BIOARRAY
Genetic Diagnosis

Parque Científico y Empresarial de la UMH. Edificio Quorum III
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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

1. I understand that if a genetic alteration is not detected, this does not exclude the existence of a genetic disease.
2. 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.
3. 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 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.
4. Results of this test may have implications for my family.
5. 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.

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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

1. Only the physician or reference center of my choice will receive a copy of the result report, in order to preserve absolute confidentiality.
2. 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

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

BIOARRAY S.L. is responsible for the processing of personal data of the Interested Party and informs that these data will be treated in accordance with the provisions of Regulation (EU) 2016/679 of April 27 (GDPR) and Organic Law 3/2018 of 5 December (LOPDGDD), so the following treatment information is provided:

Purposes and legitimation of the treatment

By the legitimate interest of the responsible party (GDPR, Article 6.1.f): maintaining a professional relationship, sending communications, analysing data and publishing scientific and informative articles.

By consent of the interested party (GDPR, article 6.1.a): sending communications, analysing 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:

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□ Yes □ No

Informed person (Name and Signature):
ID/Passport no.:
Relationship with patient:

Physician (Name and signature):