Oreana®
neonatal screening

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	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	

PARENT / GUARDIAN INFORMATION

MOTHER / GUARDIAN'S INFORMATION

FIRST & LAST NAME

PHONE NUMBER

EMAIL

☐ PARENT ☐ GUARDIAN

FATHER / GUARDIAN'S INFORMATION

FIRST & LAST NAME

PHONE NUMBER

EMAIL

☐ PARENT ☐ GUARDIAN

REQUESTED TEST

☐ **Oreana**
Testing of 142 genes

For the complete list of genes tested, please visit www.medicover-genetics.com

TEST INDICATIONS

Please specify for all applicable categories

☐ FAMILY HISTORY:	☐ CARRIER PARENT(S):
☐ SYMPTOMS	☐ ABNORMAL PRENATAL TESTING:
☐ HIGH RISK ETHNICITY:	☐ OTHER

COMMENTS:

If applicable, please attach detailed medical record and clinical information.

FOR LABORATORY USE ONLY
F-OPR-01/07-V10-EN

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

RESTRICTED

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

CAP ACCREDITED COLLEGE of AMERICAN PATHOLOGISTS
LRQA CERTIFIED ISO 13485 UKAS MEDICAL ISO 9001
CYSAB ISO 15189
ISO 9001
IQNET RECOGNIZED CERTIFICATION

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PARENT/GUARDIAN CONSENT

By placing my signature below I hereby:

1. Confirm that I have read, or have had read to me, the attached Informed Consent for Oreana neonatal screening, that I understand it and consent to Medicover Genetics testing my child's sample.
2. Declare that I have had the opportunity to receive counseling from my child's referring healthcare provider on the Oreana test and to discuss with the healthcare provider all aspects of the Oreana test and this form including the benefits, risks and limitations of the Oreana test as well as the reasons for performing the test and availability of alternative testing options to my satisfaction.
3. Authorize my child's referring healthcare provider to collect the necessary buccal swab sample, and to submit this form and transport the sample to Medicover Genetics laboratories for the purposes of conducting the test 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 test requested with this form.
5. Authorize Medicover Genetics to communicate the results of the test to my child's referring healthcare provider.
6. Confirm that all the information on this form is true to the best of my knowledge.

☐ I wish to be informed if my child is a carrier for a genetic disorder tested by the Oreana test, and give permission to Medicover Genetics to report the carrier status as an incidental finding. I confirm that I have receive counseling from my child's referring healthcare provider regarding a positive carrier status for one or more genetic disorders.

The 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 child's 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 child's 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's parent/guardian has been informed about the nature and purpose of the testing.
4. The patient's parent/guardian 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 Oreana test.
5. I have answered all the patient's parent/guardian queries about the Oreana test.
6. This form has been completed according to the wishes and instructions of the patient's parent/guardian.
7. I have obtained the patient's parent/guardian informed consent and have attested their signature.

HEALTHCARE PROVIDER SIGNATURE	DATE

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PATIENT INFORMED CONSENT

OREANA TEST

Oreana screens for genetic changes (mutations) that can affect normal development, life quality and expectancy of newborns, infants or young children. These changes can lead to genetic diseases that initially may manifest without symptoms; however once symptoms begin, their damage may be irreparable and may not be reversed by treatment. The Oreana test can be useful for:

(a) Asymptomatic infants, for early detection which is most beneficial, as early clinical management reduces severity of symptoms and improves prognosis.

(b) Symptomatic infants presenting with signs or symptoms of a disease which are difficult to identify due to the complexity and variability of symptoms.

SAMPLE COLLECTION

Your healthcare provider will take two cheek swab samples from your child 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. The sample collection process is non-invasive and painless for the child, with the procedure lasting a few seconds.

RESULT INTERPRETATION

The results are communicated within 2-3 weeks directly to your child's 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 (change) indicates that a pathogenic or likely pathogenic genetic variant has been identified in a gene associated with a genetic disease. 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, symptoms, biochemical profile or family history.

No clinically significant variant detected: No clinically significant variant detected 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 will be healthy or free from genetic disorders or medical conditions.

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. Oreana 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, 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 changes in the evaluated genes. Some undetected genetic changes could be disease-related and are not tested by Oreana. A healthy carrier status is not reported by the Oreana test. If you wish to be informed whether your child is a carrier for any of the disorders tested by Oreana, please select the appropriate option on page 2 of the SIF, and the carrier status will be reported as an incidental finding. 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. 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 choices about your child's best clinical management plan, as well as for your family planning and healthcare. The results of genetic testing may have implication on other blood relatives. It is recommended that you receive genetic counseling before and after your child receives this genetic test.

QUALITY IMPROVEMENT

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

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 (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 the selected test and to process and deliver the results.
- To manage our relationship and to provide customer support, where applicable.
- To contact the customer or the referring healthcare provider on the results.
- To invoice the referring healthcare provider.

4. How we share your personal data

Personal data are shared with the referring healthcare provider, so that the results of the test can be communicated 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 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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