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MarkPap(R) Digital, a new prospective for biomarker-based gynecological cytology

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INTRODUCTION: Cervical Acid Phosphatase was introduced as a new biomarker of cervical cell abnormality in 1999 and contemplated as a surrogate end-point for colposcopy in 2003. On MarkPap® slides, the biomarker is visualized as a red deposit on a Papanicolaou modified staining background. In prior clinical trials, we demonstrated that this biomarker, exclusively present in abnormal cervical cells (dysplastic, HPV infected and malignant), enhances their visibility and reduces the chance to be missed.. Based on the optical characteristics of the biomarker, we have explored whether a combination of MarkPap test with image analysis and telecytopathology is possible, and whether it would be of an advantage for mass cervical cancer screening. MATERIAL & METHODS: In this pilot study, we assembled several low cost instruments and software already known as fit-for-use in cell image analysis and telecytopathology, we applied them for microscopic evaluation of MarkPap slides, and we outlined the conditions under which this combination of instruments and software could be used for MarkPap-based cervical cancer screening. The testing material were microscopic slides prepared from cervical specimens in prior clinical trials and catalogued in the BioSciCon Library of Slides. RESULTS: We have found that a multi-modular device composed of (a) image acquisition module (microscope, digital camera, barcode reader and image acquisition software), (b) image and data transferring module (Internet and E-mail connection), (c) image evaluation module (server, processing computer and monitors, image evaluation software) and (d) results reporting module (encrypted instant messaging) is amenable for the intended use after some software modification. We have also identified (e) color image compression software that separates blue and red hues and enables quantitative image analysis. In addition, we tested the system by transporting these image files across the world and collecting information of their quality for utilization in distant cervical cancer screening. The quality of images received at the evaluation site (particularly marker positive cells) allowed proper evaluation to be performed. CONCLUSION: We concluded that our compiled set of instruments and software could be integrated into a new diagnostic medical device (MarkPap Digital) intended for mass cervical cancer screening, and that further work in this direction is warranted. We believe, when developed and approved, this device would be best used in low-resource countries to replace the expensive Pap test infrastructure, while sustaining the high quality screening for cervical cancer. Authors acknowledge the support from Dr. David Hankins, New Hope Pharmaceuticals, Mr. Stephen

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