GENOMICA
Next Generation Genetics

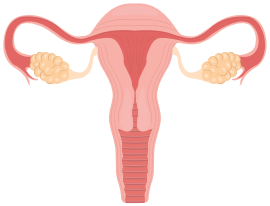
An advanced genetic test assessing the endometrial microbiome to improve the reproductive outcome of infertile patients

ENDOBIOME
ENDOMETRIAL MICROBIOME ANALYSIS

www.endobiome.it

ENDOBIOME

ENDOMETRAL MICROBIOME AND INFERTILITY



The **endometrial microbiome** consists of a set of microorganisms (endometrial microbiota) that colonize the lumen of the endometrium without damaging it, at least under normal operating conditions of the immune system.

Under **normal** conditions, in healthy women at reproductive age, the most common colonizing bacterial species is Lactobacillus. Lactobacilli act as probiotics that can inhibit the growth of bacteria, viruses and pathogenic fungi, through a lowering of pH mediated by the production of lactic acid. In these cases the endometrium is defined **Lactobacillus dominated (LD)** and contains a **percentage of lactobacilli > 90%.**

In **abnormal** conditions, the percentage of lactobacilli decreases (<90%) and the percentage of others bacteria increases (> 10%). The endometrium is then defined **non-Lactobacillus-dominated (NLD).**

Women with idiopathic infertility are often characterized by an altered endometrial microbiota, with an increase in colonization by anaerobic bacteria such as Atopobium, Prevotella, Veillonella, Ureaplasma and Escherichia.

The most relevant example of pathology caused by an alteration of the endometrial microbiota is **chronic endometritis (CE).** CE is characterized by persistent inflammation of the endometrial mucosa, caused by the presence of bacterial pathogens in the uterine cavity. Because CE is often asymptomatic and not detectable by vaginal ultrasound, it is often overlooked. The prevalence of CE in infertile patients has been estimated to be approximately 39%; it has been reported as high as 60% in women with recurrent pregnancy loss (RPL) and 66% in women characterized by repeated implantation failure (RIF)[1-2].

1. Cicinelli et al. Reprod Sci 2014; 21(5):640-7.

2. Cicinelli et al. Hum Reprod, 2015; 30(2):323-30.

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ENDOMETRAL MICROBIOME ANALYSYS TO IMPROVE THE REPRODUCTIVE OUTCOME OF INFERTILE PATIENTS

The delicate balance between the bacterial species that colonize the endometrium is a key element for a successful embryo implantation. The presence of dysbiotic or pathogenic bacteria may alter the endometrial microbiome, and disrupt the uterine environment, thus causing ***implantation failure and pregnancy loss[3].***

Pathogenic bacteria

Dysbiotic bacteria

Optimal microbiome

ENDOMETRIAL BACTERIAL INFECTION	ENDOMETRIAL DYSBIOSIS	ENDOMETRIAL EUBIOSIS
Staphylococcus, Streptococcus, Enterococcus, Mycoplasma, Ureaplasma, Enterobacteria, (Escherichia, Klebsiella), Chlamydia e Neisseria.	*Bifidobacterium, Prevotella, Sneathia, Atopobium, Veillonella*	*>90% Lactobacillus*
NLD ENDOMETRIUM		**LD ENDOMETRIUM**
The presence of pathogenic bacteria can cause infections and, as a consequence, implantation failure or recurrent miscarriages.	An altered bacterial balance can cause implantation failure.	A preserved bacterial balance improves the reproductive prognosis, resulting in an increased chance of pregnancy and live births

Endometrial microbiome analysis can improve the chances of pregnancy in couples with a history of previous reproductive failures.

3. Moreno et al. Am J Obstet Gynecol 2016; 215:684-703.

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AIMS AND BENEFITS OF THE TEST

To determine whether the uterine microbial environment is optimal for **embryo implantation.**
Depending on the results, the test may recommend embryo transfer (normal endometrial microbioma) or, in case of abnormal endometrial microbioma, to perform an antibiotic or probiotic treatment to restore the optimal microbial environment.

To improve the chances of pregnancy in couples with a history of reproductive failure.

