

PATIENT INFORMATION

PLEASE COMPLETE IN ENGLISH

FIRST NAME	LAST NAME	
DATE OF BIRTH	PATIENT GENETIC SEX	
ETHNICITY	PHONE NUMBER	
EMAIL	SAMPLE COLLECTION DATE	
STREET ADDRESS		
CITY	POST CODE	COUNTRY

ORDERING PHYSICIAN INFORMATION

PLEASE COMPLETE IN ENGLISH

CLINIC NAME	CLINIC ID	
REFERRING CLINICIAN		
PHONE NUMBER	FAX	
EMAIL		
STREET ADDRESS		
CITY	POST CODE	COUNTRY

REQUESTED TEST

PANELS OPTIONS

Aortopathy (48 genes) <input type="checkbox"/>	Arrhythmia (42 genes) <input type="checkbox"/>	Cardiomyopathy (98 genes) <input type="checkbox"/>	Congenital Heart Defects (80 genes) <input type="checkbox"/>
Familial Hypercholesterolemia (11 genes) <input type="checkbox"/>	Pulmonary Hypertension (11 genes) <input type="checkbox"/>	RASopathies (30 genes) <input type="checkbox"/>	<input type="checkbox"/>
Comprehensive Panel (292 genes) <input type="checkbox"/>			<input type="checkbox"/>

Includes all diseases tested in the other panels.

For the complete list of genes tested, please visit www.nipd.com/ventripanels

TEST INDICATIONS

FAMILY HISTORY (Please specify):	MEDICAL HISTORY (Please specify):
HIGH RISK ETHNICITY (Please specify):	SYMPTOMS (Please specify):
OTHER (Please specify):	

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

FOR LABORATORY USE ONLY

F-OPR-01/1/14-EN

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

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 clinician on the Ventrilia test and to discuss with the clinician all aspects of the Ventrilia test and this form including the benefits, risks and limitations of the Ventrilia test as well as the reasons for performing the test and availability of alternative testing options to my satisfaction.
3. Authorize my referring clinician to collect the necessary buccal swab sample, and to submit this form and transport the sample to NIPD Genetics laboratories for the purposes of conducting the tests requested with this form.
4. Authorize NIPD 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 NIPD Genetics to communicate the results of the test to my referring clinician.
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 NIPD Genetics improve and further develop the quality, accuracy and effectiveness of diagnosis and help us expand the scope of genetic testing. For this reason, NIPD 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 NIPD Genetics' database, the coding, storing and using of biological material.

PATIENT/GUARDIAN SIGNATURE _____

DATE _____

CLINICIAN 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 counselled about the test and has received all the advice necessary to provide their informed consent, including the benefits, risks, and limitations of the Ventrilia test.
5. I have answered all the patient's queries about the Ventrilia 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.

CLINICIAN SIGNATURE _____

DATE _____

Ventrilia TEST

Ventrilia screens for genetic changes that can cause various cardiovascular conditions. The Ventrilia test can be useful for:

- (a) Symptomatic individuals presenting signs of a cardiovascular disease
- (b) Presymptomatic individuals with a predisposing condition
- (c) Asymptomatic individuals with family history of inherited cardiovascular disease(s)

Genetic disorders are caused by certain changes in DNA (mutations). Genetic testing tries to identify these changes. 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.

SAMPLE COLLECTION

Your healthcare provider will take a buccal swab sample following the provided sample collection instructions and send it to NIPD 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 2-4 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 or likely pathogenic genetic variant (change) has been identified in a gene associated with an increased risk of a cardiovascular 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, 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 assess. A result of "no clinically significant variant" does not guarantee that the individual is healthy or free from genetic disorders or medical conditions.

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. More scientific research and data are needed to clarify VUS and their role in disease. VUS will only be reported in cases of potential pathogenicity. The carrier status in recessive conditions will not be reported.

In case of a VUS result, further analysis may be recommended by your healthcare provider. Detailed medical records or information from other family members may also be needed by your healthcare provider, 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 health professional to learn of any changes in your interpretation of your results or new developments.

DISCLOSURE

NIPD 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. Ventrilia 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 changes in the evaluated genes. Some undetected genetic changes could be disease-related and are not tested by Ventrilia. The carrier status in recessive conditions is not reported by the Ventrilia 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 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 take informed decisions about your 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 Ventrilia.

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.nipd.com

This short privacy notice provides a summary of how NIPD Genetics Public Company Ltd (NIPD) 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 from your referring clinician.

1. Important information and who we are

NIPD Genetics is the controller and responsible for your personal data.

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: NIPD Genetics Public Company Ltd (HE 275644)

Name of DPO: Mrs Meropi Georgiou

Email address: dpo@nipd.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 purposes for which we collected it which include the following:

- To register you as a new customer.
- To conduct the Ventrilia test and to process and deliver your results.
- To manage your relationship with us.
- To contact you on your results or for consultation purposes.
- To invoice the referring clinician.

4. How we share your personal data

We share your personal data with your referring clinician, 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 unless you and your referring clinician is 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.