BIOARRAY
Genetic Diagnosis

Parque Científico y Empresarial de la UMH. Edificio Quorum III
Avenida de la Universidad s/n. 03202 Elche (Alicante - Spain)
Tlf: +34 96 668 25 00 Fax:+34 96 668 25 01
info@bioarray.es www.bioarray.es

GENETIC TESTING CONSENT

Patient:
Mr. / Mrs: _____ from: _____ date of birth: __/__/____ ID: _____

Informing physician:
Dr: _____
Hospital/Clinic: _____
Requested Genetic Test: _____

I declare that I am informed and have understood that the patient _____
_____
may be affected or carry an inherited disease and that the diagnosis is based on the result of laboratory tests, which must be carried out with biological samples from the patient (and other family members when necessary).

- I give my consent for BIOARRAY, S.L. to use these samples in the diagnostic procedure, in the Centre itself and/or others designated by the Centre, when necessary:

☐ YES ☐ NO

- I consent to the storage and preservation of samples for possible use in genetic disease research: ☐ YES ☐ NO

- I consent to the use of the patient's iconographic material exclusively for scientific and diagnostic purposes: ☐ YES ☐ NO

Only health personnel duly authorised by Bioarray, S.L. may access personal data and the results of genetic tests.

DATA PROTECTION

In accordance with data protection regulations, we provide you with the following treatment information:

Responsible party: BIOARRAY, S.L.

Rights that assist you: access, rectification, portability, deletion, limitation and opposition.

The Spanish Law 14/2007 of July 3 of Biomedical Research (LIB), establishes regulation for the performance of genetic analysis with health purposes.
In accordance with Law 41/2002 on Patient Autonomy and Law 3/2018 on the Protection of Personal Data, the applicant must have the patient's consent to carry out the diagnostic tests requested and to process his/her data. In this way, and as information to be provided to the patient, we must inform you that the data collected in this form will be included in a confidential automated file, duly registered in the Spanish Data Protection Agency, in accordance with the terms established in Law 3/2018, whose ownership corresponds to Bioarray, S.L, in order to manage the diagnostic study in the form described, the patient may exercise at any time the rights of access, rectification, cancellation or opposition, recognized by the aforementioned legislation on the protection of personal data, addressing the following address : Bioarray S.L., Parque Científico de la UMH. Edificio Quorum III 03202 Elche (Alicante), email: info@bioarray.es Ph: 966682500 Fax: 966682501

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More treatment information: http://bioarray.es/es/

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Purposes and legitimation of the treatment

For the legitimate interest of the responsible party (GDPR, Article 6.1.f): maintain a professional relationship, send communications, analyze data and publish scientific and informative articles.

By consent of the interested party (GDPR, article 6.1.a): sending communications, analyzing data and publishing scientific and informative articles.

Data retention criteria: will be kept for no longer than necessary to maintain the end of the treatment and when it is no longer necessary for this purpose, they will be eliminated with adequate security measures to guarantee the pseudonymisation of the data or the total destruction thereof.

Communication of the data: the data will not be communicated to third parties, except legal obligation.

I give my consent for the storage and preservation of the samples for possible use in the research on genetic disease and I authorize the transfer of the results of the clinical studies in an anonymous form for the study and pharmacological development, the sending of communications, data analysis and publication of scientific and informative articles:

□ Yes □ No

If you understood the information provided to you, you had all your questions solved and you give your consent for genetic testing under the above terms, please affirmatively sign below this informed consent form:

Place _____ date: __/ __/ ___

Signature of Physician	Signature of Patient

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Diagnóstico Genético

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Test Requisition Form for Sample Shipment

PLEASE REQUEST SAMPLE COLLECTION AT info@bioarray.es

Requisitioner details

Medical Center / Health Facility | Service/Department | Date

First Name | Family Name | E-mail

Address | City

Province/State | Postal Code | Country | Phone

Patient details

First Name | Family Name | Gender | Date

Birthdate | Medical Record no. | E-mail

Province/State | Postal Code | Phone

Sample information

Sample type | Extraction method | Extraction date

Clinical Data *(enclosing of reports is recommended)*

Indication

Summary of relevant medical history

Requested Test

Postnatal aCGH Agilent	☐ 60k	☐ 180k	☐ 400k
Postnatal aCGH Affymetrix	☐ 750k		
Prenatal aCGH Agilent	☐ 60k		
Miscarriage (POC) aCGH Agilent	☐ 60k		
Single Gene Sequencing	Indicate gene or test reference: _____		
MLPA / del-dup test	Indicate gene or test reference: _____		
Triplet Repeat Expansion test	Indicate test reference or quotation no.: _____		
Gene Panel Sequencing	Indicate test reference or quotation no.: _____		
Whole Exome Sequencing:	☐ Single	☐ Trio	
Whole Genome Sequencing:	☐ Single	☐ Trio	

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Informed Consent - Sequencing

My signature at the end of this document indicates that I have understood and accepted the information below and that I had the opportunity to get all my questions clarified. Therefore, I express my consent to Bioarray, S. L. to use these samples in order to make the following genetic study, as well as other designated centers whenever necessary.

