

## Human Papilloma Virus

Cervical cancer (CC) is one of the most widely spread oncological pathologies that ranks second by the incidence in women in the world. Each year about 600 thousand of new CC cases are registered in the world with more than 250 thousand lethal outcomes. The virus nature of this cancer is confirmed by the World Health Organization and HPV is detected practically in 100 percent of cases of cervical precancer and cancer. Based on the frequency of detection of HPV genotypes from different grades of Cervical Intraepithelial Neoplasia (CIN Grades I – III), HPV genotypes are subdivided into High-risk HPV types (16, 18, 31 and 45), Intermediate-risk types (33, 35, 39, 51, 52, 56, 58, 59, and 68), and Low-risk types (6, 11, 42-44).

Owing to the fact that the cervical cancer (CC) has a long development period and a fail-safe recognizable pre-clinic phase there's a possibility to detect and prevent the disease on its early stage.

### Kits for screening of high carcinogenic risk HPV genotypes

The **NEW** kit **HPV 14 Screening & 16,18,45 Typing Real-TM Quant** is an *in vitro* Real Time amplification test for quantitative detection and genotyping of HPV 16,18,45 and simultaneous quantitative detection of HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68 (total 14 genotypes detected). It is known, that the parameter of viral load has a prognostic value and the viral load less than  $10^5$  HPV genomic equivalents in the swab or  $10^3$  genomic equivalents for  $10^5$  cells is considered as insignificant and indicates the presence of transitory infection, however such level of load may have a value only in cases of treatment monitoring. Viral load of more than  $10^5$  genomic equivalents for  $10^5$  cells is considered to be important with high significance and indicates the existence of dysplastic changes or high risk of their occurrence. Quantitative detection of viral load allows to evaluate the character of the infection and to make a forecast concerning the stage of the disease.

#### HPV High Risk Screen Kits

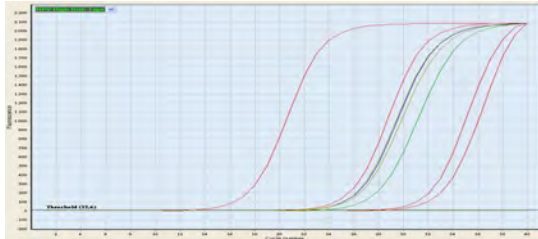
|  |   |   |    |     |                           |
|--|---|---|----|-----|---------------------------|
| V31-100/F FRT<br>SA, RG, B, iQ, MX, A        | <b>HPV 14 Screening &amp; 16,18,45 Typing Real-TM Quant</b><br>Real Time Amplification kit                          | R | €€ | 100 | $5 \times 10^2$ copies/ml |
| V31-100/2FRT<br>SA, RG, iQ, MX, A, B         | <b>HPV High Risk Screen Real-TM Quant</b><br>Real Time Amplification kit  | R | €€ | 100 | $5 \times 10^2$ copies/ml |
| TV31-100/2FRT 2X<br>SA, RG, iQ, SC, MX, A, B | <b>HPV High Risk Screen Real-TM 2X Quant (2 channels)</b><br>Complete Real Time Test with DNA-Sorb-A extraction kit | R | €€ | 100 | $5 \times 10^2$ copies/ml |
| V31-100/2FRT 2X<br>SA, RG, iQ, SC, MX, A, B  | <b>HPV High Risk Screen Real-TM 2X Quant (2 channels)</b><br>Real Time Amplification kit                            | R | €€ | 100 | $5 \times 10^2$ copies/ml |
| V-26-100F                                    | HPV High Risk Screen  | A | €€ | 110 | $1 \times 10^3$ copies/ml |

### Kits for typing of high carcinogenic risk HPV genotypes

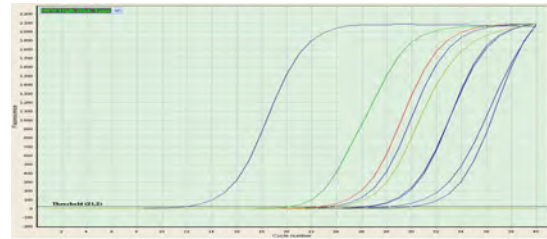
The **NEW HPV Genotypes 14 Real-TM** kit is an *in vitro* multiplex Real Time amplification test for qualitative detection and genotyping of up to 14 genotypes of *Human Papillomavirus* (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68) in urogenital swabs and biopsies.

