

AT THE CORE of QUALITY



REDTM controls



Quality Assessment Products (QAPs)

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

REDxTM 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

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

USE

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



OVERVIEW

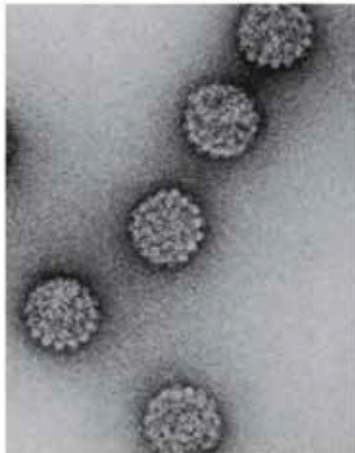
- Non-enveloped DNA virus with genome size of approximately 8 kb. HPV viral genes labelled as E1-7 and L1/2 ORF.
- hr (high-risk) HPV types 16, 18 (70%) and 45 (5%) are responsible for 75% of all HPV related cancers.

CLASSIFICATION

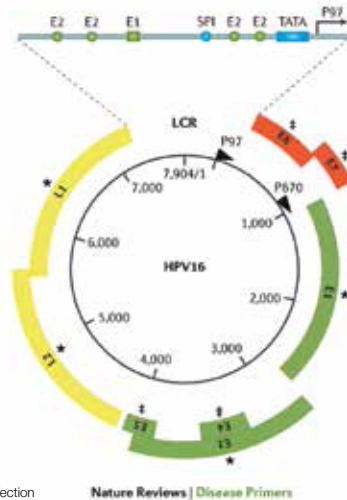
- Alpha group of HPV shares 60 - 70% of L1 ORF. HPV types within the group have less than 10% difference in L1 ORF.
- The IARC (International Agency for Research on Cancer) has divided the Alpha HPV types as IARC Group 1, 2A and 2B based on their carcinogenicity. IARC Groups 1 / 2A are responsible for 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.2016.66



Nature Reviews | Disease Primers

Alpha-Papillomavirus

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

MICROBIX
RED controls

LEGEND

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



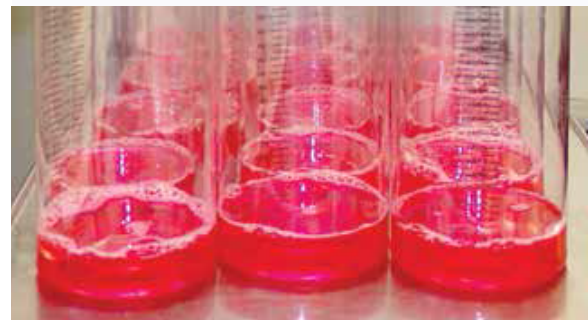
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Visit us on the web at AlphaTecSystems.com

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| Product Name | Product # |
|-------------------------------------|-----------|
| REDx™ Controls HPV Type 16 Positive | RED-62-16 |
| REDx™ Controls HPV Type 18 Positive | RED-62-18 |
| REDx™ Controls HPV Type 45 Positive | RED-62-45 |
| REDx™ Controls MDx Negative | RED-99-M1 |



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CE IVD CONTROL



REDx™ is a trademark of Microbix.

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