The confidence real-time HPV test

Technology

The CONFIDENCE™ HPV test (NEUMANN Diagnostics Ltd. CE) is a qualitative in vitro test for the detection of Human Papillomavirus (HPV) in patient specimens. It is a TaqMan-based L1 region specific multiplex real-time PCR assay for viral DNA detection (patent pending). It detects HPV16 and HPV18 separately and other high risk types (HPV31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68) in group with quality controlled high-throughput and highly automated protocols running on Tecan EVO® liquid handling platform using contamination safe workflow. After the 96-channel automated PCR setup, 5-plex quantitative real-time PCR is performed on the QuantStudio ™ 6 Flex platform in 384-well plate format. The whole procedure is standardized, and the contamination risk is monitored with a DNA preparation no template control (NTC) and PCR NTC where both results in the PCR plate should be negative for a valid PCR plate run. The quality of the sample DNA is guaranteed by the amplification of the genomic target control and internal control (artificial DNA added to the sample during DNA preparation). The PCR procedures are monitored by PCR positive control.

Validated sample types:

1. Cervical cells collected by the Cervex Brush® Combi (Rovers®) in PreservCyt®Solution (ThinPrep®, Hologic Corp)
2. Self-collected vaginal sample taken with the Qvintip® device (Aprovix).

Intended uses:

- First-line primary screening test to identify women at increased risk for the development of cervical cancer or presence of high-grade disease.
- To assess the presence or absence of hrHPV types
- To assess the presence or absence of hrHPV genotypes 16 and 18.

The clinical performance of the CONFIDENCE™ HPV test was assessed in the prospective TRACE (Triage and Risk Assessment of Cervical Precancer by Epigenetic Biomarker) trial at 4 clinical sites including outpatient and colposcopy clinics in Hungary.

The Roche cobas HPV test (Roche Molecular System, CE) was used as a clinically validated reference test with 3,270 ThinPrep® cervical samples of women above 25 years of age. The study endpoint for the analysis was histologically confirmed high-grade CIN, i.e., CIN2 or worse (CIN2+) and CIN3 or worse (CIN3+). The output and comparison of different HPV tests were evaluated by performance and bias adjusted kappa value and positive agreement. The results showed 70.4% agreement in the hrHPV positive cases, which is a very good agreement considering the recent findings in this field [1]. The performance and bias adjusted kappa value [2] of the results was 0.84 (95% CI: 0.82-0.86).

The CONFIDENCE™ HPV test for the Qvintip® self-collected vaginal sample was clinically validated by comparing the Confidence HPV test results of the clinician collected ThinPrep® cervical sample with the Qvintip® self-collected vaginal sample. In the TRACE trial 335 women were asked to self-collect a vaginal sample by using the Qvintip® self-sampling kit before the clinician obtained their cervical specimen in ThinPrep®. The results of the two sample types showed similar agreement in the hrHPV positive cases compared to the recent findings in a comparison study of the Qvintip® device [3].

The Confidence HPV test is fully integrated into GenoID's laboratory information system. The testing system is able to process up to 600 samples per day.

References

1. **Rebolj, M., et al.,** Disagreement between human papillomavirus assays: an unexpected challenge for the choice of an assay in primary cervical screening. **PLoS One, 2014. 9(1): p. e86835.**
2. **Xue, X., et al.,** A new method to address verification bias in studies of clinical screening tests: cervical cancer screening assays as an example. **J Clin Epidemiol, 2014. 67(3): p. 343-53.**
3. **Jentschke, M., et al.,** Comparative evaluation of two vaginal self-sampling devices for the detection of human papillomavirus infections. **J Clin Virol, 2015.**

SYNLAB Hungary Kft.
SYNLAB Budapest Diagnostic Center
GenoID Molecular Diagnostic Laboratory
Tel.: 00 36 1 465 0124 Fax: 00 36 1 465 0127
genoid@synlab.com • www.genoid.net • www.synlab.hu