To identify bacteria causing **chronic endometritis (CE).**
The detection of these pathogenic bacteria allows to undertake an antibiotic treatment, with the aim of improving the clinical management of patients with such silent disease.

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INDICATIONS FOR TESTING ENDOBIOME

Test may be beneficial for:

Patients with
Recurrent Implantation Failure (RIF)

Patients with
Recurrent Pregnancy Loss (RPL)

Any patient wishing to conceive, by assessing the microbiological environment that the embryo will encounter at implantation

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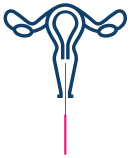
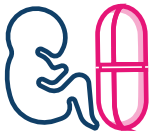
HOW THE TEST WORKS



Endometrial sample collection and DNA extraction

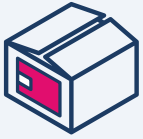
NGS analysis of 7 hypervariable regions (V2, V3, V4, V6, V7, V8 e V9) of the bacterial ribosomial RNA 16S gene

Technical Report providing information on the endometrial microbiome and recommendation on whether or not to perform a therapeutic treatment



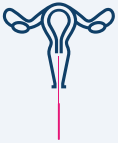
Therapeutic Treatment aimed at restoring a normal endometrial microbiota

HOW TO ORDER A TEST



Order the ***Endobiome*** shipping kit

Fill the TRF and enclose the informed consent signed from the patient



Collect the sample (endometrial biopsy or endometrial fluid)

Ship the sample to ***Genomica***

Receive results within 10 days

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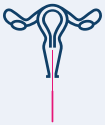
SAMPLE COLLECTION



The test can be performed from an **endometrial biopsy** or **endometrial fluid sample.** The sampling must be carried out by carefully following the instructions contained in the sampling kit.
Sample collection can be performed between day 15 and day 25 of the natural cycle, or during the uterine secretory phase in a HRT cycle.

TECHNICAL REPORT

*The test identified dysbiotic or pathogenic bacteria, causing a **non–Lactobacillus dominated (NDL)** endometrial microbiota (**<90% Lactobacillus**).*
*The test detected specific bacteria causing CE (Enterococcus spp., Enterobacteriaceae, Streptococcus spp., Staphylococcus spp., Mycoplasma spp, and Ureaplasma spp) or pathogens associated with sexually transmitted infections (e.g. Chlamydia and Neisseria spp). A positive test result is strongly correlated with **adverse reproductive outcomes** (reduced implantation rate and increased miscarriage rate).*

*The endometrial microbiome is **normal** (**Lactobacillus dominated** endometrium, with high percentage of Lactobacilli, **≥90%**)*

ENDOBIOME test report provides information on the overall microbial environment of the uterine cavity, including:

- Percentage of Lactobacilli in the endometrial sample.
- Percentage of the most represented bacteria detected in the endometrial sample.
- Whether the endometrial microbiome is **normal** or **abnormal.**
- Identification and percentages of specific bacteria causing CE (Enterococcus spp., Enterobacteriaceae (Escherichia, Klebsiella), Streptococcus spp.,
- Identification and percentages of pathogens associated with sexually transmitted infections (e.g. Chlamydia and Neisseria spp).
- Recommended probiotic/antibiotic therapy, if required.

GENOMICA
Next Generation Genetics

Advanced molecular diagnostics solutions using state-of-the art technologies

GENOMICA is recognized as one of the most advanced molecular diagnostics laboratory in Europe, both for the state-of-the-art instruments and technologies, as well as for its high quality standards.
With a **comprehensive portfolio of over 10.000 genetic tests,** GENOMICA is able to satisfy increasingly specialised requests in the field of molecular genetics, providing physicians and their patients with innovative and highly specialised diagnostic solutions for any clinical need.

- Over **100.000** genetic tests/year
- Fast TAT **10 days**
- Laboratories with **groundbreaking technologies** and high quality standards
- **Test performed in Italy** (Rome or Milan)
- **Dedicated R&D team**
- International **Partnerships**
- **Personalized genetic counseling** with genetic counselors experts in discussing genetic test results and familial risks
- **Professionals with 20+ years experience in the field of genetics and prenatal molecular diagnostics**

LABORATORIES

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