



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 DTlite¹, DTprime² 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
<i>Trichomonas vaginalis</i>	IC	<i>Neisseria gonorrhoeae</i>	<i>Chlamydia trachomatis</i>	-

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 identifier 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 - 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:

8 800 200-75-15 (toll-free call for Russia)

+7 (495) 640-16-93 (chargeable call for CIS and foreign countries).

E-mail: hotline@dna-technology.ru, www.dna-technology.ru.

Address: 117587, Moscow, Varshavskoye sh., 125g building 6, floor 5, room 14, DNA Technology, LLC.

Key to symbols

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



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