



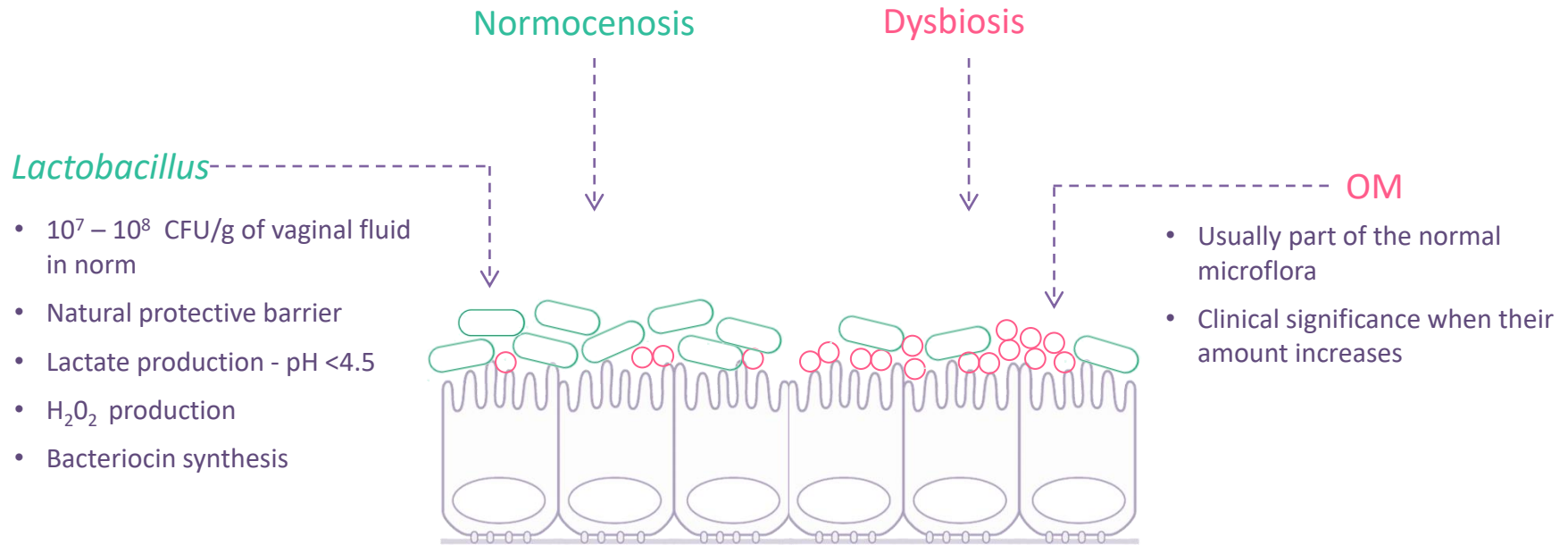
Femoflor<sup>®</sup>

Comprehensive assay for complex evaluation  
of vaginal microbiome composition



Femoflor<sup>®</sup> Real-Time PCR Kit

# Microflora of Female Urogenital Tract



*Lactobacillus*

- *L. crispatus*
- *L. jensenii*
- *L. iners*
- *L. gasseri*



OM (Opportunistic Microorganisms)

- *Gardnerella vaginalis*
- *Porphyromonas* spp.
- *Prevotella* spp.
- *Atopobium vaginae*
- *Ureaplasma* spp.
- *Candida* spp.
- others



## »» The Unmet Medical Need

Detection of opportunistic microorganisms in female urogenital tract is not evidence for an ongoing infectious process.

For accurate assessment of the state of vaginal microflora and diagnosis of dysbiosis disorders the following indicators must be considered:

- The amount of *Lactobacillus* spp.
- The amount of opportunistic microorganisms
- The proportion of *Lactobacillus* spp. and opportunistic microorganisms



The medical need is for a high sensitive and specific diagnostic approach for accurate assessment of the above indicators



