BIOARRAY
Genetic Diagnosis

Parque Científico y Empresarial de la UMH. Edificio Quorum III
Avenida de la Universidad s/n. 03202 Elche (Alicante - Spain)
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info@bioarray.es www.bioarray.es

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

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.

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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

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□ Yes □ No

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

Physician (Name and signature):

BIOARRAY
Diagnóstico Genético

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For BIOARRAY Use Only

TEST REQUISITION FORM

PLEASE, COMPLETE THIS FOR TO THE BEST OF YOUR KNOWLEDGE
IF REQUIRED FIELDS ARE NOT PROVIDED, TESTING MAY BE DELAYED.

PATIENT INFORMATION

First Name _____ Last Name _____ Patient ID _____ DOB *(MM/DD/YYYY)* _____ Sex ☐ F ☐ M

Address _____ City _____ State _____ Postal Code _____ Country _____ Primary Phone _____

CURRENT DIAGNOSIS/PATIENT HISTORY

Diagnosis (Full Description Primary Cancer type) _____ Stage _____

Sample provided: ☐ FFPE Tissue Primary Tumor ☐ FFPE Tissue Metastasis Metastasis location/description: _____
☐ Peripheral Blood

Sample tumor cellularity: _____ Collection date (Obligatory for blood samples): _____

Reason for referral

Summary Clinical History (include Histopathology description or family history if relevant):

Prior/Current Targeted Therapies *(optional)* .....

PLEASE ATTACH:

☐ Extended clinical history of the patient

☐ Test results from all other Molecular Diagnostic Assays by FISH, IHC, orother genetic assays, e.g., *ER, PR, HER2, EGFR, KRAS,* etc.

TREATING PHYSICIAN INFORMATION (Please provide best contact information for case follow-up)

Facility/Hospital

Facility /Hospital address

Treating Physician

Email

Phone

Additional Physician/contact to be copied (optional)

Email

TEST REQUEST (Mark one with an X)

Select	Test requested	Specimens accepted *
	Comprehensive Assay Plus	FFPE Tissue or Fine needle aspiration
	Comprehensive Assay	FFPE Tissue or Fine needle aspiration
	Clarity Test (Hereditary Cancer Risk Evaluation)	Peripheral Blood or Saliva
	BRCA test	FFPE Tissue (or Peripheral Blood for germline assay)
	BRCA extended test	FFPE Tissue (or Peripheral Blood for germline assay)
	Colorectal cancer test	FFPE Tissue (or Peripheral Blood for germline assay)
	MSI test	FFPE affected + normal Tissue
	Pan-cancer Liquid Biopsy	Peripheral Blood
	Breast cancer Liquid Biopsy	Peripheral Blood
	Colorectal cancer Liquid Biopsy	Peripheral Blood
	NSCLC Liquid Biopsy	Peripheral Blood

* Check information about specimen requirements, sample collection and transportation before sending samples.

ADDITIONAL TESTS (Immunohistochemistry markers)

Select	Marker requested
	MLH1
	MSH2
	MSH6
	PMS2
	HER2
	PD-L1

* Check information about specimen requirements, sample collection and transportation before sending

BILLING INFORMATION

Facility/Hospital/Insurance

Address

Contact information

Email

Phone

Authorized representative

Signature

TEST AUTHORIZATION AND PHISICIAN SIGNATURE

My signature constitutes a Certificate of Medical Necessity, certifies that this test information will inform the patient's ongoing treatment plan, and certifies that I am the patient's treating physician. I have explained to the patient the nature and purpose of the testing to be performed and have obtained informed consent, to the extent legally required, to permit Bioarray to 1. perform the testing specified herein, 2. retain the test results for an indefinite period for internal quality assurance/operations purposes, 3. de-identify the test results and use or disclose such de-identified results for future unspecified research or other purposes, and 4. release the test results to the patient's third-party payer as needed for reimbursement purposes.

My signature also authorizes Bioarray to proceed with the test, ensuring that the selected test in this form has been chosen by a medical exert following the patient case study, understanding the information that I may be able to obtain and limitations of the test.

Signature

Date

*FFPE SAMPLES

- For genetic analysis a FFPE block containing the **unstained tissue** must be sent.
- Alternatively, if sending FFPE tissue slides, 2-3 slides of 10µm each are required. Slides are requested to be sent in individual collection tubes or individual microscope slides with no cover.
- Samples of at least 20% tumor cellularity are required.
- Samples should be stored at room temperature and kept away from extreme temperatures.

*BLOOD SAMPLES

- Liquid biopsy testing: 1 tube of peripheral blood must be provided (10mL). Blood will be collected into tubes containing Streck preserving medium (10mL). After blood collection, tube should be gently but properly mixed by inverting (10 times) and kept at room temperature, away from extreme temperatures (do not freeze, do no refrigerate). Samples should be sent as soon as possible after blood extraction. We strongly advise to send the same sample the same day that the extraction is performed.
- Clarity test: 1 tube of peripheral blood must be provided (10mL). Blood will be collected into EDTA tubes (10mL). After blood collection, tubes should be gently but properly mixed by inverting and kept at room temperature, away from extreme temperatures (do not freeze). Samples should be sent as soon as possible after blood extraction.
- Non-liquid biopsy blood samples: 1 tube of peripheral blood must be provided (10mL). Blood will be collected into EDTA tubes. After blood collection, tubes should be gently but properly mixed by inverting and kept at room temperature, away from extreme temperatures (do not freeze). Samples should be sent as soon as possible after blood extraction.

- All samples must be properly identified with patient credentials.
- All samples should be transported at room temperature with appropriate containers that buffer significant temperature changes.
- Blood samples should be sent the day of the collection or the following day so ensure the integrity of the sample.

DO NOT HESITATE TO CONTACT OUR TEAM FOR QUESTIONS RELATED TO SAMPLE COLLECTION, ACCEPTED MATERIAL OR TRANSPORTATION METHODS.