eurofins | Genoma

Eubiome
MICROBIOMA VAGINALE

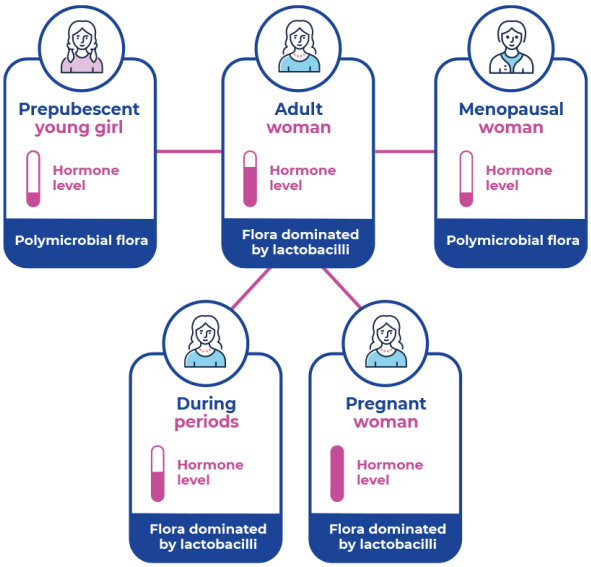
PRE-TEST INFORMATION SHEET

Vaginal microbiome:

The term *vaginal microbiome* refers to the genomes of microorganisms that under **physiological conditions colonise the genital district without damaging it** (*vaginal microbiota*).
The composition of the microbiota may change throughout a woman's life cycle as a result of hormonal changes. as well as being It might also be influenced by lifestyle, and external factors such as drug therapies or frequent vaginal douches as well. In balanced conditions, the vaginal microbiota is mainly composed of **lactobacilli**, whose function is both to produce **lactic acid** in order to maintain the **acidic vaginal pH**, and to act as a **defence system of the mucosa against infectious agents**.

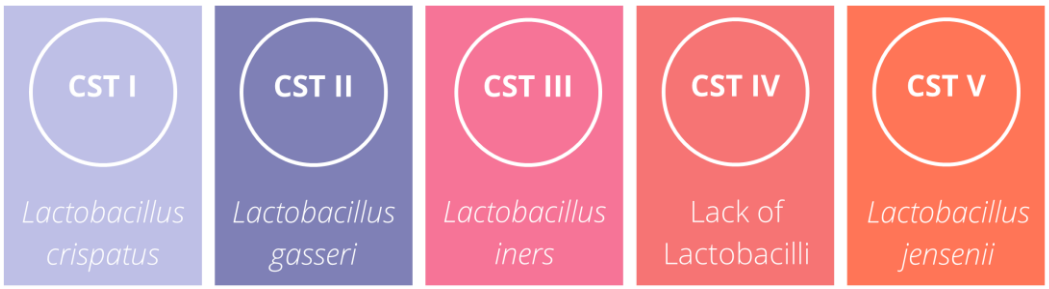
Vaginal microbiota is influenced by:

- Estrogens levels
- Frequent vaginal douches
- Diet and eating habits
- Drug therapies
- Number of partners



What is the CST?

The term CST (Community State Type) is used in microbiology to describe a microbial community with similar composition and abundance.
Five vaginal CSTs have been defined, characterised respectively by the prevalence of specific lactobacilli:



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Sede Legale / Registered Office
Via di Castel Giubileo, 11
00138 Roma
C.F. e P.Iva 05402921000
REA 883.995
Iscr. Reg. Impr. 369761/1197

Laboratorio e Studi Medici/ Laboratories
Rome - Milan
+ (39) 06.164161500
info@laboratoriogenoma.eu

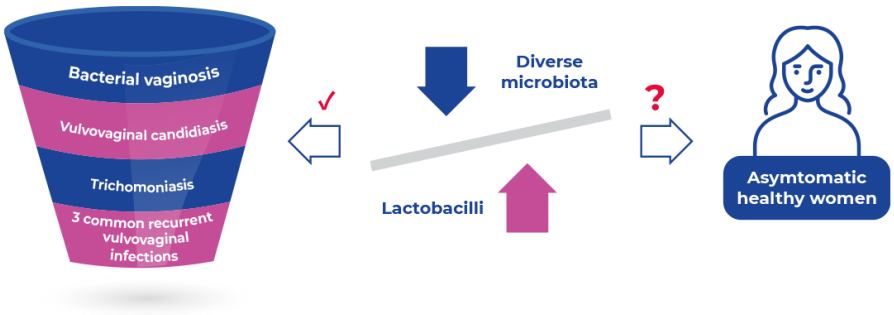
www.laboratoriogenoma.eu

Purpose of the analysis:
Two different analysis can be performed: **Eubiome** or **Eubiome Active.**

Both analyses evaluates the health status of the cervical-vaginal district by classifying it into five "**scores"**, each of which is representative of a characteristic microbial community or "**Community State Type"** (CST) (AMCLI 01_Vaginiti_MAL_20100308).
Each score correlates with an increasing risk of dysbiosis (alteration of the bacterial flora) on a scale of **1** to **5**, resulting in an increased risk of infection with opportunistic germ. Together with the microbial community classification, which consists mainly of lactobacillary flora, **Eubiome** and **Eubiome *Active*** identify the presence of **fungi** and **opportunistic bacteria** associated with **vaginitis and/or bacterial vaginosis**.