## Microscopy

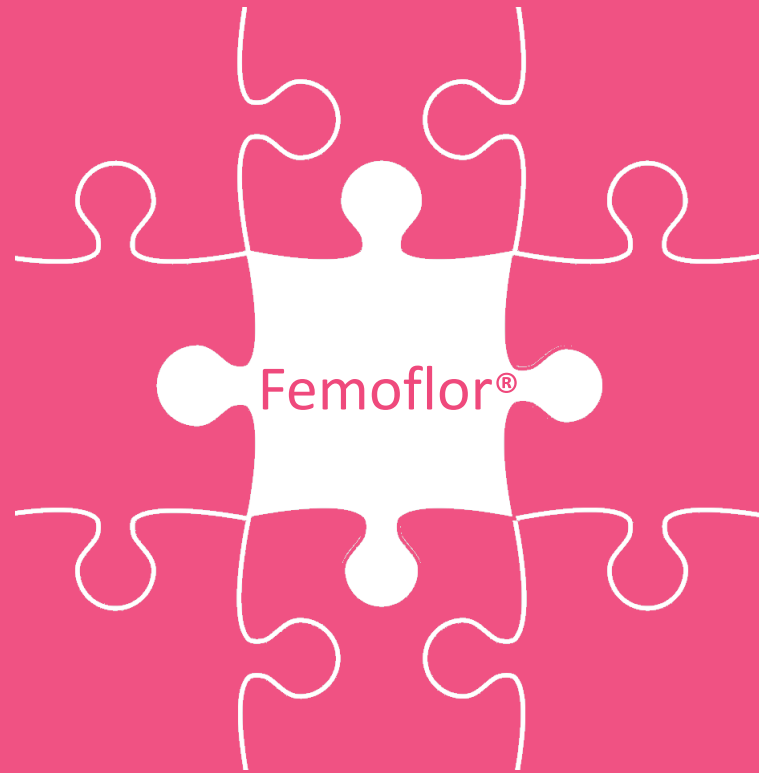
- + Rapid assessment of the state of vaginal microflora and the presence of inflammation
- Fail to detect many types of pathogenic and opportunistic microorganisms due to their small size (*Mycoplasma* spp., *Ureaplasma* spp., *Atopobium vaginae*, *Chlamydia trachomatis*)
- Do not allow quantitative determination
- Subjective interpretation – the accurate interpretation is influenced by many factors (method of sampling, shipping and storage, slide preparation, operator skills and experience)

## Culture method

- + Determination of antibiotic susceptibility
- + Allows species identification
- Subjective interpretation of microorganisms quantity – approximate quantitative determination is possible but influenced by many factors (shipping, storage of samples)
- Difficult to cultivate many opportunistic and pathogenic microorganisms – anaerobic microorganisms, *Mycoplasma* spp., *Ureaplasma* spp., *C. trachomatis*
- Time-consuming – time to result 2-5 days



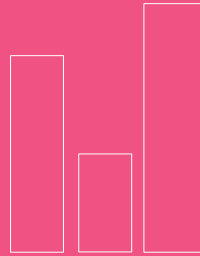
IS THERE ANY METHOD WHICH OVERCOMES THE DISADVANTAGES OF  
THE CURRENT METHODS AND IS A REAL BREAKTHROUGH IN THE  
DIAGNOSIS OF UROGENITAL INFECTIONS?



