

Specific identification and quantification of low-risk and high-risk human papilloma virus types by real-time polymerase chain reaction



**HPV-QUANT-21®** – detection of HPV 6, 11, 16, 18, 26, 31, 33, 35, 39, 44, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, 82

**HPV-QUANT-15®** – detection of HPV 6, 11, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68

**HPV-QUANT-4®** – detection of HPV 6, 11, 16, 18

**The quantitative assessment of viral load allows to**

- determine further patient management tactics
- monitor dynamics and treatment
- evaluate prognosis of the disease



High-speed testing  
from 2,5 hours, including sample preparation



Multiplex format



**Biomaterial:** epithelial cell swabs,  
prostate fluid, ejaculate, urine,  
biopsy material



Automatic generation  
of the results form

According to the International Agency for Research on Cancer, **human papilloma virus (HPV)** is the main etiological factor in the development of a wide range of oncological diseases, such as cancer of the cervix, vulva, vagina, anal canal, penis, head and neck, esophagus, and also anogenital warts and recurrent respiratory papillomatosis. The target cells for the virus are basal epithelial stem cells. HPV are divided into low-risk and high-risk types depending on the ability of the virus to cause neoplastic processes. According to WHO, types with a high oncogenic risk include HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68.



HPV infection causes about 5% of all cancer diseases in the world. HPV-associated cancer is diagnosed annually in 625 600 women and 69 400 men. HPV types 16 and 18 cause about 50% cervical pre-cancers. In other cases different types of HPV are etiological agents, and it is therefore important to identify the maximum possible number of high-risk HPV types.

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HPV infection during pregnancy might negatively impact both maternal and infant health, increasing the risk of severe pregnancy complications, such as spontaneous abortion, preterm birth, preeclampsia, intrauterine growth restriction, premature rupture of membranes and fetal death.



A number of studies suggest a link between HPV and decreased fertility and reproductive potential. A higher prevalence of HPV infection is observed in male infertility. HPV infection causes changes in the pH level of seminal fluid, a decrease in the number of morphologically normal sperm and their functional activity. PCR diagnostics of HPV is recommended for the examination of infertile couples as part of the programs for assisted reproductive technologies.

According to several studies, a viral load has an important prognostic value. A low viral load can indicate the presence of transitory infection. It also has a value in cases of treatment monitoring. A high viral load may correlate with existence of dysplastic changes or high risk of their occurrence.

Every clinical situation should be analyzed individually; quantitative detection of viral load must be combined with other diagnostics methods to maximize sensitivity and specificity in screening and determine further tactics of patient management.

## Specific reports of HPV-QUANT®

### HPV-QUANT-4®

Nº	Name of research	Results		
		Relative, Lg (X/SIC)*	Quantitative, Lg (copies/sample)	Qualitative
1	HPV 6	7.2	9.1	
2	HPV 11	not detected	not detected	
3	HPV 18	not detected	not detected	
4	HPV 16	not detected	not detected	
5	SIC		6.9	

\* HPV DNA copies/10<sup>5</sup> cells (Lg)

#### Detecting of HPV:

- High-risk types: 16, 18
- Low-risk types: 6, 11

### HPV-QUANT-15®

Nº	Name of research	Results		
		Relative, Lg (X/SIC)*	Quantitative, Lg (copies/sample)	Qualitative
1	HPV 16, 31, 33, 35, 52, 58	<3.0	2.9	
2	HPV 56	not detected	not detected	
3	HPV 18, 39, 45, 59	7.6	7.6	
4	HPV 6, 11	not detected	not detected	
5	HPV 51	5.0	5.0	
6	HPV 68	not detected	not detected	
7	SIC		5.0	

\* HPV DNA copies/10<sup>5</sup> cells (Lg)

#### Detecting of HPV:

- High-risk types: 16, 18, 31, 33, 35, 39, 45, 52, 58, 59 (without differentiation) 51, 56, 68
- Low-risk types: 6, 11 (without differentiation)

### HPV-QUANT-21®

Nº	Name of research	Results		
		Relative, Lg (X/SIC)*	Quantitative, Lg (copies/sample)	Qualitative
1	HPV 31	7.5	7.5	
2	HPV 35	not detected	not detected	
3	HPV 16	not detected	not detected	
4	HPV 52	not detected	not detected	
5	HPV 33	not detected	not detected	
6	HPV 68	not detected	not detected	
7	HPV 45	not detected	not detected	
8	HPV 82	not detected	not detected	
9	HPV 51	not detected	not detected	
10	HPV 6	not detected	not detected	
11	HPV 44	4.1	4.1	
12	HPV 11	not detected	not detected	
13	HPV 18	not detected	not detected	
14	HPV 39	not detected	not detected	
15	HPV 58	not detected	not detected	
16	HPV 66	not detected	not detected	
17	HPV 26	not detected	not detected	
18	HPV 53	not detected	not detected	
19	HPV 59	not detected	not detected	
20	HPV 56	not detected	not detected	
21	HPV 73	not detected	not detected	
22	SIC		5.0	

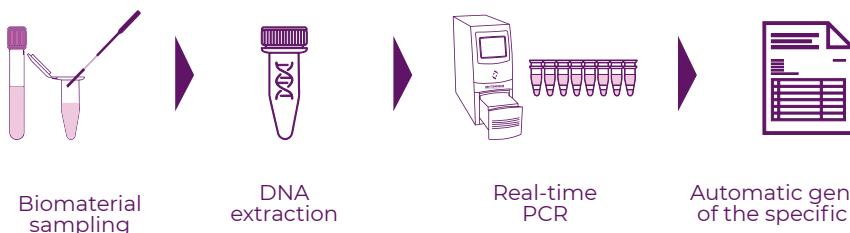
#### Detecting of HPV:

- High-risk types: 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, 82
- Low-risk types: 6, 11, 44

\* HPV DNA copies/10<sup>5</sup> cells (Lg)

Biomaterial	<ul style="list-style-type: none"> <li>■ epithelial cell swabs</li> <li>■ prostate fluid</li> <li>■ ejaculate</li> <li>■ urine</li> <li>■ biopsy material</li> </ul>
DNA extraction kits	<ul style="list-style-type: none"> <li>■ PREP-NA PLUS</li> <li>■ PREP-GS PLUS</li> <li>■ PREP-MB RAPID</li> </ul>
Package	package S
Equipment	<ul style="list-style-type: none"> <li>■ DTprime</li> <li>■ DTlite</li> </ul>
Analytical sensitivity	5 copies of DNA in amplification tube
Time of analysis	from 2,5 hours (including sample preparation)
Number of samples	24*/48 tests, including control samples

\* For the package S of HPV-QUANT-2I®



**Specialized software** — automatic result interpretation  
and creation of a result form



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