Eubiome also identifies the presence of **sexually transmitted pathogens** as well as **High Risk (HR) Human Papilloma Virus (HPV) virotypes**.

The innovation of this analytical approach is represented by the following picture, where it is shown that the **three main classes of recurrent vulvo-vaginal infections** (**Bacterial Vaginosis**, **Vulvovaginal candidiasis** and **Trichomoniasis**), must still be considered in relation to the lactobacillary flora and to its ability to defend the genital mucosa, even in asymptomatic patients.



Kalia et al. Ann Clin Microbiol Antimicrob (2020) 19:5

Opportunistic germs and commensal lactobacilli may be in balance; in this case they may not activate a syndromic pathogenic pathway.
In case of dysbiosis, the referring physician will define **possible therapies to repopulate or strengthen the lactobacillary flora** and possibly **treat infections** caused by the presence of opportunistic germs.

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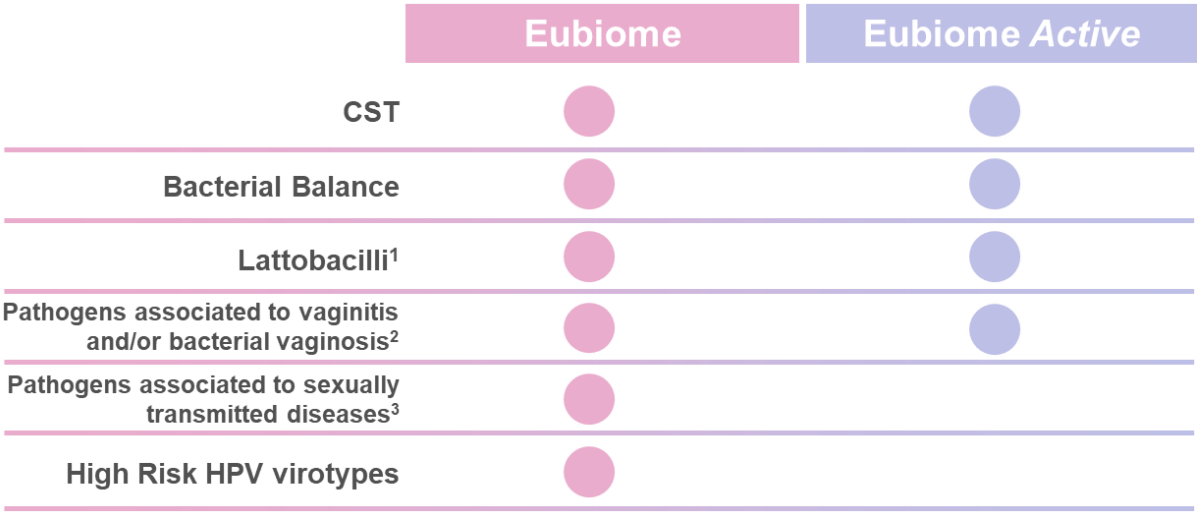
Results of the analysis:

Eubiome and **Eubiome *Active*** result will indicate:

- Whether a condition of **eubiosis** (correct microbial balance) or **dysbiosis** has been identified;
- The primary Community State Type and, if present, the secondary Community State Type, by analyzing 4 lactobacillary species (*L. crispatus, L. gasseri, L. iners* and *L. jensenii*);
- The "Bacterial Balance" score, i.e. the relative quantification between the lactobacillary flora and any bacterial vaginosis and/or vaginitis-associated germs (*Gardnerella vaginalis*, *Atopobium vaginae* and Candida spp.). This score is representative of the balance between protective flora (lactobacilli) and opportunistic germs present.
- The outcome of the analysis of microorganisms associated to vaginitis and/or bacterial vaginosis.

Eubiome result will also indicate:

- The outcome of the analysis of microorganisms associated to vaginitis and/or bacterial vaginosis.
- The outcome of the analysis of High Risk Human Papilloma Virus virotypes (Table 1).



1. *L. crispatus, L. iners, L.jensenii, L. gasseri*
2. *Atopobium vaginae, Candida albicans, Candida glabrata, Candida krusei, Candida parapsilosis, Gardnerella vaginalis, Trichomonas vaginalis*
3. *Chlamydia trachomatis, Mycoplasma genitalium, Mycoplasma hominis, Neisseria gonorrhoeae, Streptococcus agalactiae, Ureaplasma parvum, Ureaplasma urealyticum*

Table 1: High Risk (HR) virotypes analysed

Six individual HR HPV virotypes						Three HR HPV virotype groups		
16	18	45	31	51	52	P1(33, 58)	P2 (35, 39, 68)	P3 (56, 59, 66)

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Pre-test information service
According to Genetic Guidelines, Eurofins Genoma is able to provide a free pre-test brief consultation, to drive patients within the test purposes, benefits, limitations and possible results.

Genetic counselling
Our centre offers **specialized counselling** to manage test result in relation with clinical patients features.

