BIOARRAY
Genetic Diagnosis

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Informed consent for endometrial biopsy and Endometrial Receptivity test (BioER)

My signature at the end of this document indicates that I understood and accepted the information contained herein and that I had the opportunity to clarify all my questions. I give, therefore, consent to Bioarray S.L. to use these samples in the performance of the genetic study indicated in the attached form, as well as in other centers assigned by it when necessary.

WHAT IS BioER?

BioER is a molecular diagnosis test that is used to determine if the endometrium (mucous lining of the uterus) is receptive after five full days of progesterone exposure, the time at which the endometrium is typically ready for embryo implantation. The test measures the expression profile of more than 300 genes of endometrial tissue using Next Generation Sequencing (NGS).

Consequently BioER helps determine if the endometrium presents the ideal conditions for embryo implantation and therefore enables the embryonic transfer to occur at the ideal time for the endometrium. Thus increasing the chances of successful in vitro fertilization treatment.

PROCEDURE, RISKS, LIMITATIONS

BioER requires an endometrial biopsy performed by inserting a very thin cannula through the vagina until it reaches the uterus, where a small cylinder of endometrial tissue is taken. This is the least invasive technique available to obtain a sufficient amount of endometrial material. This procedure may cause some discomfort and slight bleeding after the biopsy. However, this is a standard procedure with no added risks.

The biopsy must be performed seven days after the LH surge (natural cycle), seven days after the hCG injection (natural hCG cycle) or after five full days of progesterone exposure (hormone replacement -HRT- cycle).

If BioER detects a shifted window of implantation, the result will recommend the optimal day/time for embryo transfer, differently than the day/time at which biopsy was taken. In some cases, a second endometrial biopsy may be required and will be taken according to the test result.

In approximately 1% of the cases a non-informative result is obtained. There is a small chance (lower than 5%) that a sufficient quantity and/or quality of tissue is not obtained by the biopsy in order to perform the test. In both situations above, a new endometrial biopsy will be required.

The results obtained with BioER must be jointly interpreted with other clinical data, within the context of a medical practice run by physicians. The report is strictly confidential.

In order to process the sample, it is necessary properly fill the required the fields in the test requisition form. If any of these fields are not properly completed, then the analysis could be delayed until the information is sent to our laboratory.

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CONFIDENTIALITY

Only experienced personnel will have access to the sample, test information and results. All results will be kept confidential in accordance with applicable laws and guidelines. The results will only be disclosed to your doctor and the requesting health care institution.

Only the requested and authorized test shall be carried out on the identified sample.
The results obtained may be used in scientific publications or presentations, but the identity of all persons studied will not be revealed at any time. The collection of the information obtained is part of a laboratory's standard practice for quality purposes and is required by laboratory accreditation.

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:

□ Yes □ No

Informed patient (Name and signature):

ID number (if available):

Physician (Name and signature):

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Informed Consent for Microbiome Study

DESCRIPTION, PURPOSE AND BENEFITS OF THE ANALYSIS

The test which assesses the endometrial and vaginal microbiome named **MicroVE** is a molecular test which evaluates the global profile of the bacterial populations present in the endometrium and vagina. This analysis is based on bacterial DNA detection via NGS (Next Generation Sequencing); which determines the different profiles that have been seen to affect the process of implantation and successful pregnancy. **MicroVE** can be beneficial to any woman who wishes to be a mother, especially those who experience recurring implantation failure, analysing the microbiome in the uterine and vaginal cavities, including the pathogens which most commonly cause alterations in these tissues. **MicroVE** will inform of the bacterial populations present in the samples and recommend the most appropriate actions in order to re-establish the most physiologically suitable microbiome in the uterus for embryo implantation.

PROCEDURE, RISKS AND LIMITATIONS

In order to carry out the test, an endometrial biopsy sample must be taken. This is obtained when a very thin cannula is inserted through the vagina and into the uterus, where a small cylinder of tissue is absorbed. This small sample is enough to carry out the complete analysis. During this procedure you may feel some discomfort and may slightly bleed after the biopsy, but this is a common consequence with no additional risk.

In order to process the sample, the Sample requisition Form must be completed and given in. On the contrary, the analysis may be detained until this required information is provided to the laboratory.

Due to the complexity of the genetic tests and the important implications of the test results, said results must be interpreted along with other clinical data, within the general context of a medical consultation which must be directed by health professionals. The results reports will be strictly confidential.

The test results will be available in approximately 15 working days. A small percentage of samples may be variably delayed due to unpredictable causes. If this happens the delay will be notified to the corresponding clinical entity.

