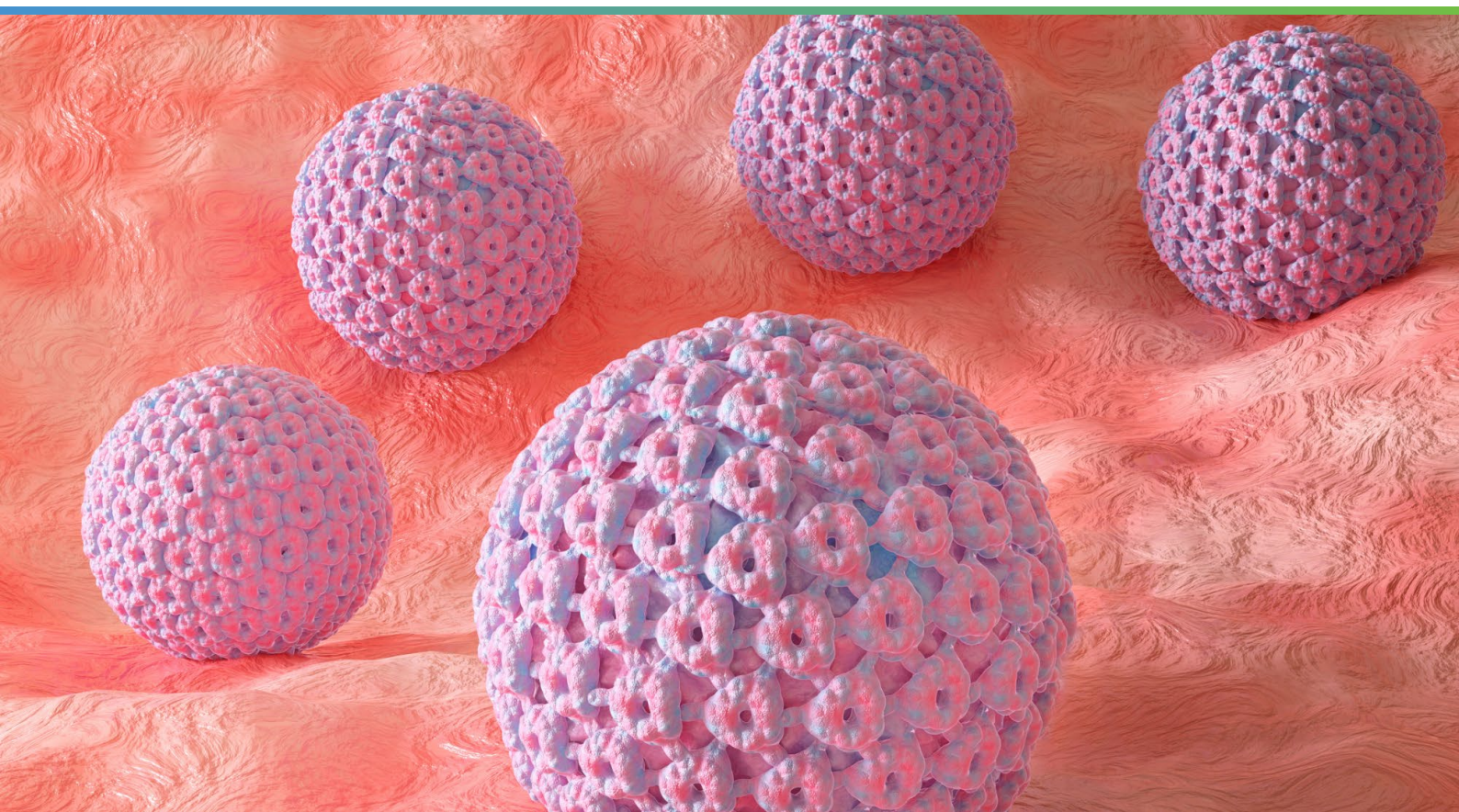


ViroKey® MP HPV 16, 18 PCR Test (CE-IVD)

Qualitative Detection of HPV from Cervical Swab Samples



The ViroKey MP HPV 16, 18 PCR Test is a real-time PCR based in vitro diagnostic test to be used for qualitative detection of 18 genotypes of human papillomavirus (HPV) DNA, including the differentiation of high-risk HPV genotypes 16 and 18 from types 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73 and 82 in one run from cervical shedding cell samples, aiding in the diagnosis of HPV infection.



Comprehensive Detection

Detects 18 high/medium-risk HPV types in one run



CE-IVD Marked

Assist clinicians in making treatment decisions with confidence



Manual Workflow

Simple workflow with no batching required



Differentiate High-Risk GTs

Identify HPV 16, 18 independently



Highly Concordant

With leading PCR kits in the market



Broad Compatibility

With most common PCR cyclers

ViroKey MP HPV 16, 18 PCR Test Assay Specifications

Parameters	Specifications	
Regulatory Status	CE-IVD	
Workflow	Manual	
Detection & Differentiation of HPV Genotypes	Total GTs Detected	18 Genotypes
	High-Risk GTs Detected	16 and 18
	Medium/Low-Risk GTs Detected (Pooled)	26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73 and 82
Controls	1 positive control and 1 negative control	
Sample Types	Cervical swabs	
Clinical Sensitivity	HPV 16: 100% (95%CI: 94.87, 100), HPV 18: 100% (95%CI: 93.12, 100), Medium/Low-Risk GTs Detected (Pooled): 97.85% (95%CI: 95.97, 98.87)	
Clinical Specificity	HPV 16: 99.28% (95%CI: 98.16, 99.72), HPV 18: 99.65% (95%CI: 98.74, 99.9), Medium/Low-Risk GTs Detected (Pooled): 99.03% (95%CI: 96.53, 99.01)	
Limit of Detection (LoD)	2 x 10 ³ copies/mL (HPV16, 18) 1 x 10 ⁴ copies/mL (other GTs)	
Turnaround Time	1 - 3 hours depending on sample throughput and proficiency	
Hands-on Time	0.5 hours depending on sample throughput and proficiency	
Validated Instruments	Applied Biosystems 7500 Real-Time PCR system Bio-Rad CFX96 Real-Time PCR Detection System	
Fluorescence Detectors (Dyes)	FAM/Green	HPV 16
	HEX/VIC/Yellow	HPV 18
	ROX	Other types (HPV 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73 and 82)
	Cy5/Red	Internal Control

Ordering Information

Product Name	Pack Size	Item Number
ViroKey MP HPV 16, 18 PCR Test (24)	24 tests	301119
ViroKey MP HPV 16, 18 PCR Test (2x24)	48 tests	301147
ViroKey MP HPV 16, 18 PCR Test (4x24)	96 tests	301148

IVD: For in vitro diagnostic use. Not for distribution in the US.

Vela Operations Singapore Pte Ltd

Reg No: 201106974H
50 Science Park Road
#05-07 The Kendall
Singapore 117406

T: +65 6672 6060
T: 1800 225 8352 (Toll-Free)
F: +65 6672 6066
E: infoAPAC@veladx.com

Vela Diagnostics Germany GmbH

Albert-Einstein-Ring 15
22761 Hamburg
Germany

T: +49 40 890 662233
F: +49 40 890 662299
E: infoEMEA@veladx.com