ORIGINAL ARTICLE

The Extended Stability of Cervical Swabs in *care*HPV™ Collection Medium

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ABSTRACT

Introduction: The *care*HPV™ Test is a US FDA approved, CE mark, and WHO prequalified *in vitro* diagnostic test designed to screen for 14 high-risk human papillomavirus (HRHPV) genotypes. The *care*HPV™ Test is one of the commercial HPV test validated to be used in low resource settings, boasting the economy of processing a maximum of 90 samples per batch and a near point-of-care turnaround time of 3 hours. According to the manufacturer, cervical swabs stored in *care*HPV™ Collection Medium are stable for 30 days when stored between 2-8°C. However, we often had difficulty consolidating enough samples for a full batch-test within 30 days, especially when screening women living in the low-density villages in rural Sarawak, Malaysian Borneo. This study aimed to evaluate the stability and repeatability of cervical swabs preserved in *care*HPV™ Collection Medium stored at 4°C exceeding the recommended 30 days using the *care*HPV™ Test. **Methods:** Two groups of confirmed HRHPV-positive and HRHPV-negative cervical swab samples in *care*HPV™ Collection Medium consisting of 4 samples each were maintained at 4°C and tested using the *care*HPV™ Test at Day -38, -123, -131, -223, and -395. **Results:** All cervical swabs in the *care*HPV™ Collection Medium stored at 4°C remained stable for testing and demonstrated 100% repeatability for at least 395 days from the day of collection. **Conclusion:** The *care*HPV™ Test can be successfully performed on cervical swabs preserved in *care*HPV™ Collection Medium, which were stored at 4°C for at least 395 days.

Keywords: *care*HPVTM, Human papillomavirus, Cervical swabs, Extended stability, Cervical cancer

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INTRODUCTION

Cervical cancer is the fourth most frequently diagnosed cancer and the fourth leading cause of cancer death in women worldwide. Cervical cancer is responsible for approximately 570,000 cases and 311,000 deaths annually (1). It was estimated that more than 80% of cervical cancer incidences were from low and medium-income countries (LMICs) that lack organised screening and human papillomavirus (HPV) vaccination programmes(2). There is also a significant disparity between the urban and rural populations(3,4), mainly due to the inequitable access to proper healthcare facilities, poverty, and other cofactors (5).

Human papillomavirus (HPV) is the primary factor in the development of cervical cancer (6). Currently, more than 200 HPV genotypes have been identified with approximately 40 genotypes are sexually transmitted, and 14 of them are oncogenic and referred to as high-risk HPV (HR-HPV) (7). Since oncogenesis from infection to the development of precancerous lesions and cancer is a long and complicated process, this opens up a window of opportunity for prevention, diagnosis, and treatment (8). Early cervical cancer screening combined with HPV vaccination will effectively reduce cervical cancer incidence, as demonstrated in many developed countries (1). Cervical cancer screening using the conventional Papanicolaou (Pap) smear was initiated in Malaysia in 1969, with an annual cost of approximately RM3.55 million (approximately USD800,000) in 2003 (9). Despite the investment, the national Pap smear coverage was only 23% in 2002 and 22% in 2012, far from the recommended coverage of 80% by the World Health Organisation (WHO)(10). Pap smears have a very high specificity of 98-99%, but their sensitivity is generally accepted as 50% (11). A successful Pap smear programme with trained healthcare professionals, including smear takers, cytotechnologists, cytopathologists, colposcopists, and programme managers, could achieve a sensitivity of 75% (11). Nonetheless, a cross-sectional study in 2013 involving 316 eligible women in West Malaysia