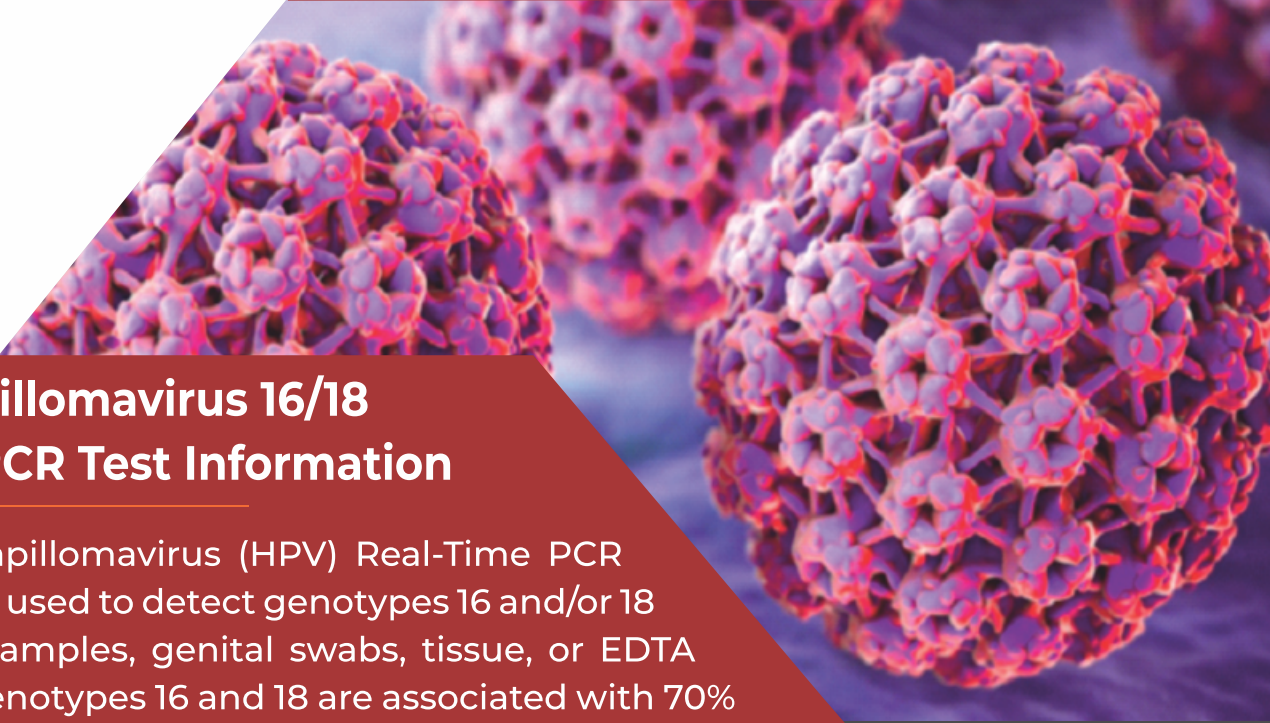




COSARA
DIAGNOSTICS
PVT. LTD

SARAGENE™ Human Papillomavirus 16/18 Real-Time PCR Test

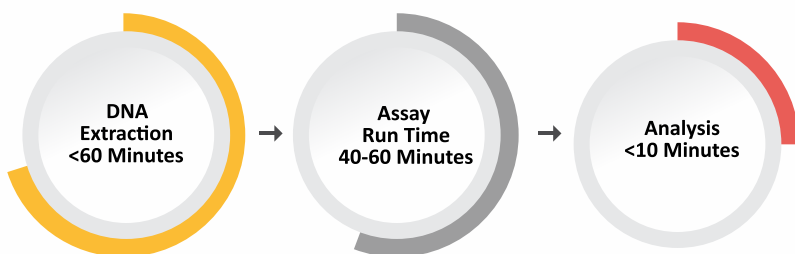


Human Papillomavirus 16/18 Real-Time PCR Test Information

The Human Papillomavirus (HPV) Real-Time PCR (RT-PCR) Test is used to detect genotypes 16 and/or 18 from cervical samples, genital swabs, tissue, or EDTA plasma. HPV genotypes 16 and 18 are associated with 70% of cervical cancer and 70% of anal or genital cancer in women and men.

Results within two hours

The HPV tests can be performed in less than two hours. The test requires a clean, contamination free environment with a hood, centrifuge, pipettes, and RT-PCR machine. The test is compatible with most RT-PCR devices with green, yellow, and orange channels and it can be customized to work with a myriad dyes and PCR technologies.



HPV 16/18 RT-PCR KIT

- Compatible with multiple sample types, platforms and sample extractions
- Simple and streamlined workflow
- Includes internal control to verify sample quality
- Includes positive control
- Produces results that are easy to interpret

IVD



Sarabhai Campus,
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Ranoli - 391350, Dist. Vadodara, India.

Sensitive, Fast and Affordable Molecular Diagnostics
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SARAGENE™ Human Papillomavirus 16/18 Real-Time PCR Test Specifications

About CoDx™ Technology

The HPV kit is developed using a revolutionary molecular diagnostics technology called CoPrimers™, a technology invented and patented by Co-Diagnostics, Inc (Utah, USA).

CoDx technology is mathematically engineered to enhance the speed, accuracy and cost-effectiveness of RT-PCR. The technology is based on cooperative theory, a mathematical model developed by Brent Satterfield, Ph.D. This model applies advanced algorithms and bioinformatics to optimize design parameters with analyte targets. In comparison with other technologies, the CoPrimers reduce the formation of primer-dimers, increase specificity and increase ability to multiplex. The Journal of Molecular Diagnostics (March 2014) introduced CoPrimers as a “new class of primer technology that greatly reduces primer-dimer propagation, showing a 2.5 million-fold improvement in reduction of nonspecific amplification.”

Application	Qualitative RT-PCR Genotyping									
Sample type	Cervical samples, genital swabs, EDTA plasma or serum									
Type of detection	Presence or absence of HPV genotypes 16 and/or 18									
Specificity	HPV genotypes 16 and/or 18									
Limit of Detection	<table border="1"> <thead> <tr> <th>Gene Marker</th> <th>Genotype</th> <th>Limit of Detection (copies/μL)</th> </tr> </thead> <tbody> <tr> <td>HPV</td> <td>16</td> <td>100</td> </tr> <tr> <td>HPV</td> <td>18</td> <td>100</td> </tr> </tbody> </table>	Gene Marker	Genotype	Limit of Detection (copies/μL)	HPV	16	100	HPV	18	100
Gene Marker	Genotype	Limit of Detection (copies/μL)								
HPV	16	100								
HPV	18	100								
Thermal cycler compatibility	Most RT-PCR systems with the following channel compatibilities: Green (FAM™), Yellow (CAL Fluor® Orange 560), and Orange (CAL Fluor® Red 610)									

HPV 16/18 Kit Includes

MM	Master Mix
PC	Positive Control
NC	Negative Control

Ordering Information

Product Name	Number of Reaction
SARAGENE™ HPV 16/18 Real-Time PCR KIT	25 RxS
	50 RxS
	100 RxS

* RT PCR machine available on request

The performance of the HPV RT-PCR Test has been evaluated for precision, accuracy, sensitivity, and specificity for relevant HPV genotypes.

Intended Use:

For the Detection of Human Papillomavirus (HPV16/18)



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