

INFORMED CONSENT ARRAY CGH

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. Array CGH is indicated for disorders in which a chromosomal anomaly is suspected as the cause.
2. This test studies patient's genome to search for genetic material gains or losses which cause most of genetic diseases.
3. A positive result of this test indicates there is a chromosomal alteration with clinical significance. A negative result indicates there's not any alteration or the discovered alterations have no clinical significance. Sometimes, the test detects clinical alterations of unknown significance, making difficult to achieve a diagnosis and to even get a conclusive result. In some of these cases, parents' analysis may be necessary to clear up the result.
4. Array CGH is not the only technique to detect chromosomal alterations, so my doctor can recommend this test to me before or after I do other genetic testing. This technique cannot detect chromosomal alterations in which the total amount of the individual's genetic material stays unaltered. Slight changes which are under the test resolution could be unnoticed too.
5. Some genome's areas can show copy number variations, without necessarily being a cause for pathology. This is a normal variation among people.
6. Although methods used by this test are highly specific and sensitive, a very slight risk of technical failure or a misinterpretation still exists.

About test results:

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 material gains or losses which explain the disorder I suffer (or my child suffers). Moreover, these genetic alterations can have long-term health implications which I ignore now. My doctor will inform me of these implications, although this test does not detect all of long-term medical risks.
3. Test results may have implications for my family.
4. 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 elected by me, always with highest confidentiality.
5. Only this doctor or a center elected by me will receive a copy of the results report, in order to keep absolute confidentiality.
6. I can revoke my authorization for doing this genetic study at any time.
7. I express my consent for the storage and conservation of samples for its possible use in genetic disease research.
8. I express my consent to use patient's iconographic material for medical or scientific purposes only.

☐ Yes

☐ No

☐ Yes

☐ No

DATA PROTECTION

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

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
Rev00

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 legitimization 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:

☐ Yes

☐ No

Informed person (Name and signature):

ID number (if available):

Relationship with the patient:

Physician (Name and signature):