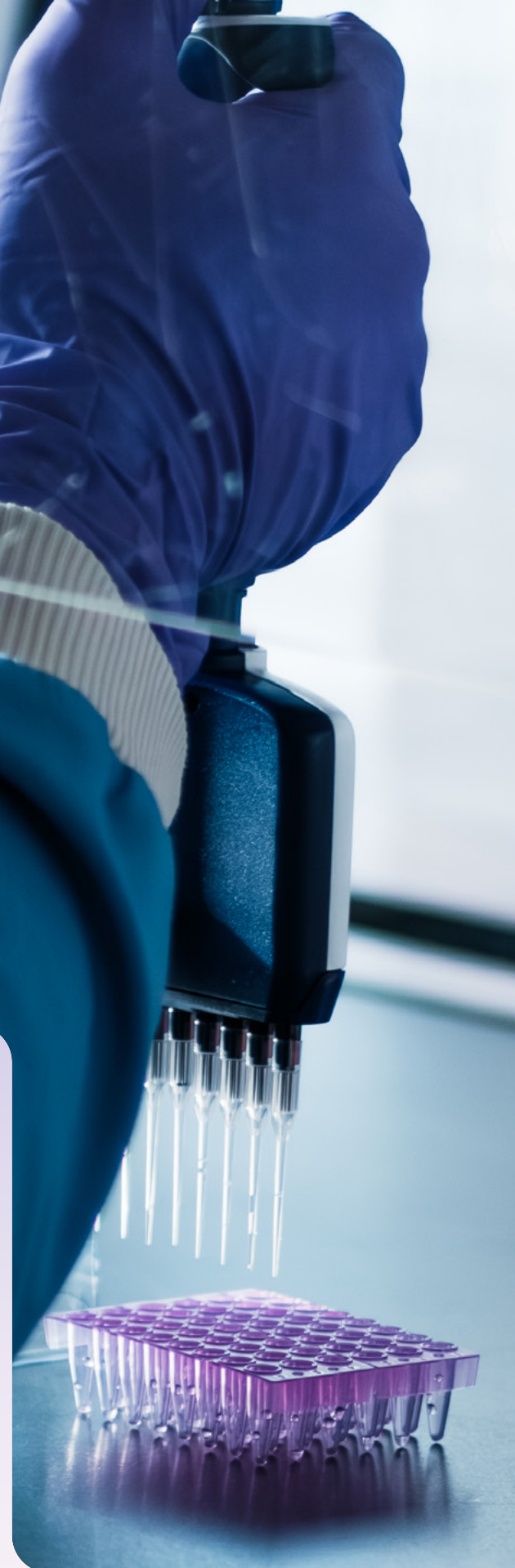


Highly Sensitive HPV Detection and Genotyping

HPV SPF10 PCR-Detection/
Typing Kits



Human Papillomavirus

(HPV) Stands as a Well-Established Risk Factor for Cervical Cancer, as well as Head-and-Neck Cancer.

Research into HPV vaccines requires meticulous genetic analysis to pinpoint various (high risk) HPV genotypes.

Similarly, epidemiological studies demand comprehensive genetic scrutiny of prevalent HPV strains. Detailed analyses of the prevalent HPV strains is there with essential in a variety of clinical conditions such as anogenital and head-and-neck cancers (including carcinoma in oral cavity and larynx) and anal, penile and vulvar squamous cell carcinoma.

Since 2017, direct HPV testing is recommended in the revised WHO/IARC classification to assess a correct diagnosis of the Head and Neck Squamous Cell Carcinoma (HNSCC).

Cerba Research offers specialized HPV diagnostic testing kits tailored to detect and identify HPV genotypes in vaccine and epidemiology studies. Our assay excels in analyzing HPV in formalin-fixed-paraffin-embedded (FFPE) tissues, facilitating correlation between histological findings and specific HPV genotypes.