# >> What is Femoflor®?



Molecular diagnostic test



Quantitative method



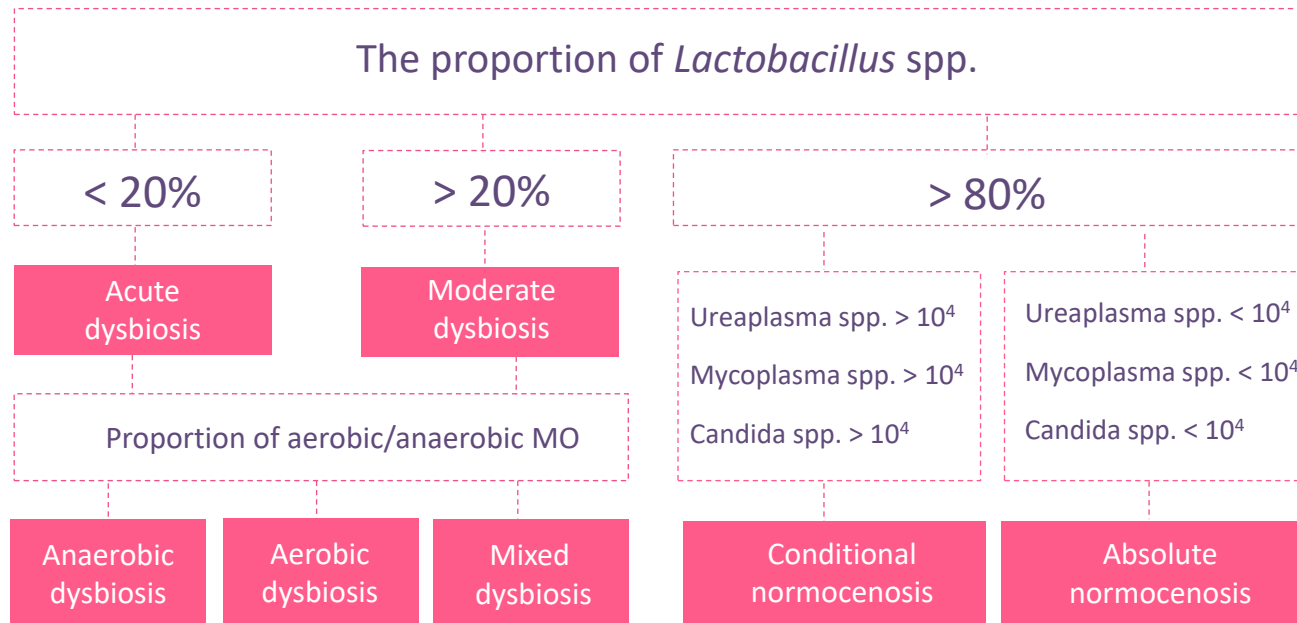
Personalized approach

## »» What Information Do You Get With Femoflor®?

- Quantitative determination of the total number of microorganisms present in the female urogenital tract and the number of *Lactobacillus* spp.
- Comparison of the amount of *Lactobacillus* spp. with the amount of total number microorganisms for assessment of the state of microbiocenosis
- Quantitative determination of etiologically significant aerobic and anaerobic opportunistic microorganisms, *Mycoplasma* spp. and *Candida* spp. involved in development of dysbiosis disorders
- Comparison of the amount of opportunistic microorganisms with the amount of *Lactobacillus* spp. to determine the severity of dysbiosis (normocenosis, moderate dysbiosis and acute dysbiosis)
- Evaluation of the type of dysbiosis – aerobic, anaerobic or mixed type dysbiosis
- Detection of sexually-transmitted pathogens – *C. trachomatis*, *N. gonorrhoeae*, *T. vaginalis*, *M. genitalium*, Cytomegalovirus, HSV1 and HSV2



