

RESEARCH ARTICLE

Evaluation of Sample Pooling Strategies for Point-of-Care HPV DNA Testing Using the STANDARD™ M10 Platform

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ABSTRACT

Human papillomavirus (HPV) DNA testing is the recommended primary screening method for cervical cancer prevention. However, implementation in resource-limited and geographically challenging settings is constrained by cost, logistics, and time-sensitive screen-and-treat workflow. Sample pooling may improve testing efficiency, but evidence for its feasibility on point-of-care molecular platforms remains limited. We evaluated the analytical performance and feasibility of sample pooling for high-risk HPV (hrHPV) detection using the STANDARD™ M10 HPV point-of-care assay. Archived self-collected vaginal swab samples from a rural cervical cancer screening programme, Programme SUARA, in Sarawak, Malaysia, were used, including four hrHPV-positive samples spanning a range of cycle threshold (Ct) values and seven hrHPV-negative samples. Pooling strategies of 2-in-1, 4-in-1, and 8-in-1 were assessed using a Dorfman two-stage testing approach. Qualitative agreement, sensitivity, Ct shifts, and concordance with individual testing were analyzed. All hrHPV-positive samples were consistently detected across individual and pooled formats, with no false-negative results observed. Sensitivity remained 100% for all pooling strategies, with perfect agreement between pooled and individual testing ($\kappa = 1.0$). Pooling resulted in modest Ct shifts, with mean increases of +1.0, +1.7, and +1.8 cycles for 2-in-1, 4-in-1, and 8-in-1 pools, respectively, without compromising qualitative detection, including samples with low viral loads. Sample pooling for hrHPV DNA testing using the STANDARD™ M10 platform is analytically reliable and operationally feasible. These findings support pooled testing as an evidence-based strategy to improve throughput, reduce resource consumption, and enable same-day screen-and-treat workflows in resource-limited and remote settings.

1 | Introduction

Human papillomavirus (HPV) is the primary cause of cervical cancer and is also implicated in a range of anogenital and oropharyngeal cancers. Currently, more than 200 HPV genotypes have been identified and categorized into high-risk HPV (hrHPV) and low-risk HPV (lrHPV), with HPV16 and HPV18 accounting for approximately 70% of cervical cancer cases

worldwide [1]. Globally, cervical cancer remains a major public health concern, with an estimated 660,000 new cases and 350,000 deaths reported annually [2]. In Malaysia, cervical cancer is the fourth most common cancer among women, contributing approximately 1740 new cases and nearly 1000 deaths each year [3]. Despite the Malaysian government's ongoing national cervical cancer screening programme since