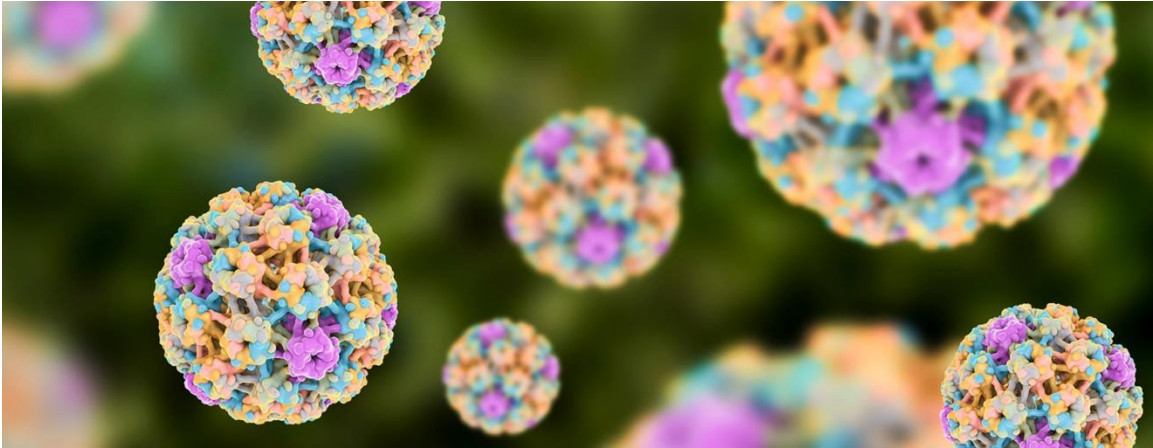


TRUPCR® HPV High Risk Genotyping Kit

NEED

Human Papillomaviruses (HPV) infections are among the most common sexually transmitted infections. Persistent infection with human papillomavirus (HPV) is the principal cause of cervical cancer. The presence of HPV has been implicated in more than 99% of cervical cancers worldwide, including both cervical squamous cell carcinoma and cervical adenocarcinoma. In 2018, an estimated 570,000 women were diagnosed with cervical cancer worldwide and about 311,000 deaths were reported due to this disease. HPV High Risk testing in cervical cancer screening offers a high degree of certainty.



SOLUTION BY TRUPCR®

TRUPCR® HPV High Risk Genotyping Kit is a Real-Time Amplification test for the qualitative detection of Human Papilloma Virus (HPV) DNA in clinical samples.

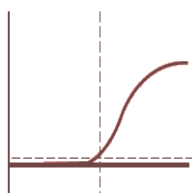
It is intended for the detection and genotyping of 14 HPV high/intermediate-risk types. It is a Real Time PCR assay based on oligonucleotide hydrolysis principle which allows higher specificity and sensitivity of E6/E7 region by primer and probes specific for detection and genotyping of 14 High Risk HPV Genotypes.

TARGET GENOTYPES

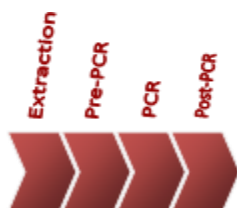
Primer Probe Mix-1			Primer Probe Mix-2			Primer Probe Mix-3		
FAM	HEX	Tex Red	FAM	HEX	Tex Red	FAM	HEX	Tex Red
HPV 59	HPV 18	HPV 56	HPV 33	HPV 31	HPV 35	HPV 58	HPV 45	HPV 68

Primer Probe Mix-4			Primer Probe Mix-5		
FAM	HEX	Tex Red	FAM	HEX	Tex Red
HPV 52	HPV 39	HPV 51	HPV 16	HPV 66	IC

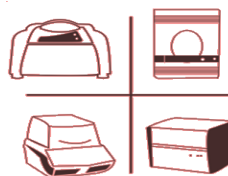
KEY FEATURES



Endogenous Internal Control incorporated within the kit to ensure reliable results



Complete workflow solution available from Extraction of sample to Post-PCR analysis



Platform agnostic as compatible with various platforms



Rapid and reliable results within 90-100 minutes after PCR Start

TECHNICAL SPECIFICATIONS

- Sample Type – Cervical Swab Specimen, Urine Specimen, FFPE Sample
- Clinical Validation – Validated on more than 2000 clinical samples
- Target Regions – E6/E7 region of the HPV HR Genome
- Reaction Volume – 25 µl in each tube
- LOD Data: 10² IU/ml
- Compatible Instruments – Applied Biosystems™ 7500 series, Applied Biosystems™ StepOne series, Applied Biosystems™ QuantStudio® series, Rotor-Gene Q, Bio-Rad CFX96, Roche - LightCycler® 480 – II

CLINICAL DATA

		Reference Method		
		Positive	Negative	Total
TRUPCR Method	Positive	219	1	220
	Negative	1	39	40
Total		220	40	260

Parameters	Estimate
Sensitivity	99.55%
Specificity	97.50%
Positive Predictive Value	99.55%
Negative Predictive Value	97.50%



ORDERING INFORMATION

Cat. No.	Description	Size
3B1423	TRUPCR® HPV HR Genotyping Kit	48 Reactions
3B1424	TRUPCR® HPV HR Genotyping Kit	96 Reactions

PUBLICATIONS

1. Clinical evaluation and application of TRUPCR® HPV High Risk Genotyping Kit for detection and genotyping of High-risk human papillomavirus (HPV) in clinical samples (<https://www.issrf2021.com/assets/Abstract%20Book%20ISSRF-2021.pdf>)
2. Human Papilloma virus: A review study of epidemiology, carcinogenesis, diagnostic methods and treatment of all HPV-related cancers (http://mjiri.iums.ac.ir/browse.php?a_id=7163&sid=1&slc_lang=en&ftxt=1)