HPV SPF10

Detection and Typing

Our test kit portfolio includes:

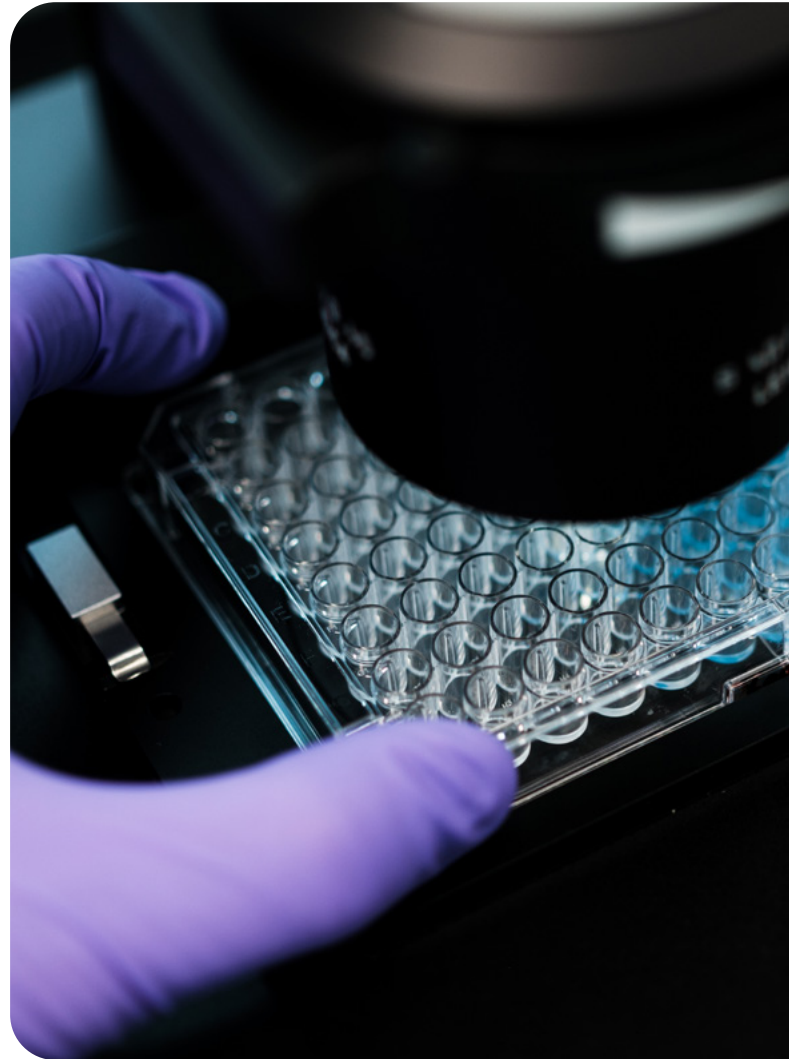
DNA ELISA Kit HPV SPF10
(CE-IVD certified)

RHA Kit HPV SPF10-LiPA25
(CE-IVD certified)

These tests boast high sensitivity and specificity, making them ideal for HPV-vaccine and HPV-epidemiological studies. The short PCR fragments (65 base pairs) generated with the HPV SPF10 PCR are optimal for studies using FFPE tissue specimens.

The DNA ELISA kit HPV SPF10, allows an easy, reliable and highly sensitive detection of mucosal HPV genotypes, including at least HPV 3-8, 11, 13-14, 16, 18, 20, 26, 27, 30-35, 37, 39, 40, 42, 43-45, 51-56, 58, 59, 61, 62, 64-76, 82-84, 87 and 89-91.

The RHA Kit HPV SPF10-LiPA25, allows an easy and reliable identification of HPV genotypes using the same HPV SPF10 PCR products.



DNA ELISA Kit HPV SPF10

Intended use

Sensitive HPV detection in cervical scrapes, biopsies and formalin fixed paraffin embedded (FFPE) samples of e.g. cervical, anogenital, head and neck, oral, vulvar and penile origin.

