DNA-TECHNOLOGY

For research use only

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Femoflor Screen REAL-TIME PCR Detection Kit

REF R1-P804-S3/5EU

Package: S (standard)

General information

Intended use:

The DNA-Technology Femoflor Screen REAL-TIME PCR Detection Kit is intended for the study of vaginal microbiocenosis (specifically for the detection of the pathogens, opportunistic flora and normal flora and their qualitative and quantitative evaluation).

Method:

Real-time PCR; quantitative and qualitative multiplex analysis.

Samples:

Epithelial cells scrapes from the urethra, cervical canal, or posterolateral vaginal wall.

DNA extraction:

The DNA-Technology's PREP-NA PLUS and PREP-GS PLUS extraction kits are recommended.

Features:

Simultaneous detection of up to four DNA-targets in one tube (multiplex).
PCR-Mix contains internal control (IC) for evaluation of PCR quality.
PCR-Mix contains sample intake control (SIC) for evaluation of sampling quality.
Defined tubes contain ROX dye label – "Marker". It tags the tube/strip orientation.
We also recommend including in assay the negative control ("C-") which is not supplied but is very helpful for contamination control purposes. Use deionized water or sterile buffered saline instead of sample, starting from extraction step.

Devices:

The automatic analysis for Femoflor Screen REAL-TIME PCR Detection Kit is available on "DNA-Technology" made DTlite[1], DTprime[2] and DT-96 REAL-TIME Thermal Cyclers; software version is not lower than 7.3.4.0; the current version of the software is available for download at http://www.dna-technology.ru/eng/support/.

Overall time needed to perform the analysis (including sample preparation procedure):

2.5 hours at average.

The number of tests:

24

Kit contents:

Reagent	Quantity	
• Paraffin sealed PCR-mix	20 µL	24 8-tube strips
• MAX Taq-polymerase solution	500 µL	4 tubes
• Mineral oil	1.0 mL	4 tubes
• Positive control	160 µL	1 tube
Accessories:		
• Strip's caps		24 8-caps strips

[1] - supported by 4S1, 4S2, 5S1, 5S2, 6S1, 6S2 instruments.
[2] - supported by 4M1, 4M3, 4M6, 5M1, 5M3, 5M6, 6M1, 6M3, 6M6 instruments.

Strip content, colour codes and detection channels

№ of the tube	Channel				Color of the buffer
	Fam	Hex	Rox	Cy5	
1	Total bacterial mass	IC	–	–	Blue
2	Normoflora – *Lactobaccilus* spp.	IC	–	–	Colorless
3	*Gardnerella vaginalis/ Prevotella bivia/Porphyromonas* spp.	IC	–	–	
4	*Ureaplasma* (*urealyticum* + *parvum*)	IC	–	–	
5	*Candida* spp.	SIC	Marker	–	
6	*Mycoplasma hominis*	IC	*Mycoplasma genitalium*	–	
7	*Trichomonas vaginalis*	IC	*Neisseria gonorrhoeae*	*Chlamydia trachomatis*	
8	*Herpes simplex virus 2*	IC	*Cytomegalovirus*	*Herpes simplex virus 1*	

Procedure

1 PCR amplification

1.1 Mark one strip with paraffin sealed PCR-Mix for each test sample, negative control ("C-") and positive control ("C+").

⚠ One strip is used for analysis of one sample.

Example. If you need to test 2 samples, mark two strips for the samples to be tested, one strip for "C-" and one strip for "C+". Total number of strips – 4.

1.2 Vortex the MAX Taq-polymerase solution thoroughly (3-5 sec), then spin briefly (1-3 sec).
1.3 Add 10 µL of MAX Taq-polymerase solution into each tube. Avoid paraffin layer break.
1.4 Add one drop (~20 µL) of mineral oil into each tube. Close strips tightly.
1.5 Add 5.0 µL of the DNA sample into each tube of a strip assigned to test samples. Open the strip, add DNA sample, then close the strip before proceeding to the next DNA sample to prevent contamination. Use filter tips. Do not add DNA into the "C-", "C+" strips.
1.6 Add 5.0 µL of the "C-" which passed whole DNA extraction procedures into tubes of corresponding strip. Add 5.0 µL of the "C+" into tubes of corresponding strip. Avoid paraffin layer break.
1.7 Spin strips for 1–3 seconds to collect drops.
1.8 Set the strips to Real-time PCR instrument.
1.9 Launch the RealTime_PCR application in Device operation mode. Upload Femoflor_en.ini file before the first run. In subsequent runs add test "Femoflor Screen". Specify the number and identificator of samples. Define position of tubes in software interface according to position they were set in the thermoblock (see 1.8). Run PCR.

2 The PCR and post-PCR analysis is operated by software and held in automatic mode.

Storage, shipping and handling requirements

Femoflor Screen REAL-TIME PCR Detection Kit should be stored at the temperatures between 2 °C and 8 °C during the storage period.

⚠ Paraffin-sealed PCR-mix should be stored in a dark place at the temperatures between 2 °C and 8 °C during the storage period.
Transportation can be held by all types of roofed transport at temperatures between 2 °C and 8 °C over the transportation.
Shelf-life – 12 months since the date of production in compliance with all transportation, storage and operation conditions.

Contact our customer service department regarding quality issues with the kit:
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Key to symbols

	Temperature limitation		Consult instructions for use	REF	Cataloque number
	Expiration date		Manufacturer	LOT	Batch code
	Date of manufacture		Number of tests		Do not expose to sunlight
	Caution				

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