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Evaluation of the NanoCHIP HPV screening panel, a new molecular-based test for simultaneous detection of high- and low-risk human papillomavirus (HPV) infections utilizing micro-array technology, compared to two other tests

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Background: Persistent human papillomavirus (HPV), a highly prevalent sexually transmitted infection, is associated with the development of cervical intraepithelial lesions and invasive carcinoma. HPV types are classified into low- and high-risk groups according to their oncogenic potential, when High-risk types 16 and 18 together account for about 70% of all cervical cancers. Therefore, current immunization against these HPV strains does not exempt women from further cervical screening. The present gold standard, the Pap smear test, has limited sensitivity for detecting abnormal cervical epithelial cells in the early course of their development. Savyon Diagnostics has recently developed a novel molecular-based screening test for simultaneous detection of the most abundant high (HR) and low risk (LR) HPV infections utilizing its proprietary NanoCHIP® molecular electronic microarray system. The aim of this work is to evaluate the clinical performance of the NanoCHIP® HPV test versus a test routinely used in a regional medical center in north of Israel.

Material/methods: The clinical evaluation was conducted in Carmel Medical Center, Haifa, Israel. Overall the study included 477 samples from symptomatic patients. Specimens in ThinPrep liquid-based cytology (LBC) vials were tested by HPV Direct Flow CHIP (Master Diagnóstica, Spain) as part of the clinical routine in the lab, and by the NanoCHIP® HPV test. Discrepant analysis was carried out using PapilloCheck® HPV-Screening test (Greiner Bio-One), performed at LEM Laboratory, Rehovot, Israel.

Results: The current evaluation refers to the results of HPV types 18, 16, a pool of other eighteen high-risk types, and 6 and 11 pooled low-risk types. The positive percent agreement of the NanoCHIP® test versus the Direct Flow CHIP test was 95%, 94%, 92% and 75% for the aforementioned evaluation targets, respectively. However discrepant analysis versus the PapilloCheck® test revealed 100%, 100%, 96% and 95%, respectively. In terms of negative percent agreement, the three tests were in full accordance. The Negative Predictive Values of the NanoCHIP® test were above 95% for all the evaluated targets.

Conclusions: The clinical performance data of the NanoCHIP® test versus the PapilloCheck® test performed in a typical clinical laboratory at community settings was previously reported. In the current study, performed in a regional medical center, we extended the analysis to include another reference genotyping assay, HPV Direct Flow CHIP. The currently obtained results, based on the comparison with the other two tests, however without additional clinical data, further support the suitability and usefulness of the newly developed NanoCHIP® HPV test to be used in the clinical laboratory, especially when medium-high throughput processing is needed. It should be noted that the high NPV values obtained for all the evaluated targets reinforces the NanoCHIP® HPV test as a suitable assay for identifying high- or low-risk types in patients with suspicious cytology findings.