# Algorithm for Assessment the State of Vaginal Microflora

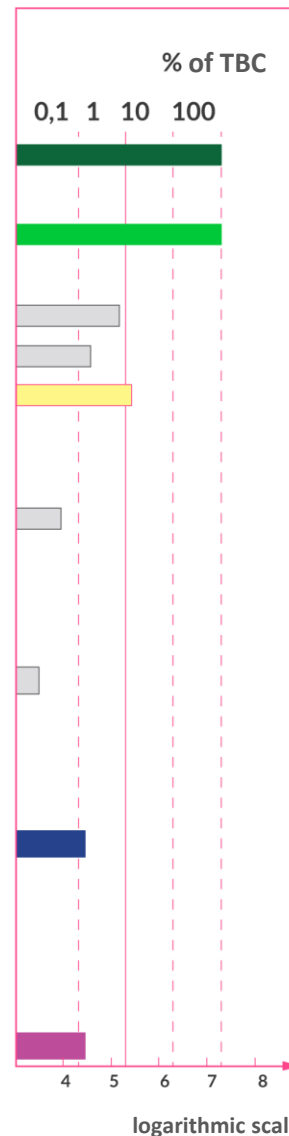




# Diagnostic Panels

Group	Analyzed indicators	Femoflor®-16	Femoflor® Screen
<b>CONTROLS</b>	Positive control	✿	✿
	Sample intake control	✿	✿
<b>TOTAL BACTERIAL COUNT</b>	Total bacterial count	✿	✿
	Lactobacillus spp.	✿	✿
<b>AEROBIC MICROORGANISMS (facultative anaerobes)</b>	Enterobacterium spp.	✿	
	Streptococcus spp.	✿	
	Staphylococcus spp.	✿	
	Streptococcus agalactica	✿	
<b>ANAEROBIC MICROORGANISMS (obligate anaerobes)</b>	Prevotella bivia/Porphyromonas spp.	✿	✿
	Gardnerella vaginalis	✿	✿
	Enterococcus spp.	✿	
	Euterococcus spp.	✿	
	Sneathia spp./Leptotrichia spp./Fusobacterium spp.	✿	
	Megasphaera spp./Veillonella spp./Dialister spp.	✿	
	Lachnobacterium spp./Clostridium spp.	✿	
	Mobiluncus spp./Corynebacterium spp.	✿	
	Peptostreptococcus spp.	✿	
Atopobium vaginae	✿		
<b>MYCOPLASMAS</b>	Mycoplasma hominis	✿	✿
	Mycoplasma genitalium	✿	✿
	Ureaplasma urealyticum	✿	✿
	Ureaplasma parvum	✿	✿
<b>FUNGUS</b>	Candida spp.	✿	✿
<b>PATHOGENS</b>	Trichomonas vaginalis		✿
	Neisseria gonorrhoeae		✿
	Chlamydia trachomatis		✿
	Herpes simplex virus 1		✿
	Herpes simplex virus 2		✿
	Cytomegalovirus		✿

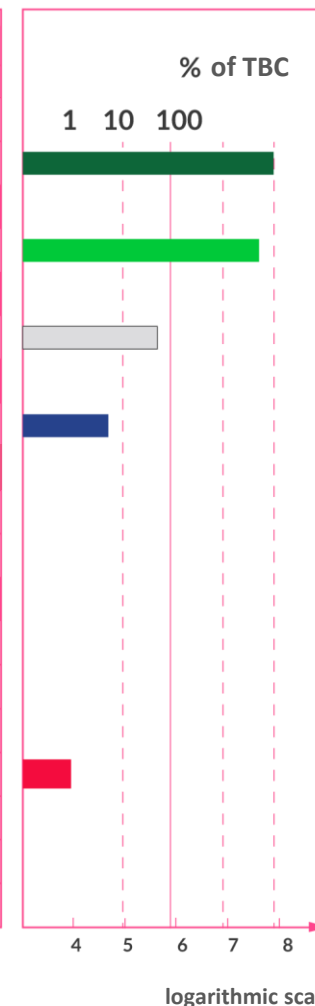
Nº	Analyzed indicator	Results	
		Quantitative	Relative Lg (O/TBC)
	Sample intake control	10 <sup>4.4</sup>	<input checked="" type="checkbox"/>
1	Total Bacterial Count	10 <sup>7.3</sup>	<input type="checkbox"/>
<b>Normal microflora</b>			
2	Lactobacillus	10 <sup>7.3</sup>	0,0 (83-100 %) <input checked="" type="checkbox"/>
<b>Facultative anaerobic microorganisms</b>			
3	Enterobacteriaceae	10 <sup>5.0</sup>	-2,3 (0,4-0,6 %) <input type="checkbox"/>
4	Streptococcus spp.	10 <sup>4.4</sup>	-2,9 (0,1-0,1 %) <input type="checkbox"/>
5	Staphylococcus spp.	10 <sup>5.4</sup>	-1,9 (1,2-1,6 %) <input type="checkbox"/>
<b>Obligate anaerobic microorganisms</b>			
6	Gardnerella vaginalis + Prevotella bivia + Porphyromonas spp.	not detected	<input type="checkbox"/>
7	Eubacterium spp.	10 <sup>3.9</sup>	-3,4 (< 0,1 %) <input type="checkbox"/>
8	Sneathia spp. + Leptotrichia spp. + Fusobacterium spp.	not detected	<input type="checkbox"/>
9	Megasphaera spp. + Veillonella spp. + Dialister spp.	not detected	<input type="checkbox"/>
10	Lachnobacterium spp. + Clostridium spp.	not detected	<input type="checkbox"/>
11	Mobiluncus spp. + Corynebacterium spp.	10 <sup>3.7</sup>	-3,9 (< 0,1 %) <input type="checkbox"/>
12	Peptostreptococcus spp.	not detected	<input type="checkbox"/>
13	Atopobium vaginae	not detected	<input type="checkbox"/>
<b>Yeast-like Fungi</b>			
14	Candida spp.*	10 <sup>4.4</sup>	<input checked="" type="checkbox"/>
<b>Mycoplasma</b>			
15	Mycoplasma hominis*	not detected	<input type="checkbox"/>
16	Ureaplasma (urealyticum + parvum)*	not detected	<input type="checkbox"/>
<b>Pathogens</b>			
17	Mycoplasma genitalium**	detected	<input checked="" type="checkbox"/>



