

Evaluation of CellDetect® for cervical cancer screening in a reference cytology laboratory in India

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Background

CellDetect® is an innovative histochemical assay providing color discrimination between normal, precancerous and cancerous cells alongside morphological examination in cervical smears. The study was designed to evaluate the usability and performance of CellDetect® in comparison with standard Papanicolaou (Pap) stain in the screening of cervical cancer smears in a reference cytology laboratory in India.

Design

Smears from women age ≥18 years screened for cervical cancer were included in this study. Two SurePath® slides were prepared from each sample, one for Pap staining and one for CellDetect® staining. Diagnosis accuracy and turnaround time were assessed for each slide. For the CellDetect® slides, the use of the color feature, the ability to highlight abnormal cells, the convenience of slide interpretation and the efficiency of the screening process were also reported on a scale from 1 to 5 (5 for best).

Results

130 women enrolled to the study at the age range of 27-75 years. The diagnostic results are shown in figure 1. Two cases should be highlighted as one case was diagnosed as LSIL by Pap versus ASCUS by CellDetect®. A second case was diagnosed as Cancer by Pap and HSIL by CellDetect®.

The turnaround time per a CellDetect® slide showed a reduction of 21%. The average turnaround time analysis by diagnosis is shown in figure 2.

CellDetect® color feature received positive feedback by the pathologist, particularly for suspicious cases. The slide analysis was considered simplified and the screening process efficient for both normal and suspicious cases (All scored above average).

Figure 1 – Summary of diagnostic results:

n=130 Age 40±11	Diagnosis by	
	CellDetect®	PAP
Normal	109	109
ASCUS	4	3
ASC-H	5	5
LSIL	0	1
HSIL	10	9
Cancer	2	3

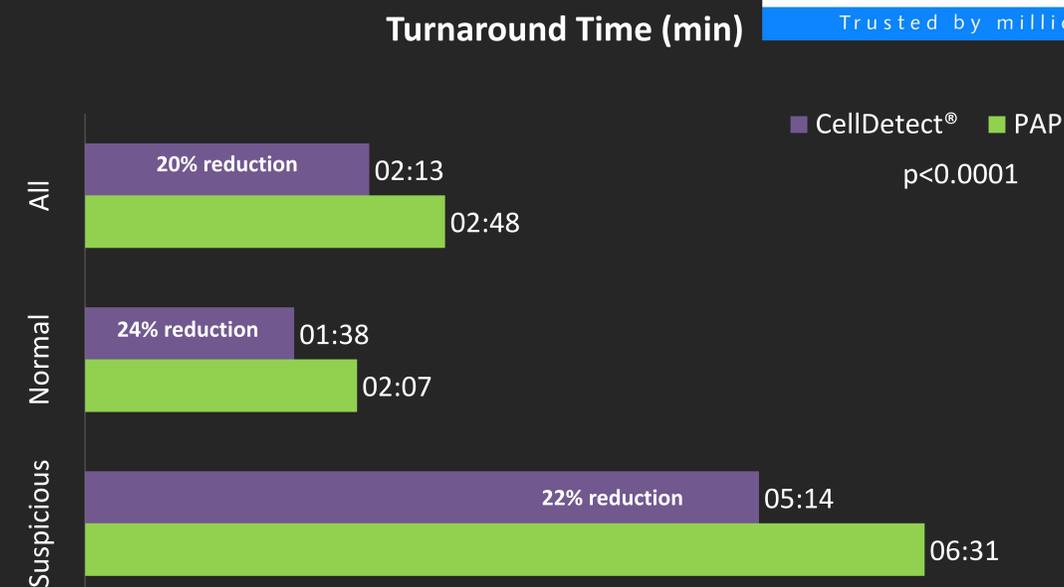
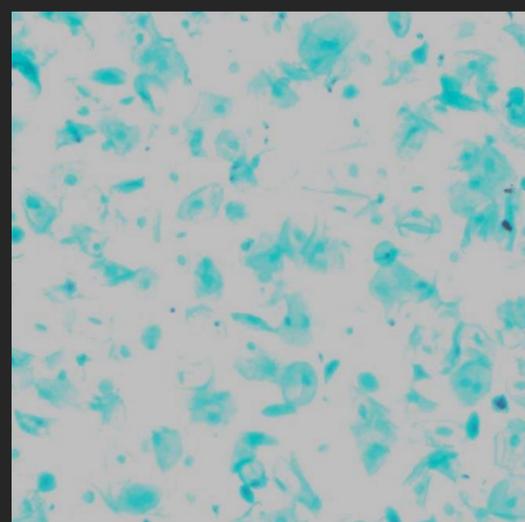
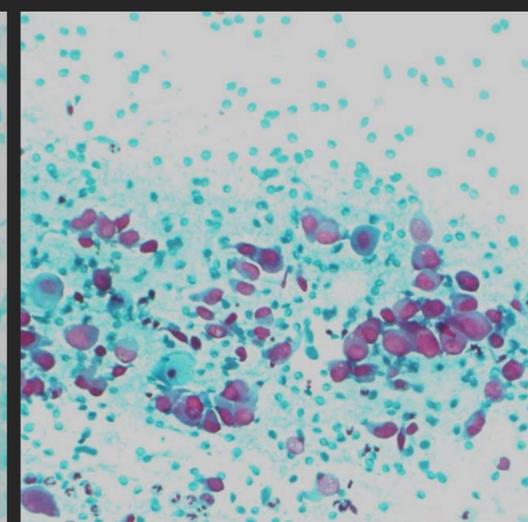


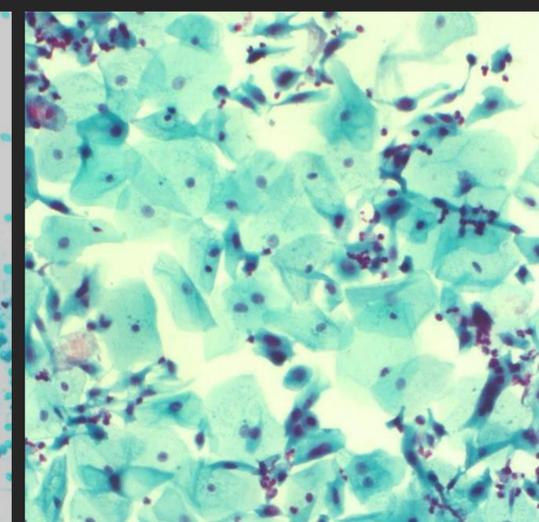
Figure 2: Turnaround diagnosis time was assessed for each case and the two stains methods were compared.



Negative case - the nuclei of normal cells are stained in green



HSIL case - the nuclei of positive cells are stain purple



ASCUS case - the nuclei of atypical cells are stain purple

Conclusions

The study validates the contribution of CellDetect®'s color feature to shorten the time spent to interpret a CellDetect® slide compared to a standard Pap smear, generating a significant increase in overall throughput. CellDetect® acts as useful tool for evaluation of most suspicious cases and simplified for interpretation.

Concluding that CellDetect® stain not only adds color discrimination to morphology but serves as a new dimension in interpretation of suspicious cases.