It is convenient if the sampling is as close as possible to embryo transfer cycle, because the endometrial and vaginal populations could fluctuate over time due to different factors (hormonal changes, hygiene habits, general health fluctuations, the immune system, sexual relationships, additional medical treatments, etc.). It is also important that the patient has not had any antibiotic treatments within the last month before the sampling procedure. If this cannot be avoided, it must be indicated on the sample requisition form. In some cases the result may not allow a diagnosis to be established, which can occur due to insufficient bacterial DNA in the sample ot because the sample has been contaminated during the sampling process, pickup or transport. If this were to happen, a new sample may be requested.

DATA PRIVACY, STORAGE AND USE OF SAMPLES FOR RESEARCH

Your privacy is a priority for Bioarray. Your identity and the data regarding your personal information will be strictly confidential. Access will only be allowed for qualified personnel at Bioarray and corresponding authorities when jurisdiction laws apply and require it.

We would like to inform you that your personal data will only be used for the following puposes: (1) Complete the obligations derived from the services hired by you; (2) Check and guarantee quality in our offered services (internal audits, quality controls, external validation of the laboratory); (3) Educational purposes, however always maintaining anonymity and not allowing identification during the analysis of the data, which will be eliminated from any publications; (4) Investigation purposes, scientific publications and presentations, in which in no case will identity data of any patients be revealed; (5) Offer personalised attention to any queiries and suggestions the patient may have during the process and to ensure the correct execution and resolution of the test, including the undefined conservation of your data, except of local jurisdiction laws apply and establish the contrary; y (6) Get in contact with the patient in the future in order to

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request an assessment of our service, carry out comercial communications as well as participate in market research and the development of new products.

Therefore, you give consent for your gynaecologist to provide us with the information regarding the personalised embryonic transfer which is associated to the result of this test, with the purpose of completing the endometrial clinical evaluation.

You declare that you understand and accept that you will not obtain, now nor in future, any economic benefit for any investigation, and that you will not be compensated for the development of any products from any of these investigations.

Bioarray reserves the right to carry out part of or the totality of the analyses which make up the test via third accredited laboratories with well recognised quality standards, or which are periodically evaluated by Bioarray. The results obtained this way will be assessed by Bioarray.

As stated by the Personal Data Protection Act, the requisitioner must provide the patient's consent form in order to carry out the requested diagnostic tests for data analysis. You may exert at all times your right of access, rectification, opposition, deletion, automated decisions, limitation and portability of data

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I DECLARE, HAVING READ AND UNDERSTOOD THE DESCRIPTION ABOVE, I AM INFORMED:

My signature at the end of this document means that I comprehend and accept the information which described here and I have had the opportunity to clear all my queiries. Therefore, I give my consent to Bioarray S.L. to use these samples in the performance of the indicated test, as well as in other centers designated by it when necessary.

DATA PROTECTION

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□ **Yes** □ **No**

Patient's Signature: _____

Name: _____

Date: _____

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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Requisition for MicroVE (Microbiome) and BioER (Endometrial Receptivity)

Requisitioner Details

Medical Center/Health Facility | Department | Date

Medical Specialist | Phone number | e-mail

Address | City | State | Country

Requested test

☐ **MicroVE**
- ☐ Single test price
- ☐ Follow-up program price (includes 2nd and 3rd tests when alteration detected and treatment follow-up is required)

☐ **BioER**

Patient Details

Name and Surname | Age | Date of birth

ID | Phone number | e-mail

Diagnosed gynecological condition (if applies)

☐ IVF Failure (number of previous cycles: ___)
☐ Miscarriage (number of previous miscarriages: ___)

Shipping this sample along with this form to Bioarray implies the acceptance of the previously provided quotation.
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Sample Details

Sample type

☐ **Endometrial Biopsy** BIOARRAY Sticker

Endometrial biopsy method: ☐ Pipette ☐ Curette ☐ Hysteroscopy | Sample size: ____ mm

Biopsy date: _____ time: _____ ☐ 1st biopsy / ☐ 2nd biopsy

Cycle type and collection date:

☐ HRT:	P+____ (e.g. P+5)[1]	First P4 intake:	date _____ time _____
☐ Natural:	LH+____ (e.g. P+7)[2]	LH surge:	date _____ time _____
	hCG+____(e.g. hCG+7)[3]	hCG injection:	date _____ time _____

[1] Day of the first progesterone intake is P+0.
[2] Day of the LH surge is LH+0.
[3] Day of the hCG injection is hCG+0.

☐ **Vaginal Sample** BIOARRAY Sticker Sampling date: _____

Have you had any antibiotics treatment in the last month? ☐ NO ☐ YES

If you replied YES, please fill the requested information bellow:

Antibiotic prescribed	Treatment lenght	End-date of treatment

Have you ever had a prior microbiome analysis using microVE? ☐ NO ☐ YES

If you replied YES, please fill the requested information below:

Report date	Results	Treatment prescribed

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