Principles of the procedure

The DNA ELISA kit HPV SPF10 employs an initial SPF10 PCR followed by a hybridization detection assay (DNA-Elisa or DEIA). This highly sensitive test detects more than 50 different HPV genotypes and is designed to be used in conjunction with the RHA kit HPV SPF10LiPA25 for HPV genotyping of PCR/DEIA positive samples.

RHA Kit HPV SPF10-LiPA25

Intended use

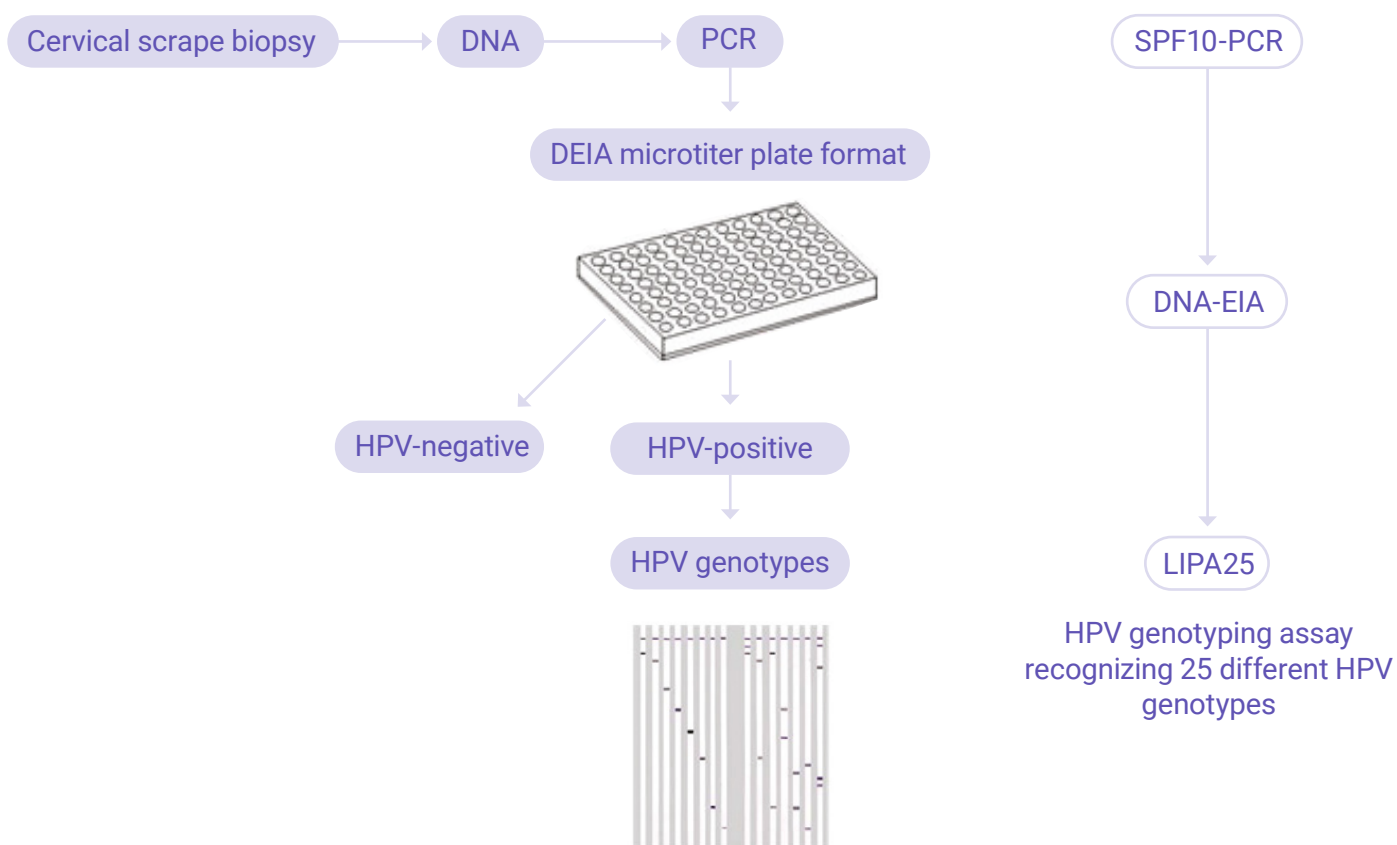
Sensitive qualitative identification of Human Papillomavirus (HPV) genotypes.

