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CER818: A Highly Specific and Sensitive HPV L1 High-Risk Serological Lateral Flow Rapid Test for Early Detection of Cervical Cancer and Its Precursor Lesions

Abstract:

Objective: The objective of the study is to validate a new human papillomavirus (HPV) L1 high-risk specific serological assay in a case-control study.

Methods: Serum samples of 138 patients (cervical intraepithelial neoplasia (CIN) 1, 2, and 3 and cervical cancer), 21 vaccinees, and 246 female controls were tested for the presence of HPV L1 high-risk specific antibodies.

Results: HPV L1 high-risk antibodies were detected in 100% of the CIN1 and 2, 86.6% of the CIN3 and 82.4% of the cervical cancer cases, 100% of the vaccinees, and 3.9% of the female controls. Area under the curve (AUC) was calculated with 0.91 for controls versus CIN2+, 0.923 for controls versus CIN1+, and 0.968 for controls versus CIN1/2.

Conclusion: The HPV L1 high-risk specific serological lateral flow rapid test shows promising data in the field of early detection of HPV high-risk induced cervical cancer and its precursor lesions. This easy-to-use, robust, and affordable approach could offer a chance to reach women in low- or middle-income countries (LMICs) that could not be reached by HPV molecular testing-based cervical cancer screening programs.

Keywords: cervical cancer screening; CIN; HPV high risk; L1 serology; LMICs

Biography :

Over 30 years working on HPV with a strong focus on HPV related prognostic and diagnostic test systems, PhD at the University of Mainz in Virology, Immunology, Molecular and Human Genetics.

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