

AT THE CORE of Quality



REDTM controls

Quality Assessment Products (QAPs)

hrHPV type 16, 18, 45 Positive Controls and HPV Negative Control

REDx HPV Positive Controls are designed to meet the full needs of the modern clinical molecular diagnostic industry.

Advantages:

- Contain natural HPV types and human cells.
- 100% clinical sample equivalence.
- Prepared in HOLOGIC[®] ThinPrep[®] PreservCyt[®] STM.
- Inactivated to meet Clinical Lab Biosafety requirements.
- Designed to meet the instrument/device Sample Adequacy requirements.
- Industry leading panel representing a significant portion of hrHPV types.
- Dedicated HPV Negative Control

Performance:

- REDx HPV Positive Controls are compatible with Roche[™] COBAS[®], Cepheid[®], GeneXpert[®], HOLOGIC[®], Aptima[®], BD Viper[®] and Seegene platforms.
- Suitable for verification/validation on HPV DNA and RNA (TMA) testing systems.

Use:

- REDx Positive Controls - are designed for In Vitro Diagnostic (IVD) use.





Overview:

- Non-enveloped DNA virus with genome size of approximately 8 kb. HPV viral genes labelled as E1-7 and L1/2 ORF.
- hr (high-risk) HPV types 16, 18 (70%) and 45 (5%) are responsible for 75% of all HPV related cancers.

Classification:

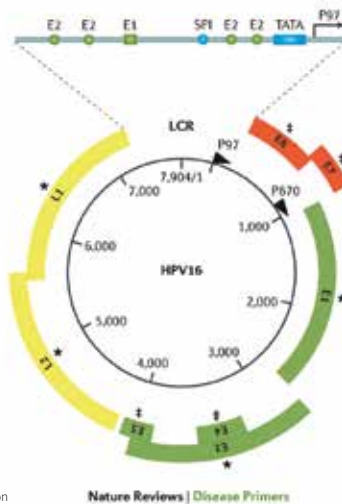
- Alpha group of HPV shares 60 - 70% of L1 ORF. HPV types within the group have less than 10% difference in L1 ORF.
- The IARC (International Agency for Research on Cancer) has divided the Alpha HPV types as IARC Group 1, 2A and 2B based on their carcinogenicity. IARC Groups 1 / 2A are responsible for 96% of the HPV related cancers.

References:

1. Clin Microbial Rev. 2016 Apr; 29(2):291-319. doi: 10.1128/CMR.00013-15. Human Papillomavirus Laboratory Testing: the Changing Paradigm. Burd EM



Schiffman, M. et al. (2016) Carcinogenic human papillomavirus infection *Nat. rev. Dis. Primers* doi:10.1038/nrdp.2016.86

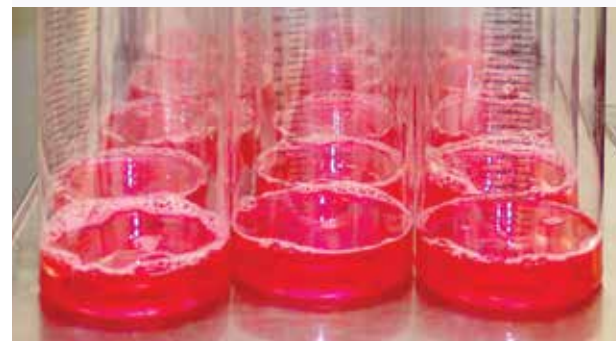


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HPV type Catalogue

HPV 16 Positive	RED-62-16
HPV 18 Positive	RED-62-18
HPV 45 Positive	RED-62-45
HPV Negative	RED-99-M1



Alpha-Papillomavirus	Alpha-5	26	51	69	82					
	Alpha-6	30	53	56	66					
	Alpha-7	18	39	45	59	68	70	85	97	MICROBIX
	Alpha-9	16	31	33	35	52	58	67	RED	controls
	Alpha-11	34	73	177						

LEGEND:

- IARC group 2A, possibly carcinogenic
- IARC group 1, carcinogenic
- IARC group 2B, probably carcinogenic



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