**Conclusion:**  
 Conditional normocenosis. Increased concentration of *Candida albicans* with clinically significant value. Detected DNA of *Mycoplasma genitalium*

\* Quantitative Analysis Lg (X)  
 \*\* Qualitative Analysis

Nº	Analyzed indicator	Results	
		Quantitative	Relative Lg (O/TBC)
	Sample intake control	10 5,5	<input checked="" type="checkbox"/>
1	Total Bacterial Count	10 7,9	<input type="checkbox"/>
<b>Normal microflora</b>			
2	Lactobacillus spp.	10 7,9	-0,1 (70-94 %) <input checked="" type="checkbox"/>
<b>Obligate anaerobic microorganisms</b>			
3	Gardnerella vaginalis + Prevotella bivia + Porphyromonas spp.	10 5,8	-2,2 (0,6-0,8 ) <input type="checkbox"/>
<b>Yeast-like Fungi</b>			
4	Candida spp.*	10 4,4	<input checked="" type="checkbox"/>
<b>Mycoplasma</b>			
5	Ureaplasma spp.*	not detected	<input type="checkbox"/>
6	Mycoplasma hominis*	not detected	<input type="checkbox"/>
<b>Pathogens</b>			
7	Mycoplasma genitalium**	not detected	<input type="checkbox"/>
8	Trichomonas vaginalis**	not detected	<input type="checkbox"/>
9	Neisseria gonorrhoeae**	not detected	<input type="checkbox"/>
10	Chlamydia trachomatis**	detected	<input checked="" type="checkbox"/>
11	HSV-2**	not detected	<input type="checkbox"/>
12	CMV**	not detected	<input type="checkbox"/>
13	HSV-1**	not detected	<input type="checkbox"/>



\* Quantitative Analysis Lg (X)

\*\* Qualitative Analysis

**Conclusion:** Conditional normocenosis. Increased concentration of *Candida albicans* with clinically significant value. Detected DNA of *Mycoplasma genitalium*

## »» The Advantages of Femoflor®

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- Quantitative assessment and comparison of the individual groups of microorganisms
- Detection of difficult to cultivate or non-culturable microorganisms involved in the development of dysbiosis disorders and urogenital tract pathogenesis
- Monitoring the effectiveness of therapy and the recovery of normal microflora composition
- Personalized approach to therapy – treatment decisions based on the individual microflora composition
- Highly specific and selective treatment – avoid the inappropriate use of antibiotics
- Reducing the risk of disease recurrence
- Evaluation of the quality and quantity of the sample material to prevent false-negative results



## »» When is Femoflor® Recommended?

Evaluation the causes of infertility

When planning a pregnancy and before in-vitro fertility procedure

Prior to invasive gynecological manipulations with increased risk of infectious complications

During pregnancy (all trimesters)

Chronic and recurrent vaginal infections

In case of recurrent spontaneous miscarriages

Monitoring and preventative care of microflora composition in healthy women

Discrepancy between clinical symptoms and laboratory results





# Femoflor® Benefits

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## For physicians



- Accurate diagnostic and treatment decisions based on an advanced molecular-diagnostic approach
- Detailed results report and conclusions
- Improve patient care

## For women



- Correct diagnosis and treatment
- Improve health and quality of life
- Better reproductive success

## For laboratory



- Minimal hands-on-time
- Fast turnaround times
- Automated interpretation of results
- Reduce operator errors



IMPROVING DIAGNOSTICS FOR ACCURATE TREATMENT