The RHA kit HPV SPF10-LiPA25 is an in vitro reverse hybridization assay for the qualitative identification of DNA from Human Papillomavirus (HPV) genotypes 6, 11, 16, 18, 31, 33-35, 39, 40, 42-45, 51-54, 56, 58, 59, 66, 68/73, 70 and 74.

Principles of the procedure

The RHA Kit HPV SPF10-LiPA25, is based on the reverse hybridization principle. With this easy to use technique, specific positive HPV types are visible as colored lines at specified positions on the membrane strips.

Outline of the HPV SPF10 Test System



Unique features of the HPV SPF10 kits

- Trusted technology with a long track record of supporting epidemiological and vaccine studies.
- CE-IVD certified kits.
- Unique technology for sensitive detection and genotyping of HPV in FFPE samples.

Contact information

For information and ordering please contact:
xelleratepsd@cerbaresearch.com

Ordering information

REF: K-27-4 DNA ELISA KIT HPV SPF10,
version 1, 384 tests.

REF: S-1071 RHA Kit HPV SPF10-LiPA25, version 1,
50 tests.

REF: S-1026 RHA Kit HPV SPF10-LiPA25, version 1,
500 tests.



References

References – HPV SPF10 tests, development and validation

1. Kleter B et al. Novel short-fragment PCR assay for highly sensitive broad-spectrum detection of anogenital human papillomaviruses. *Am J Pathol.*, 153, 1731-1739 (1998).
2. Kleter B et al. Development and Clinical Evaluation of a Highly Sensitive PCR-Reverse Hybridization Line Probe Assay for Detection and Identification of Anogenital Human Papillomavirus. *J Clin Microbiol.*, 37, 2508-2517 (1999).

References – HPV SPF10 and vaccine studies

3. Harper DM et al. for the GlaxoSmithKline HPV Vaccine Study Group. Efficacy of a bivalent L1 virus-like particle vaccine in prevention of infection with human papillomavirus types 16 and 18 in young women: a randomised controlled trial. *The Lancet*, 364, 1757–1765 (2004).
4. Harper DM et al. for the GlaxoSmithKline HPV Vaccine Study Group. Sustained efficacy up to 4.5 years of a bivalent virus-like particle vaccine against human papillomavirus types 16 and 18: follow-up from a randomized control trial. *The Lancet*, 367, 1247-55 (2006).
5. Van Doorn LJ et al. Highly effective detection of human papillomavirus 16 and 18 DNA by a testing algorithm combining broad-spectrum and type-specific PCR. *J Clin Microbiol.*, 44, 3292-8. (2006).
6. The GlaxoSmithKline Vaccine HPV-007 Study Group, Sustained efficacy and immunogenicity of the human papillomavirus (HPV)-16/18 AS04-adjuvanted vaccine: analysis of a randomised placebo-controlled trial up to 6.4 years. *The Lancet*, 374, 1975-1985 (2009).
7. Qiao YL et al. Efficacy, Safety and Immunogenicity of an Escherichia coli – Produced Bivalent Human Papillomavirus Vaccine: An Interim Analysis of a Randomized Clinical Trial. *JNCI*, 112-2, 145-153 (2020).
8. Wei LH et al. Age distribution of human papillomavirus infection and neutralizing antibodies in healthy Chinese women aged 18-45 years enrolled in a clinical trial. *Clin Microbiol Infect.* 2020 Aug;26(8):1069-1075.
9. Hu SY et al. Performance of Cervical Screening a Decade Following HPV Vaccination: The Costa Rica Vaccine Trial. *JNCI* (2022) 114(9):djac107.
10. Zhao FH et al. Efficacy, safety, and immunogenicity of an Escherichia coli-produced Human Papillomavirus (16 and 18) L1 virus-like-particle vaccine: end-of-study analysis of a phase 3, double-blind, randomised, controlled trial. *Lancet Infect Dis.* 2022 Dec;22(12):1756-1768. doi: 10.1016/S1473-3099(22)00435-2. Epub 2022 Aug 26.
11. Tsang SH et al. HPV16 infection decreases vaccine-induced HPV16 antibody avidity: the CVT trial. *Vaccines* (2022)7:40.
12. Hoes J et al. High vaccine effectiveness persists for ten years after HPV16/18 vaccination among young Dutch women. *Vaccine* 41 (2023), 285-289.

