



Multiplex REAL-TIME PCR Detection Kits

HPV 6,11

REF R1-P321-23/9EU
 R1-P321-S3/9EU

HPV 16,18

REF R1-P320-23/9EU
 R1-P320-S3/9EU

General information

Intended use:

HPV 6,11 and HPV 16,18 Multiplex REAL-TIME PCR Detection Kits are intended for detection and typing of two most oncogenic and persistent high-risk human papilloma virus types (HPV 16, HPV 18) and two low-oncogenic risk human papilloma virus types (HPV 6, HPV 11) by method of multiplex Real-Time PCR.

Kit formats:

HPV 6,11 is intended for detection and typing of types 6 and 11 human papilloma virus.

HPV 16,18 is intended for detection and typing of types 16 and 18 human papilloma virus.

Method:

Multiplex Real-Time PCR, qualitative analysis.

Samples:

Epithelial cell scrapes from urethra, cervical canal, uterine neck.

DNA extraction:

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

Features:

Multiplex analysis gives the opportunity of simultaneous detection and differentiation of several HPV types 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 HPV 6,11 and HPV 16,18 Multiplex REAL-TIME PCR Detection Kits is available on "DNA-Technology" made DTlite¹, DTprime² 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/>.



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

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

from 2.5 hours.

The number of tests: 96

Kit contents:

Reagent	Quantity	
Paraffin sealed PCR-mix	20 µL	96 separate tubes or 12 8-tubes strips
Taq-polymerase solution	480 µL	2 tubes
Mineral oil	960 µL	2 tubes
Positive control ("C+")	150 µL	1 tube

Dye label detection channels

Fam	Hex	Rox	Cy5	Cy5.5
HPV18	IC	-	HPV16	-
HPV6	IC	-	HPV11	-

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+").

For 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 Taq-polymerase solution thoroughly (3-5 sec), then spin briefly (1-3 sec).

1.3 Add 10 µL of 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+" tubes.

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 Vortex 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 corresponding ini file before the first run. Add test in subsequent runs. Specify the number and identifier of samples. Define position of tubes in software interface according to position they were set in thermal unit (p. 1.8). Run PCR.

2 Data collection and data analysis

Registration of the PCR results are held in automatic mode. Interpretation of the PCR results should be performed according to the Table 1.

Table 1

PCR results interpretation

Detection channel		Result	Result interpretation
Fam, Cy5	Hex		
Analyzed samples			
Cp is specified (in the one or two detection channels)	Is not considered	"+"	DNA of one or two HPV types is present (HPV16 and/or HPV18, HPV6 and/or HPV11)
Cp is not specified (in the both detection channels)	Cp is specified	"-"	DNA of 6/11 or 16/18 HPV types is not present
Cp is not specified (in the both detection channels)	Cp is not specified (in the both detection channels)	"n/a"	Unreliable result
Positive control sample			
Cp is specified (in the both detection channels)	Cp is specified	"+"	Positive result
Negative control sample			
Cp is not specified (in the both detection channels)	Cp is specified	"-"	Negative result

Storage and handling requirements

All kit components must be stored from 2 °C to 8 °C and out of light during the storage period. The excessive temperature and light can be detrimental to product performance.

Shelf-life – 12 months since the date of production.

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.



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