PRE-TEST INFORMATION

Nutrifert is a predictive genetic test aimed at women who are planning a pregnancy or who are having difficulty conceiving without an accurate diagnosis related to the reproductive sphere. Diet and lifestyle have a great impact on reproduction and fertility in humans, since these are essential for certain processes such as implantation, placental growth, angiogenesis and the transfer of nutrients from mother to foetus. The interaction between nutrition and fertility appears crucial for reproductive performance. The relationship between ovulatory disorders and metabolic diseases such as diabetes suggests that dietary factors exert an etiological role in some types of infertility.

Nutrifert is a combined NUTRIGENETICS and CUSTOM MEDICINE test that analyses specific genetic variants that in the scientific literature are related to fertility and gestation.
Nutrigenetics is a branch of genetics that investigates the influence of genotype (DNA sequence variants) in response to nutritional changes and on the risk of nutrition related diseases. It helps to correlate intake of nutrients with the specific genetic profile, so that nutrient metabolism and cell function can work properly. "Predictive Medicine" is a science that, on the basis of the genetic information detected, supports the specialist in indicating the most suitable diet, personal habits and clinical monitoring to the patient for a healthy reproductive life and serene gestation.

Nutrifert investigates traits that play an important role in the reproductive cycle and that can be regulated with personalised food plans according to the genetic outcome of certain variants.
The investigated traits are:

- ✓ Predisposition to OBESITY
- ✓ Predisposizion to GESTATIONAL DIABETES
- ✓ COELIC DISEASE
- ✓ Predisposition to POLYCYSTIC OVARY SYNDROME
- ✓ Predisposition to ENDOMETRIOSIS
- ✓ Predisposition to the risk of MISCARRIAGE
- ✓ Response to OVARIC STIMULATION

In addition, Nutrifert considers variants that may influence the response to ovarian stimulation after administration of FSH under a medical prescription. To be aware of how the woman will respond to

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stimulation allows to modulate consciously and safely the effectiveness of therapy, avoiding the risk of ovarian hyperstimulation or hypostimulation.

HOW THE TEST IS PERFORMED

The test is performed by a blood sample or buccal mucosa cells (swab). The sample is processed following a detailed laboratory procedure.
DNA is isolated from the nucleated cells and then amplified via Real Time PCR technology or NGS analysis.

TEST LIMITS

The genetic data identified by the Nutrifert analysis are only complete for specific variants analysed by the test. The presence of any other possible variants is not detected.
Nutrifert is not a diagnostic test, but a predictive test. Therefore, the genetic information which is obtained is not sufficient and appropriate for the diagnosis of diseases.

NUTRIFERT TEST RESULTS

Nutrifert is the result of a joint collaboration between doctors/biologists and bioinformatics experts, who have developed a complex algorithm capable of translating genetic data into clear and easy-to-read results. The report highlights any predispositions found and puts forward appropriate suggestions for a healthy, balanced lifestyle.

⚠ *If the sample is not collected as indicated in the procedure, it may not be suitable for analysis.*

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NUTRIFERT INFORMED CONSENT

Adults:

The undersigned _____

Date of birth: _____ Place of birth:_____

Resident in: _____

Address: _____

TAX Code: _____

Telephone: _____

e-mail: _____

Minors and person with legal guardians:

(Mandatory compilation and subscription of consent by both parents)

a) The undersigned _____

Date of birth: _____ Place of birth:_____

Resident in: _____

Address: _____

TAX Code: _____

Telephone: _____

e-mail: _____

AND

b) The undersigned _____

Date of birth: _____ Place of birth:_____

Resident in: _____

Address: _____

TAX Code: _____

Telephone: _____

e-mail: _____

Parent/s or Guardian/s of: _____

_____

Date of birth: _____

Place of birth: _____

I/WE DECLARE:

of having understood and considered all the aspects of the exam and of having understood the benefit and the purpose of the genetic test and its possible limits. In particular in the pre-test information:

- It has been explained to me the test purpose;
- It has been explained to me the test limits;
- I have understood the meaning of possible test results (even unexpected);
- I have been informed on the methods of digital storage of data in accordance with the law in the national territory;
- I have been informed on how to store the sample taken for scientific research purposes;
- to have the possibility to revoke the consent at any time, by signing the relevant revocation act.

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Therefore,

I/WE AUTHORIZE:

the execution of/and/the following analysis: _____

on biological material taken from: ☐ Buccal Swab ☐ EDTA ☐ Other (specify) _____

INDICATION TO THE ANALYSIS (in case of minor prescription required):

_____

_____

FURTHERMORE, I/WE DECLARE:

☐ I agree	☐ I DO NOT agree	To be informed about analysis results;
☐ I agree	☐ I DO NOT agree	that the biological material can be used in the future, for further investigations for diagnostic purposes at the center that performs the test object of this informed consent, if it wishes to perform a further analysis without the need to repeat the sampling, in accordance with the regulations in force on the protection of personal data and conservation of biological material;
☐ I agree	☐ I DO NOT agree	that the biological material can be used in the future, in compliance with current legislation on the protection of personal data, for further investigations for diagnostic purposes at other centres, even outside the European Union;
☐ I agree	☐ I DO NOT agree	to be informed about results of further investigations for diagnostic purposes;
☐ I agree	☐ I DO NOT agree	that biological material may be used in the future, in compliance with the current legislation on the protection of personal data, for research purposes and/or for studies aimed to the collectivity in medical, biomedical and the epidemiological field and for quality verification programs for the laboratory performance;
☐ I agree	☐ I DO NOT agree	to be informed about the results of the research.

Date_____/_____/_____

Patient signature:

_____

Parent/s or Guardian/s signatures:

a)_____

b)_____

The Specialist who has obtained the consent (name and surname): _____

Phone: _____ E-Mail: _____

Signature and stamp of the Specialist: _____

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