Genomer
Biyoteknoloji Arge San.ve Tic. Ltd. Şti.

FEMOBIOME®II

FEMOBIOME®PrimaScreen

FEMOBIOME®SecundaScreen

Line of tests for women microbiota assessment

Advanced Molecular Diagnostics

Comprehensive microbiota profiling for women's health

Content

What's new?

EXPANDED AND OPTIMIZED PANEL OF DETECTABLE MICROORGANISMS

enables to provide clinically significant description of microbiota composition

- More informative evaluation of normobiota state for women of different ages;
- Quantitative assessment of Group B Streptococcus – especially important during pregnancy planning and gestation;
- Control of obligate pathogens presence to exclude asymptomatic and subclinical infections;
- Detection of viruses relevant to reproductive health.

SYSTEM OF VISUAL MARKERS FOR CONVENIENT CLINICAL INTERPRETATION

- Test report with personalized comments and infographics;

NEW TYPES OF BIOMATERIAL

- Cervical swabs collected in transport medium for liquid-based cytology;
- Self-collected vaginal samples

EXPANDED LINE OF FEMOBIOME® TEST KITS

- **FEMOBIOME II** – universal test for assessment women microbiota state with the most comprehensive capabilities;
- **FEMOBIOME®PrimaScreen** – a shortened version of FEMOBIOME®II for diagnostics of bacterial vaginosis;
- **FEMOBIOME®SecundaScreen** – a complex test for diagnostics of infectious and inflammatory urogenital diseases.

Comparing of FEMOBIOME® tests

		FEMOBIOME®	
	FB®II	Prima Screen	Secunda Screen
Number of tubes	16	8	8
Indicators			
Human genomic DNA	●	●	●
Total bacterial load	●	●	●
Normobiota			
Lactobacillus spp.	●	●	●
L. crispatus	●		
L. jensenii/ L. mulieris	●		
L. gasseri/ L. paragasseri	●		
L. iners	●	●	●
L. non-iners		●	●
Bifidobacterium spp.	●		
Aerobes			
Staphylococcus spp.	●		●
Streptococcus spp.	●		●
Streptococcus agalactiae	●		
Enterobacteriaceae	●		●
Enterococcus spp.	●		●
Haemophilus spp.	●		●
Anaerobes			
Gardnerella vaginalis	●	●	●
Fannyhessea vaginae (Atopobium vaginae)	●	●	●
Mobiluncus spp.	●	●	●
Anaerococcus spp.	●		●
Peptostreptococcus spp.	●		●

	FB®II	Prima Screen	Secunda Screen
Bacteroides spp./Porphyromonas spp./Prevotella spp.	●		●
Sneathia spp./Leptotrichia spp./Fusobacterium spp.	●		●
Megasphaera spp./Veillonella spp./Dialister spp.	●		●
BVAB1 / BVAB2 / BVAB3	●		●
Mycoplasmas			
Ureaplasma urealyticum	●	●	●
Ureaplasma parvum	●	●	●
Mycoplasma hominis	●	●	●
Yeast fungi			
Candida spp.	●	●	●
Candida albicans	●	●	●
SEXUALLY TRANSMITTED INFECTIONS (STI)			
Chlamydia trachomatis	●		●
Mycoplasma genitalium	●		●
Neisseria gonorrhoeae	●		●
Trichomonas vaginalis	●		●
Herpesviruses			
HSV-1	●		●
HSV-2	●		●
CMV	●		●
Human papillomaviruses			
HPV 16	●		
HPV 18	●		
HPV 45	●		
HPV 31/33/35/39/51/52/56/58/59/66/68	●		

FEMOBIOME®II – more clinically relevant information for the same price

How to choose test?

Clinical situation	FB®II	FEMOBIOME® Prima Screen	FEMOBIOME® Secunda Screen
Infectious diseases of reproductive system			
Inflammatory symptoms	O	O	
Symptoms of BV	O		O
Asymptomatic cases			
Preparation for pelvic surgery	O	O	
Preventive screening	O	O	
Treatment monitoring			
Treatment of infection diseases	O	O	
BV treatment	O		O
Obstetrics			
Pregnancy planning, ART	O	O	
Prophylactic examinations during pregnancy	O	O	
Infertility, miscarriage	O	O	

Types of biomaterial

- **Vaginal swab.** The sample can be collected by a healthcare specialist or self-collected by woman using special devices.

- **Cervical swab** collected in transport medium, including transport medium for liquid cytology.

Sample collection and preparation

Common recommendations

PCR analysis is a direct method of laboratory research; therefore, the biological material needs to be collected from the foci of infection. The biomaterial type is selected by the physician based on the collected anamnesis and clinical picture of the disease.