References – HPV SPF10 testing, association with diseases, epidemiology

13. Quint WGV et al. Comparative analysis of human papillomavirus infections in cervical scrapes and biopsy specimens by general SPF10 PCR and HPV genotyping. *J Pathol.*, 194, 51–58 (2001). (DOI: 10.1002 /path.855).
14. Quint WGV et al. Comparative analysis of human papillomavirus infections in cervical scrapes and biopsy specimens by general SPF10 PCR and HPV genotyping. *J Pathol* 2001; 194: 51–58. (DOI: 10.1002 /path.855).
15. Schiffman M et al. Human papillomavirus and cervical cancer. *The Lancet*, 370, 890–907 (2007).
16. Chen W et al. Human papillomavirus type-distribution in cervical cancer in China: the importance of HPV 16 and 18. *Cancer Causes Control.* 2009 Nov;2009:1705-13.
17. De Sanjose S et al. on behalf of the Retrospective International Survey and HPV Time Trends Study Group. Human papillomavirus genotype attribution in invasive cervical cancer: a retrospective cross-sectional worldwide study. *Lancet Oncology* 2010; 11: 1048-1056.
18. Cornall AM et al. Anal and perianal squamous carcinomas and high-grade intraepithelial lesions exclusively associated with low-risk HPV genotypes 6 and 11. *International Journal of Cancer*, 133, 2253–2258 (2013).
19. Skinner SR et al. Progression of HPV infection to detectable cervical lesions nor clearance in adult women: Analysis of the control arm of the VIVIANE study. *Int J Cancer*, 2016 May 15; 138(10): 2428-2438.
20. Molijn A et al. Chinese HPV Typing Group. The complex relationship between human papillomavirus and cervical adenocarcinoma. *Int J Cancer.* 2016 Jan 15; 138(2):409-16.
21. Chen W et al. Chinese HPV typing group. The variable clinicopathological categories and role of human papillomavirus in cervical adenocarcinoma: A hospital based nation-wide multi-center retrospective study across China. *Int J Cancer.* 2016 Dec 15; 139 (12):2687-2697.
22. Chen W et al. The Variable Characteristics of Human Papillomavirus in Squamous Cell Carcinoma and Adenocarcinoma of Cervix in China. *J Low Genit Tract Dis.* 2018 Oct;22(4):355-361.
23. Voltaggio L et al. A novel group of HPV-related adenocarcinomas of the lower anogenital tract (vagina, vulva, and anorectum) in women and men resembling HPV-related endocervical carcinomas. *Modern Path.* (2020) 33:944- 952.
24. Geis Vde et al. Identifying Molecular Changes in Early Cervical Cancer Samples of Patients That Develop Metastasis. *Fonc.* 2021.715077.
25. Yao X et al. Naturally acquired HPV antibodies against subsequent homotypic infection: A large-scale prospective cohort study. *Lancet Reg Health West Pac.* 2021 Jul 16;13:100196.

