Pronacera
Showing R&D results

TEST REQUISITION FORM

MiFERT&t

Patient information

First Name*: _____
Last name*: _____
DOB*: _____
Weight (kg)*: _____ Height (cm)*: _____
Country: _____
Email: _____
Preferred language for results report:

◯ Spanish ◯ English

Clinic information

Name* : _____
Phone number: _____
Email: _____
Country: _____
City: _____
Ordering physician*: _____
Email: _____
Phone number: _____

Study information

Last period date*: _____
Menstrual cycle day: _____
Medication at the time of the study: _____
_____
_____
_____

Required studies:

◯ Receptivity
◯ Inmunology
◯ Microbiome (endometrial biopsy)

Cycle information

Type of cycle*: ◯ Natural cycle ◯ HRT cycle

1st P4 intake: Date* _____ Time* _____ P+ _____ (p.e. P+5*)
*The first day of P4 administration is considered as P+0

LH peak: Date* _____ Time* _____ LH+ _____ (p.e. LH+7*)
*The peak day is considered as LH+0

hCG injection: Date* _____ Time* _____ hCG _____ (p.e. hCG+7*)
*The day of the hCG injection is considered as hCG+0

Sample information

Type of sample: Endometrial biopsy
Collection date*: _____
Time*: _____

◯ First sample
◯ Second sample
◯ Third sample

(It is recommended to measure and record the endogenous P4 concentration prior to its exogenous administration)

◯ Other (specify): _____
_____

In case of repeat biopsy, indicate if previous treatment has been received along with the duration and dosage of treatment: _____
_____
_____

Study indication

◯ Implantation failure (1 or 2)
◯ Implantation failure (3 or more)
◯ Miscarriage (1 or 2)
◯ Miscarriage (3 or more)
◯ Single embryo avaiable
◯ Adenomyosis
◯ Obesity
◯ Euploid embryo failure
◯ Ovodonation failure
◯ Endometriosis
◯ Endometritis
◯ Other (abnormal discharge, pelvic pain, stinguing, vaginal swelling, candidiasis): _____
_____

Patient authorization and consent

This consent provides information about the endometrial receptivity test (s) and microbiotic status. You are considering accesing this test (es) to determine the state of your endometrium prior to embryo transfer by in vitro fertilization (IVF) methods. This study is completly optional, and you are not required to authorize testing, even if it has been recommended by your healthcare provider. The risks, benefits and limitations that exist when using this test (s) should be discussed in detail with a physician, geneticist and/or medical advisor, after that you can authorize by signing this consent form. You are responsible of informing your doctor or authorized healthcare provider of any relevant changes in your medical or family history. Signing this consent form indicates that you understand the risks, benefits and limitations of the study and give your consent:

- In order to carry out each study (receptivity and/or microbiota imbalance), different types of samples will be requested, among which are: an intervention for taking and endometrial biopsy, a vaginal swab and vaginal sample using a brush. Depending on the test, additional data may be requested, through additional forms or analytics, to complete diagnosis.
- The extraction and pre-processing procedure of the genetic material sample have a risk percentage of <5% to not be able to get a result, in which case a new sample collection would be required for this purpose.
- The techniques used to carry our the study, real-time polymerase chain reaction (RT-PCR) or traditional PCR and/or restriction fragment length polymorphisms technique (RFLPs) are not 100% accurate. Due to this, a new sample could be requested.
- The test (s) results do not guarantee a successful embryo implantation or pregnancy.
- The results reported and their interpretations are based exclusively on the analysis requested and on the female reproductive system, without taking into account the quality of the embryo or other factors not incluided on thepresent study(ies), that could affect implantation nor pregnancy.
- Incidential findings may be discovered as part of the genetic processing of your sample. In this case, findings considered potentially clinically significant will be communicated to your doctor.
- For a correct perfomance of the study, it may be necessary to take a sample of endometrial biopsy and/or vaginal mucosa. Pronacera does not participate in drawing biological material. Samples will be performed at your gynecological center of IVF, where a specialist must discuss any associated risk with you before the procedure.
- Pronacera does not participate in the sampling procedure, identification, initial processing or packaging. Therefore, Pronacera is not responsable for them.

Please read each item below carefully, and sign the informed consent only if you fully understand each of them:

1. It is my responsibility to decide to carry out the study, therefore I agree to cooperate, communicating any information that may affect and suspend the search for pregnancy, throughout the study cycle by means of “mechanical barrier” (condoms) or abstinence methods.
2. I understand that I should not perform the study if I am under any medication or supplementation treatment other than those I have informed my autorized health care provider about.
3. I understand that I should not take any type of medication without my doctor’s consent, considering that it may affect the results of the study.
4. I understand that I should not perform the study if I am pregnant or if I think I am.

◯ Yes ◯ No

5. I authorize Pronacera to store and use my personal contact information to request information that may be of interest to carry out and complete research studies related to the test developed.

◯ Yes ◯ No

Patient authorization and consent

As applicant of the test, I sign that I have been informed, I understand and I authorize the processing of my personal dat:

Date:
Name and surename:
ID:

Signed:

I agree that I have been informed and authorize the processing of the personal data of my family member/represented person*:

*IF THE CONSENT IS GIVEN BY A FAMILIY MEMBER OR LEGAL REPRESENTATIVE

Attachment:
Date:
Name and surename:
ID:

Signed:

Professional prescribing the test:

Date:
Name and surename:
ID:

Signed:

*The absence or error in any of the information provided in this form may result in an extension of the results delivery time.

Basic information abouit data protection:
PRONACERA THERAPEUTICS, S.L. treat the information you provide us in order to provide service and treat the data and documents that make up your clinica historymanage, use and access your data, perform biling and comply with the applicable legal obligations, being the legal basis the execution of a contract and his own consent. The personal data and the clinical documentation of the patient will be kept at least during the legally required years and longer during the time necessary to provide the request service, as regulated in the RGPD 2016/679 of April 27, 2016 as well as the legislation Current health data may be transferred to third parties in order to carry out the requested service and in cases where there is a legal obligation. In any case, all personnel who access, in the use of their skills, any data of the clinical history will be subject to the duty to keep secrecy about the data of the same. You have the right to obtains confirmation as to whether PRONACERA THERAPEUTICS, S.L. We are treating your personal data, as well as to exercise your rights as an interested limitation, modification, rectification or deletion. You can obtain more information by contacting: PRONACERA THERAPEUTICS, S.L. – B90198458 – Dir. Postal: C/ MIRO Nº11, 41804, OLIVARES (SEVILLA) – Teléfono: +34 955 44 17 43.