The **HPV Genotypes 14 Real-TM** kit is based on two major processes: isolation of DNA from specimens and multiplex Real Time amplification of 4 tubes for each sample. The test uses primers directed against regions of HPV types and  $\beta$ -globine gene used as Internal Control. If the swab is not correctly prepared (high quantity of mucous or insufficient quantity of epithelial cells) the Internal Control will not be detected.

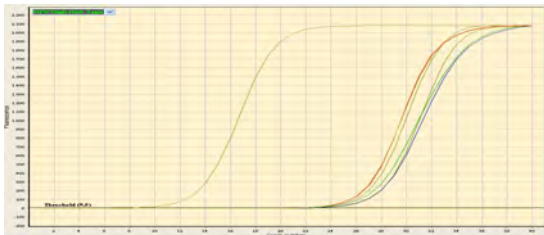




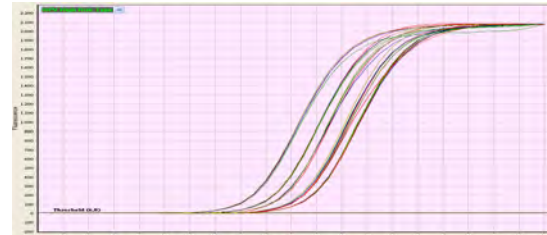
**FAM/Green channel:** HPV genotypes 16, 39, 33 and 58



**JOE/HEX channel:** HPV genotypes 31, 45, 35 and 52



**ROX channel:** HPV genotypes 18, 59, 56 and 51



**Cy5 channel:** HPV genotypes 66, 68 and  $\beta$ -Globine

### HPV High Risk Typing Kits

|   |  |   |   |     |                              |
|---|--|---|---|-----|------------------------------|
| V67-100FRT<br>SA, RG, MX, iQ, A, B      | <b>HPV genotypes 14 Real-TM Quant</b><br>Real Time Amplification kit for detection and quantification of high risk genotypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68 | R | € | 100 | 5 x10 <sup>2</sup> copies/ml |
| TV12-100FRT<br>SA, RG, SC, MX, iQ, A, B | <b>HPV 16/18 Real-TM Quant</b><br>Complete Real Time Test with DNA-Sorb-A extraction kit   | R | € | 100 | 5 x10 <sup>2</sup> copies/ml |
| V12-100FRT<br>SA, RG, iQ, SC, MX, A, B  | <b>HPV 16/18 Real-TM Quant</b><br>Real Time Amplification kit  | R | € | 100 | 5 x10 <sup>2</sup> copies/ml |
| V-25-50F                                | HPV High Risk Typing   | A | € | 55  | 1 x10 <sup>3</sup> copies/ml |

### Low carcinogenic risk

A group of **low carcinogenic risk HPV** is represented by more than 12 genotypes and they are called “low risk” because they cannot cause cervical cancer. Sometimes low-risk HPV types can cause visible changes in the genital area, called genital warts. Genital warts are growths or bumps in the genital areas of men and women. They usually are painless. They may be raised, flat, small or large, and single or multiple. Among low risk HPV the genotypes **6** and **11** are of greatest importance as they are responsible for the overwhelming amount of low-carcinogenic pointed condylomas of genital organs and for more than 90 percent of cases of condylomatosis of the larynx in children.

### HPV Low Risk Typing Kits

|   |   |   |   |     |                              |
|---|---|---|---|-----|------------------------------|
| TV11-100FRT<br>SA, RG, iQ, SC, MX, A, IL, B | <b>HPV 6/11 Real-TM</b><br>Complete Real Time Test with DNA-Sorb-A extraction kit | R | € | 100 | 5 x10 <sup>2</sup> copies/ml |
| V11-100FRT<br>SA, RG, iQ, SC, MX, A, IL, B  | <b>HPV 6/11 Real-TM</b><br>Real Time Amplification kit                            | R | € | 100 | 5 x10 <sup>2</sup> copies/ml |
| V-135-100F                                  | HPV 6/11  | A | € | 55  | 5 x10 <sup>2</sup> copies/ml |