26. Morais E et al. Oral human papillomavirus (HPV) and associated factors among healthy populations: The design of the PROGRESS (PREvalence of Oral hpv infection, a Global aSSessment) study. *Contemp Clin Trials*, 2022 Apr;115:106630.
27. Morais E et al. The BROADEN study: The design of an observational study to assess the absolute burden of HPV-related head and neck cancer. *Contemp Clin Trials*, 2022 Apr;115:106631.
28. Cosmas NT et al. Prevalence of vaginal HPV infection Among adolescent and early adult girls in Jos, North-Central Nigeria. *BMC Inf Dis* (2022)22:340.
29. Geus V de et al. Identifying Molecular Changes in Early Cervical Cancer Samples of Patients That Developed Metastasis. *Fonc Jan 2022 Vol 11 715077*.
30. Chakravarthy A et al. Integrated analysis of cervical squamous cell carcinoma cohorts from three continents reveals conserved subtypes of prognostic significance. *Nature Communications* (2022)13:5818.
40. Giuliano AR et al. Oral Human Papillomavirus and Genotyping Among Healthy Adult Population in the US. *JAMA Otolaryngol Head Neck Surg*. 2023 Sep; 149(9);783-795.
31. Pouwer AW et al. Prognostic value of HPV-PCR, p16 and p53 immunohistochemical status on local recurrence rate and survival in patients with vulvar squamous cell carcinoma. *Virchos Archiv* 08 Nov 2023.
32. Zhang C et al. Assessment of the relationships between invasive endocervical adenocarcinoma and human papillomavirus infection and distribution characteristics in China: According to the new WHO classification criteria in 2020. *Cancer Epidemiol*. 2023 Oct;86:102442.
33. Kamp Damgaard R et al. High prevalence of HPV16 and high-grade cytology in women undergoing active surveillance for cervical intraepithelial neoplasia grade 2. *AOGS* 2023;102:1227-1235.
34. Su Y et al. Pattern of multiple human papillomavirus infection and type competition: An analysis in healthy Chinese women aged 18-45 years. *Hum Vaccin Immunother*. 2024 Dec 31;20(1):2334474.

References – HPV SPF10 test algorithm compared to other tests

35. Van Doorn LJ et al. Genotyping of human papillomavirus in liquid cytology cervical specimens by the PGMV line blot assay and the SPF(10) line probe assay. *J Clin Microbiol.*, 40, 979-83 (2002).
36. Van Hamond D et al. Evaluation of the SPF10-INNO LiPA Human Papillomavirus test and the Roche Linear Array HPV Genotyping test. 2006 *J.Clin. Microbiol.* 44(9), 3122-3129.
37. Safaeian M et al. Comparison of the SPF10-LiPA system to the Hybrid Capture 2 Assay for detection of carcinogenic human papillomavirus genotypes among 5,683 young women in Guanacaste, Costa Rica. *J Clin Microbiol.*, 45, 1447-54 (2007).
38. Hesselink AT et al. Comparison of GP5+6+-PCR and SPF10-Line Blot Assays for detection of high-risk human papillomavirus in samples from women with normal cytology results who develop grade 3 cervical intraepithelial neoplasia. *J Clin Microbiol.*, 46(10), 3215-3221 (2008).
39. Geraets DT et al. The original SPF10 LiPA25 algorithm is more sensitive and suitable for epidemiological HPV research than the SPF10 INNO-LiPA Extra. *J o Vir Meth*, Vol215-216, April 2015, 22-29.
40. Eer van K et al. Evidence for Missing Positive Results for Human Papilloma Virus 45 (HPV-45) and HPV-59 with the SPF10-DEIA-LiPA25 (Version 1) Platform Compared to Type-Specific Real-Time Quantitative PCR Assay and Impact on Vaccine Effectiveness Estimates. *J Clin Microbiol*. 2020 Nov; 58(11); e01626-20.
41. Guo M et al., Detection accuracy of the Cobas HPV assay for high-risk HPV in head and neck FNA biopsy specimens. *Cancer Cytopathology* July 2022 523-530.



Interested in How We Can Shape Your **Laboratory Strategy** for Better Outcomes?

Get in touch today and see how Cerba Research
will support your next program.

cerbaresearch.com