Reporting time
The **turnaround time** (TAT) is approximately **7-10 working days**. TAT could be delayed in case of repeated examinations, suboptimal results, second level investigations.

Privacy
All personal data will be treated with extreme confidentiality and according to current privacy legislation (Legislative Decree No. 196 of June 30, 2003). Test results will be released only to the health professionals involved in the execution of the test or to the geneticist (where necessary). In addition, test results may be released to those who, by law, may have access to them.

Sample storage
Biological specimens are identified by a barcode and a numeric ID, so no identifying information is associated with the tube. Therefore, it is impossible to trace personal data. In any case, 30 days after reporting, biological samples will be cleared according to current regulations.

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Eubiome and Eubiome *Active*: Kit composition and analyses

Eubiome and Eubiome *Active* share the same kit and Test Requisition Form (TRF).
Both vaginal and endo-cervical swabs are required for **Eubiome**, whereas only the vaginal swab is required for **Eubiome *Active***. Please fill in the TRF accordingly, specifying the analysis required, and use only the necessary sampling device/s.
Feel free to discard unnecessary sampling devices if they are not needed.

Eubiome:

Sampling devices:

a) 

b) 

1 x Vaginal swab (a)
2 x Endo-cervical swabs (b)

Analysis:

- CST
- Bacterial Balance
- 4 Lactobacilli: *L. crispatus, L. gasseri, L. iners e L. jensenii*
- 14 microorganisms: *Atopobium vaginae, Candida albicans, Candida glabrata, Candida krusei, Candida parapsilosis, Chlamydia trachomatis, Gardnerella vaginalis, Mycoplasma genitalium, Mycoplasma hominis, Neisseria gonorrhoeae, Streptococcus agalactiae, Trichomonas vaginalis, Ureaplasma parvum, Ureaplasma urealyticum*
- High Risk (HR) HPV Virotypes

Eubiome – *Active*:

Sampling device:

1 x Vaginal swab

Analysis:

- CST
- Bacterial Balance
- 4 Lactobacilli: *L. crispatus, L. gasseri, L. iners e L. jensenii*
- 7 microorganisms: *Atopobium vaginae, Candida albicans, Candida glabrata, Candida krusei, Candida parapsilosis, Gardnerella vaginalis, Trichomonas vaginalis*

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EUBIOME TEST INFORMED CONSENT

Adults	Minors and person with legal guardians *(mandatory compilation and subscription of consent by both parents)*
The undersigned _____	a) The undersigned _____
Date of birth _____ Place of birth_____	Date of birth _____ Place of birth_____
Resident in _____ Address _____	Resident in _____ Address _____
Telephone: _____	Telephone: _____
e-mail: _____	e-mail: _____
	AND
	b) The undersigned _____
	Date of birth _____ Place of birth_____
	Resident in _____ Address _____
	Telephone: _____
	e-mail: _____
	Parent/s or Guardian/s of _____
	Date of birth _____
	Place of birth _____

I/WE DECLARE:

of having received, during the meeting with Doctor _____ on the date _____, detailed information about the genetic analysis I am about to perform, 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. I had the chance to ask all the questions I considered worthwhile and I received answers I consider complete. In particular:

- **It has been explained to me the test purpose;**
- **It has been explained to me the test limits;**
- **I have discussed the possible risks, benefits and limits connected to the test;**
- **I have understood that the result of the genetic test may have medical and psychological consequences for my family and I;**
- **I have understood the meaning of possible test results (even unexpected);**
- **I've been informed about the people who will have access to the biological sample;**
- **I've been informed about the people who will have access to the test result;**
- **To have the possibility to revoke the consent at any time, by signing the relevant revocation act.**

Therefore,

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COMPANY WITH QUALITY SYSTEM CERTIFIED BY DNV ISO 9001

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I/WE AUTHORIZE:

the execution of/and/the following analysis: ☐ **Eubiome** ☐ **Eubiome *Active***
on biological material taken from: ☐ vaginal swab ☐ endocervical swab

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**	to share the results with Dr. _____
☐ **I agree**	☐ **I DO NOT agree**	that biological material can be used in the future, in compliance with the current legislation on the protection of personal data, for further investigations for diagnostic purposes for the examined pathology at the centre that performs the analysis;
☐ **I agree**	☐ **I DO NOT agree**	that biological material can be used in the future, in compliance with the current legislation on the protection of personal data, for further investigations for diagnostic purposes for the examined pathology in other centres, even outside European Union;
☐ **I agree**	☐ **I DO NOT agree**	to be informed about results of further investigations for diagnostic purposes for the examined pathology;
☐ **I agree**	☐ **I DO NOT agree**	to be informed about analysis results even in relation to unexpected news, which may have a benefit in terms of therapy, prevention or awareness about reproductive choices;
☐ **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.

The undersigned declares that the above is true and undertakes to promptly communicate any change of opinion on the matter.

Date_____/_____/_____

Patient signature:

_____

Parent/s or Guardian/s signatures:

a)_____

b)_____

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

Phone _____ E-Mail _____

Signature and stamp of the Specialist: _____

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