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Molecular diagnosis of sexually-transmitted pathogens

NOVEL NANOCHIP® XL-BASED MOLECULAR TESTS FOR SCREENING AND GENOTYPING THE MOST ABUNDANT HUMAN PAPILLOMAVIRUS (HPV) HIGH- AND LOW-RISK STRAINS

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Objectives. Persistent human papillomavirus (HPV), a highly prevalent sexuallytransmitted infection, is necessary for the development of cervicalintraepithelial lesions and invasive carcinoma. Cervical cancer is the thirdmost common cancer among women and the second female cancer-related cause ofdeath worldwide. HPV types are classified into low- and high-risk groupsaccording to their potential for oncogenesis, when the High-risk types 16 and18 together account for about 70% of all cervical cancers. Therefore, current immunization against these carcinogenetic HPV strains doesnot exempt women from further regular cervical screening. The present goldstandard the Pap staining has limited sensitivity for detecting abnormalcervical epithelial cells in the early course of their development. SavyonDiagnostics is engaged with development of the concept of two separate andconsecutive molecular-based tests, i.e. screening and genotyping of HPV high-and low-risk strains on our proprietary NanoCHIP®XL molecularelectronic microarray system. The reagents used in the tests were developed byMaster Diagnóstica (Spain) as part of collaborative efforts in the project. Theaim of this work is to demonstrate the usefulness of the newly developed tests inproviding a comprehensive solution to the need for efficient screening, earlydetection and HPV genotyping.

Methods. The first HPVkit allows full genotyping of the most prevalent HPV types 16 and 18 andscreening of 16 other high risk HPV types together with the most abundant lowrisk types 6 and 11. The second HPV kit allows specific detection of 18high-risk types of HPV and the two low-risk HPV types 6 and 11. Both tests werecompared to the microarray test Papillocheck (Greiner, Germany) and to HPVDirect Flow CHIP (Master Diagnóstica, Spain), utilizing a cohort ofcharacterized liquid-based cytology (LBC) specimens and DNA purified fromclinical specimens.

Results. The results ofthe screening as well as the genotyping tests were in accordance with bothmolecular-based tests that were used for the evaluation. The accordance isdemonstrated in the purified DNA as well as in LBC specimens. For screeningpurpose the system has proven to efficiently process 96 samples within 8 hourswith minimal hands-on time and eliminating the need to extract the DNA from thespecimens.

Conclusions. The newlydeveloped NanoCHIP®XL based tests constitute a concept in whichefficient screening is followed by identifying the etiological strains on thesame platform. The sensitivity of the system is expected to enable earlydetection of pre-cancerous cervical lesions, which is currently an apparentlimitation of the Pap smear-based diagnosis. The effective screening ispredicted to provide a better negative predictive value, thus allowing for longerscreening intervals.