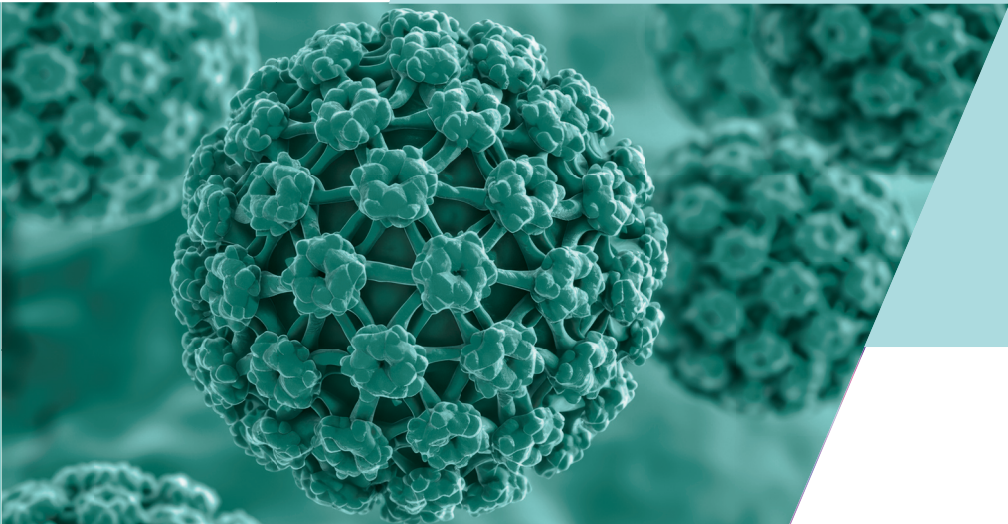


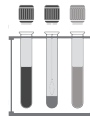
# HPV SCREEN HR14(16-18-45)



Detection of 14 types of high-risk human papilloma virus (HPV)  
with differentiation of HPV 16, 18, 45



**Detecting HPV** 16, 18, 31, 33, 35,  
39, 45, 51, 52, 56, 58, 59, 66, 68  
**Differentiating HPV** 16, 18, 45



**Biomaterial:** epithelial smears/  
scrapes from the mucous  
membrane of the cervical  
canal and the vagina



Multiplex format



Human genomic DNA as  
Sample intake control (SIC)



Automatic generation  
of the results form



High-speed testing  
From 1.5 h

**Human papillomavirus (HPV)** is the main etiologic factor in the development of cervical cancer. According to WHO, high-risk HPV types include 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68.

HPV infection is the cause of 5% of all cancer cases worldwide. Annually HPV-associated cancer is diagnosed in 625,600 women and 69,400 men. About 50% of precancerous cervical diseases are caused by HPV 16 and 18.



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HPV is a sexually transmitted infection; most people become infected with HPV shortly after starting being sexual active. The virus infects the mucous membrane and produces viral particles in epithelial cells. Viral oncoproteins E5, E6 and E7 affect the regulation of the cell cycle, which leads to uncontrolled cell division and the accumulation of genetic damages.

In many cases virus may self-eliminate in several years. But the presence of high-risk HPV in squamous epithelial cells is a precondition for the development of cervical precancer, while persistent HPV infection is the main risk factor for squamous cell cervical cancer.



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HPV infection during pregnancy can negatively affect the health of both mother and baby, increasing the risk of severe pregnancy complications. It may be spontaneous abortion, premature birth, preeclampsia, intrauterine growth restriction, premature rupture of membranes, and fetal death.

## HPV screening


An effective way to prevent cervical cancer is HPV screening and treatment of precancerous conditions.

- WHO recommends to use HPV DNA detection as the preferred primary screening test (compared to cytology and 3-5% acetic acid test).
  - WHO recommends routine screening every 5-10 years: detecting high-risk HPV DNA as the primary screening test in the general population of women.
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- It is recommended to identify HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68.
  - It is recommended to include HPV typing 16/18, as well as HPV type 45 in the screening.




Extended genotyping is necessary not only for squamous cell lesions of the cervix, but also for screening cervical glandular neoplasia due to the high prevalence of HPV 16, 18 and 45 in neoplasia and changes preceding it.


Biomaterial	epithelial smears/scrapes from the mucous membrane of the cervical canal and the vagina
Sample pretreatment	PREP-PK (for scrapes taken in the transport & fixation medium for liquid cytology BD SurePath)
DNA extraction kits	<ul style="list-style-type: none"> <li>■ PREP-NA</li> <li>■ PREP-GS</li> <li>■ PREP-RAPID</li> <li>■ PREP-MB RAPID</li> </ul>
Variants of package	<ul style="list-style-type: none"> <li>■ package S, strips</li> <li>■ package S, tubes</li> </ul>
Equipment	<ul style="list-style-type: none"> <li>■ DTprime 5M1, 5M3, 5M6</li> <li>■ DTlite 5S1, 5S2</li> </ul> When using detection amplifiers with 4 detection channels, HPV 45 is not typed
Analytical sensitivity	5 DNA copies per amplification tube
Time of analysis	From 1,5 hours
Number of samples	96 tests, including control samples



**Biomaterial collection**



**Sample pretreatment**  
(for scrapes taken in the transport & fixation medium for liquid cytology BD SurePath)



**DNA extraction**



**Real-time PCR**

### An example of the result form

#### HPV SCREEN HR14 (16-18-45)

Date:  
Number of tube:  
Patient name:  
Sex:  
Age:  
Physician:  
Comment:



Laboratory information

Sample ID:

Test name	Result
HPV 16	not detected
HPV 18	not detected
HPV 45	not detected
HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68	not detected

**IMPORTANT:** the interpretation of the results must be made strictly by the attending physician

 +2 ... +8 °C  
12 months

**Specialized software** — automatic result interpretation and creation of a result form.  
**RealTime\_PCR software**



dna-technology.com

 hotline@dna-technology.ru  
 +7 (495) 640-17-71



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