carrier of an X-linked disorder tested in this panel. The test does not take into consideration possible consanguinity. The referring clinician is responsible for counselling including the provision of advice regarding the need for additional genetic testing. Other diagnostic tests may still be necessary.

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 replace or add to the information currently known.

DISCLOSURE

Medicover 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. Medicover Genetics Donor-Recipient test is highly accurate, however, there is a small possibility for false positive, false negative or inconclusive 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, incorrect family history 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 test ordered. This test will not detect all genetic changes in the evaluated genes. Some undetected genetic changes could be disease-related and are not tested by this test. 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 change even though one exists. This may be due to limitations in current medical knowledge or testing technology. Re-evaluation of data in the future, when more clinical information is available may provide more information. This test does not have the ability to detect all the long-term medical risks, even if a genetic variant is identified. Other diagnostic tests may still be necessary.

BENEFITS

Your genetic test results may help you and your doctor make informed choices about your family planning, healthcare and management. The results of genetic testing may have implication 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 this test.

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 as it contains information about our data processing.

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

With this form we collect, use and store the following categories of personal data, where applicable:

- 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. 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.
- 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 may store 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 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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