Test description

1. Genetic alterations can be caused by alterations in the DNA sequence of a gene, but also by deletions (losses) or duplications (gains) of genetic material. Deletions or duplications can affect part of the gene, the whole gene or multiple genes.
2. This test examines one or several genes of the patient, in search of genetic alterations which help determine whether the patient is affected, or at increased risk, of suffering a specific genetic alteration.
3. This test cannot determine all kinds of mutations, deletions or duplication causing genetic alterations. Especially, it does not detect alterations affecting genes which are not included within the test's targeted genes. My doctor can provide the information regarding the specific alterations this test can detect. This information can also be found at Bioarray's website (http://www.bioarray.es/en).
4. A positive result of this test indicates there is a genetic alteration with clinical significance. A negative result indicates either that no alteration was found or that the found alterations have no clinical significance. Sometimes, the test detects genetic alterations of unknown significance, making difficult to achieve a diagnosis or even making impossible to get a conclusive result. In some of these cases, testing of patient's parents may be necessary to elucidate the result.
5. This test is not the only approach to search for genetic alterations, so my doctor may recommend this test before or after completing other genetic testing.
6. Although methods used by this test are highly specific and sensitive, a very slight risk of technical failure or a misinterpretation still exists.
7. This tests requires high quality DNA. Sometimes additional patients sample may be necessary if initial volume, quality and/or condition of the sample is not adequate.
8. I can revoke the authorization for performing this genetic test at any time.

About the results of the test

9. I understand that if a genetic alteration is not detected, this does not exclude the existence of a genetic disease.
10. I understand that this test can detect genetic alterations which explain the disorder I suffer (or my child suffers). Moreover, these genetic alterations can have long-term health implications which I now ignore. My doctor will be informed of these implications, although this test does not detect all long-term health risks.
11. There can be incidental findings: alterations that are detected coincidentally and are unrelated to the disease or condition being studied. However, they can have relevant effects on the patient and/or their family's health.
12. In this analysis, variants of uncertain significance (VUS) can be found. This means that an alteration which has an unknown effect on the pathology has been detected, meaning that it could be a benign variant or the cause of an alteration. In these cases, it could be necessary to analyze the parents to determine whether the alteration is the cause of the pathology or not.
13. I understand that this test can find genetic alterations of unknown significance. This means that the test found an alteration whose pathological implication is unknown, so it can be either a benign

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variant or a pathological one. In such cases, it may be necessary to tests patient's parents in order to determine whether the found alteration is cause of pathology or not.

14. Results of this test may have implications for my family.
15. It is advisable that the patient or the family receive genetic counseling before and after performing the test. Because of the complexity and important implications of genetic studies, test results will be communicated to me by means of a doctor or a genetic expert of my election, always with the highest confidentially.

Limitations

1. Sometimes the test will not identify the molecular cause of the pathology even if there is a genetic alteration. This may be due to limitations caused by the lack of knowledge of the complete gene structure; because not all the alterations which cause the pathology have been identified, because the test does not detect all kinds of genetic alterations, or because the alteration exists in a very low number of patient's cells (mosaicism) that cannot be detected.
2. For an accurate interpretation of the test it is sometimes required to know the real biological relationships in the family. The unawareness of these relationships may lead to an incorrect interpretation of the results.

Confidentiality

3. Only the physician or reference center of my choice will receive a copy of the result report, in order to preserve absolute confidentiality.
4. The results can be used in scientific papers or presentations, with all tested people's identities will not be revealed whatsoever at any time.

Samples preservation

1. Biological samples (e.g. blood) received by Bioarray will not be preserved.
2. DNA samples used for testing will be kept in the lab for 5 years. These samples will be available for additional testing, if required.

Data protection

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□ Yes □ No

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□ Yes □ No

Informed person (Name and signature):
ID number (if available):
Relationship with the patient:

Physician (Name and signature):