

# Reliable results – HPV quality assessment products

Cross-assay human papillomavirus Positive/Negative Controls





### Commutable:

In clinically relevant matrix



#### Flexible:

Cross-assay and cross-instrument compatible



#### **Practical:**

IVD quality control and controls for validation and verification



# Information on HPV QAPs from Microbix

## Your advantages



#### **Extensive portfolio**

Controls for most common high-risk HPV-Types



#### **Robust**

Stable for 1.5 years, Storage at 2 - 8 °C



#### Workflow

Controls are included into the overall workflow like a patient sample



#### Comparability

Contain natural HPV types and human cells



#### Specifics:

- Ensure day-to-day consistency of an analytical process
- Assists in determining reliability of the diagnostic test outcomes



#### Specifics:

- Verification of device specifications in internal processes
- Ensure customer needs include acceptance criteria for external users (validation)

## Human Papillomaviruses

Human papillomavirus (HPV) infections can affect various human tissues, especially skin and mucous membranes<sup>(1)</sup>. Of particular interest are infections in the genital tract<sup>(2)</sup>. Based on their potential to promote the development of cancer, these genital HPV types are divided into "high-risk" (hr) and "low-risk" HPV types<sup>(1)</sup>. The hr HPV types 16 and 18 are responsible for 71% and HPV 45 for 6% of all HPV-associated cervical cancers<sup>(3)</sup>.

Product	Art. No.	
	PROCEEDx™	REDx™controls
HPV 16 Positive	VP-62-16	RED-62-16
HPV 18 Positive	VP-62-18	RED-62-18
HPV 31 Positive	VP-62-31	
HPV 33 Positive	VP-62-33	
HPV 39 Positive	VP-62-39	
HPV 45 Positive	VP-62-45	RED-62-45
HPV 67 Positive (hr Negative)	VP-62-67	
STI Negative Control		RED-99-M1

- Inactivated whole genome samples containing all common assay targets (E1, E6, E7, L1), episomal and integrated viral DNA, viral RNA and proteins.
- 100% clinical samples equivalence.
- Prepared in HOLOGIC® ThinPrep® PreservCyt® transport medium.
- Inactivated to meet Clinical Lab Biosafety requirements.
- Tested with HPV assays from HOLOGIC®, Seegene Inc, Cepheid®, Roche and others.
- 1. von Knebel Doeberitz M. New markers for cervical dysplasia to visualise the genomic chaos created by aberrant oncogenic papillomavirus infections. Eur J Cancer. 2002;38(17):2229-42.
- 2. Woodman CB, Collins SI, Young LS. The natural history of cervical HPV infection: unresolved issues. Nat Rev Cancer. 2007;7(1):11-22.
- 3. de Sanjose S, Quint WG, Alemany L, Geraets DT, Klaustermeier JE, Lloveras B, et al. Human papillomavirus genotype attribution in invasive cervical cancer: a retrospective cross-sectional worldwide study. Lancet Oncol. 2010;11(11):1048-56.