DNA-TECHNOLOGY

For research use only

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T.vaginalis, N.gonorrhoeae, C.trachomatis
Multiplex REAL-TIME PCR Detection Kit

REF R1-P111-23/9EU
R1-P111-S3/9EU

General information

Intended use:
T.vaginalis, N.gonorrhoeae, C.trachomatis Multiplex REAL-TIME PCR Detection Kit is intended for detection of true-pathogens *Trichomonas vaginalis, Neisseria gonorrhoeae* and *Chlamydia trachomatis* DNA in human biological samples by method of multiplex Real-Time PCR. Current modification of the method allows simultaneous detection and differentiation of *Trichomonas vaginalis, Neisseria gonorrhoeae, Chlamydia trachomatis* DNA in the same tube.
T.vaginalis, N.gonorrhoeae, C.trachomatis Multiplex REAL-TIME PCR Detection Kit can be used in clinical diagnostic labs and in scientific research practice.

Method:
Multiplex Real-Time PCR, qualitative analysis.

Samples:
Urina; epithelial cell scrapes from urethra, cervical canal, posterior vaginal vault.

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

Features:
Multiplex analysis gives the opportunity of simultaneous detection and differentiation of *Trichomonas vaginalis, Neisseria gonorrhoeae, Chlamydia trachomatis* DNA in the same tube.
PCR-Mix contains an internal control (DNA-IC). IC is intended for PCR quality and sufficiency of DNA assurance.
We also recommend including in assay the negative control ("C-") which is not supplied but 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 *T.vaginalis, N.gonorrhoeae, C.trachomatis* Multiplex 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 7.3.3.10; the current version of the software is available for download at http://www.dna-technology.ru/eng/support/.

⚠ Please enquire DNA-Technology company's representative about compatibility of third-party Real-time instruments.

Overall time needed to perform the analysis:
2 hours at average.

The number of tests:
96

Kit contents:

Reagent	Quantity	
Paraffin sealed PCR-mix	20 µL	96 separate tubes or 12 8-tubes strips
MAX Taq-polymerase solution	500 µL	2 tubes
Mineral oil	1.0 mL	2 tubes
Positive control	150 µL	1 tube

Dye label detection channels

Fam	Hex	Rox	Cy5	Cy5.5
Trichomonas vaginalis	IC	*Neisseria gonorrhoeae*	*Chlamydia trachomatis*	-

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

Procedure

1 PCR amplification

1.1 Mark the required number of the tubes with paraffin sealed PCR-mix considering samples, negative control ("C-") and positive control ("C+").

Example. If you need to test 2 samples, mark 4 tubes (one for each sample, one for "C-", one for "C+").

Sample 1	Tube 1
Sample 2	Tube 2
"C-"	Tube 3
"C+"	Tube 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 tubes tightly.

1.5 Add 5.0 µL of the DNA sample into corresponding PCR-tubes. Open the tube, add DNA sample, then close the tube before proceeding to the next DNA sample to prevent contamination. Use filter tips. Do not add DNA into the "C-", "C+".

1.6 Add 5.0 µL of negative control sample ("C-") which passed whole DNA extraction procedure into corresponding tube. Add 5.0 µL of positive control sample ("C+") into corresponding tube. Avoid paraffin layer break.

1.7 Spin tubes for 1–3 seconds to collect drops.

1.8 Set the tubes to real-time PCR thermal cycler.

1.9 Launch the RealTime_PCR application in "Device handling" mode. Upload TNC_Complex_en.ini file before the first run. In subsequent runs add "TNC_Complex" test. Specify the number and identificator of samples. Define position of tubes in software interface according to position they were set in thermal unit. Run PCR.

2 Data collection and data analysis

Registration and interpretation of the PCR results are held in automatic mode.

⚠ Cp on the Fam, Rox, Cy5 channels less than 24 indicates high initial DNA concentrations of corresponding pathogen that may cause false-negative results for low-presented pathogen. In this case repeating of PCR amplification using DNA-Technology *Trichomonas vaginalis* REAL-TIME PCR Detection Kit*, Neisseria gonorrhoeae* REAL-TIME PCR Detection Kit *and Chlamydia trachomatis* REAL-TIME PCR Detection Kit is recommended.

Storage, shipping and handling requirements

T.vaginalis, N.gonorrhoeae, C.trachomatis Multiplex 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 – 6 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				