The quality of sampling, sample storage, transport and pretreatment are crucial for obtaining correct results. Incorrect sampling may lead to unreliable results and, therefore, to the need to repeat the sampling procedure.

Sample collection is performed using specialized medical devices.

After sample collection put the swab into the tube with transport medium and rinse it thoroughly. Remove the swab from solution, press it to the wall of tube and squeeze the rest of the liquid.

Throw out the swab. Use a new swab if you need to repeat sampling or to take sample from another biotope.

Sample collection and preparation

Women must not perform hygiene procedures or syringing prior the sampling procedure. To interpret results successfully and robustly, sample must contain the largest possible number of epithelial cells with minimum amounts of mucus and blood. Before obtaining an epithelial cell swab from the posterior vaginal vault and cervical canal, the free-flowing secretion should be removed with a sterile cotton swab.

⚠ Important Note

Most microorganisms are localized on the epithelial surface in the form of biofilm. Therefore, the sample should include a scaring of the epithelial surface with adherent microbial layer, not the contents of the organ lumen.

BEFORE THE TEST, IT IS NOT ALLOWED TO	Wait Time If Not Followed
Perform syringing and vaginal douching with antiseptics	
Use tampons	
Use PCR-inhibiting substances (ultrasound gel, heparin, chlorhexidine, other chlorine-containing products)	24 hours
Undergo transvaginal ultrasound examination	
Engage in protected sexual contacts	
Undergo colposcopy	48 hours
Engage in unprotected sexual contacts	72 hours
Take and/or use antibacterial medications, probiotics	2 weeks after therapy 4 weeks after STI therapy

The test can be prescribed to patients on antibiotic therapy (for therapy monitoring). However, antibiotics can influence the outcome. Results should be interpreted by the doctor based on the purpose of testing and patient's medical history.

Vaginal sampling

The sample must be taken prior to physical examination. Speculum can be treated with warm water before the procedure. Antiseptics and oil-based lubricants (like Vaseline) must not be used for speculum treatment. The sample must be taken from the lateral or posterolateral vaginal wall.

Self-sampling

Self-sampling is performed using specialized medical devices. Follow the manufacturer's instructions for correct use.

Self-sampling Instructions

1

Open the package and remove the swab

2

Insert the swab into the vagina up to the marked line

3

Rinse the swab for 10-30 seconds

4

Place the swab into the sterile container

5 **Deliver the sample to the laboratory**

Cervical sampling

Insert the swab 0.5–1.5 cm into the cervical canal. **Avoid any contact with the vaginal walls.**

New test report

Indicator icon color code – traffic light system

	PATHOGENS		
	Yes	No	
		Viruses or Mycoplasmas* ≥ 4 lg GE/ml or Candida** ≥ 4 lg GE/ml Yes	No
Eubiosis	🔔	⚠	✓
Moderate dysbiosis	🔔	⚠	⚠
Severe dysbiosis	🔔	🔔	🔔

* Ureaplasma urealyticum, Ureaplasma parvum, Mycoplasma hominis ** Candida spp., Candida albicans

1 **Indicator icon**

Visual summary of the microbiota status and presence of pathogens, based on the traffic light system (see table above)

2 **Linear histogram**

A graphical representation of the proportion of normobiota, anaerobes, aerobes and mycoplasmas in the microbiota composition. Color indicate the total quantity of microorganisms in each group

3 **Columnar histogram**

Microorganisms profile showing detailed distribution of conditionally pathogenic microorganisms within their groups

Main technological features

- All-in-one solution – from sample collection to interpretation the test report;
- Two PCR setup formats – automated (384-well) and manual (96-well);
- Fast nucleic acid extraction, optimized for Allsheng Auto-Pure 96 and KingFisher Flex (PREP-MB-RAPID II);

Biomaterial	epithelial swab from the mucous membrane of cervical canal, vagina
Transport medium	STOR-F STOR-M
Transport medium for liquid cytology	PreservCyt®, Hologic Inc., USA BD SurePath™ Liquid-Based Pap Test, Becton, Dickinson and Company, USA; EASYPREP, YD Diagnostics, South Korea; CellPrep, CP Biodyne, South Korea; Cell Preservative Solution, Human Lituo Biotechnology Co.Ltd, China
Sample pretreatment	PREP-PK (for scrapes taken in the transport & fixation medium for liquid cytology BD SurePath™ Liquid-Based Pap Test and CellPrep)

Time of analysis	From 2,5 hours (with sample pretreatment)
Number of samples	12 (24)** tests for package S, including control samples 24 (48)** tests for package A and A-TL, including control samples
Storage conditions	+2 °C … 8 °C – packages S, A, A-TL -18 °C …-22 °C – TechnoTaq MAX polymerase (part of package A) **12 months**

**for FEMOBIOME®PrimaScreen and FEMOBIOME®SecundaScreen

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