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Pap® Technology, a Prospective for Global Cervical Cancer Control

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NTRODUCTION: MarkPap® test is an emerging biomarker-based technology introduced in 1999. The biomarker, visualized as red pigment is exclusively present in abnormal cells e.g., dysplastic (including HPV infected) cells and cancer cells. The red-flagged abnormal cells attract the attention of the screener, thus reducing the probability of their omission even by less trained personnel. Normal squamous epithelial cells are entirely regative. The biomarker brings to the test an advantage for telecytopathology and self-sampling, thus providing an opportunity for mass cervical cancer screening worldwide. The MarkPap test may also be applied for monitoring of the success of immunization with novel HPV vaccines.

MATERIAL AND METHODS: The MarkPap technology consists of MarkPap Test, MarkPap Research Kit, MarkPap Accessories (MarkPap Solution, Control Slides), and MarkPap Auto (automated staining). Second generation products are: MarkPap Self, MarkPap Digital and MarkPap Cell Bank. Three clinical trials included 2,000 patients/specimens (1500 general population, 500 high risk patients) conducted to show the safety and efficacy of MarkPap test in comparison with controls, (www.bioscicon.com)

RESULTS: MarkPap test improved the detection of abnormal specimen for 50% in comparison with Pap smear and for 30% with liquid-based Pap. The false-negative rate was below 5%. Overall sensitivity was improved by 30%, while the specificity was equivalent within 10% range.

CONCLUSION: The MarkPap technology has been found of significance for more accurate, faster and less costly cervical cancer screening that can be applied worldwide for cervical cancer control.

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