Routine use of CellDetect® for the identification of urothelial carcinoma in voided urine

Jacob Bejar, MD[1]; Marina Zlotnik[1]; Sarel Halachmi, MD[2]; Kohava Biton[2], Noa Davis, PhD[3]; Yael Glickman, PhD[3]; Ofer Nativ, MD[2]

(1) Department of Pathology, Bnai Zion Medical Center, Haifa, Israel; (2) Department of Urology, Bnai Zion Medical Center, Haifa, Israel; (3) Micromedic Technologies Ltd., Tel Aviv, Israel

Introduction

CellDetect® histochemical stain uses a color feature to highlight neoplastic cells in urine specimens. A blinded study has recently shown the ability of CellDetect® to accurately identify 78% of low grade (LG) bladder cancer tumors in voided urine. The objective of the present study was to confirm this finding in routine clinical settings.
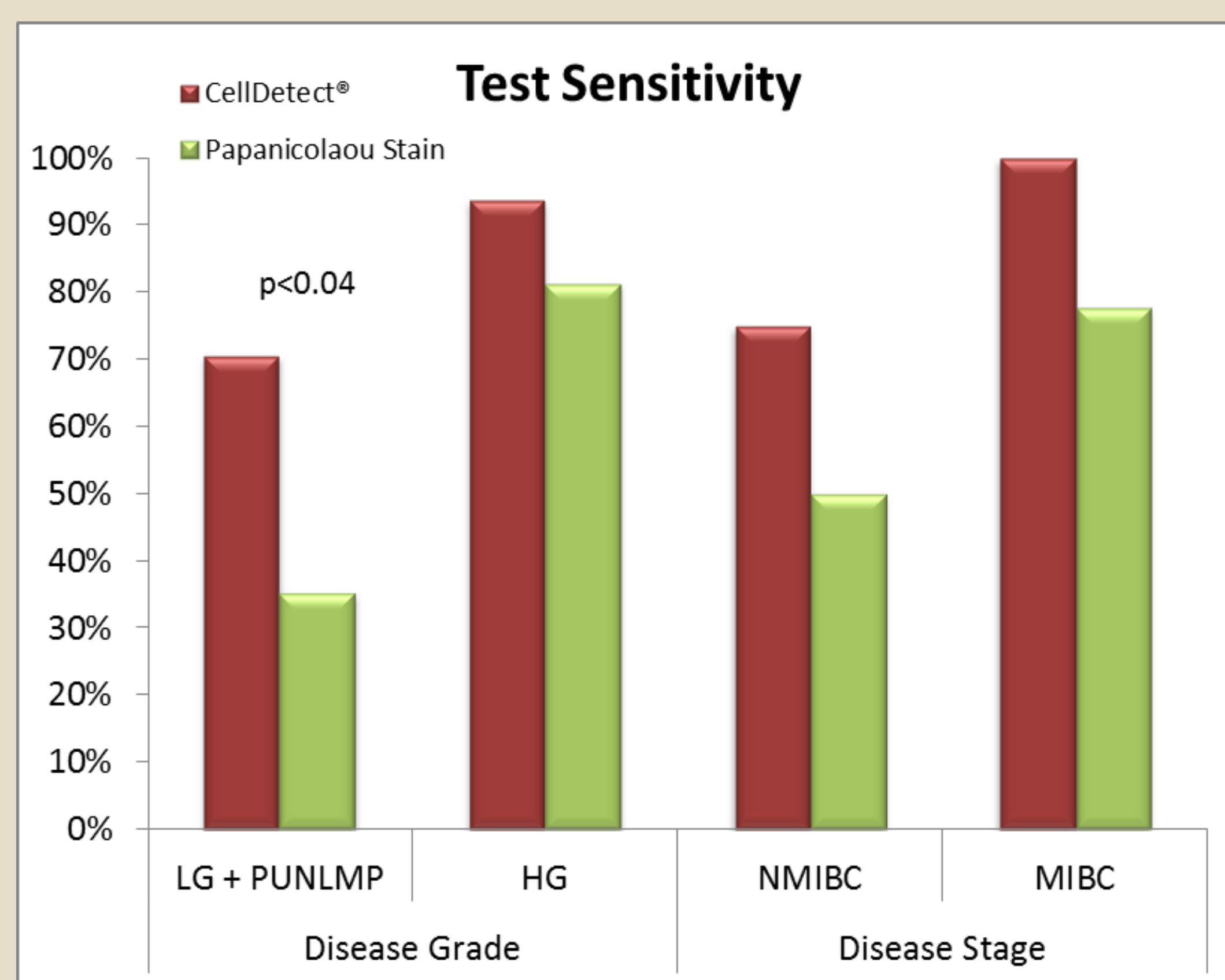
Methods

Patients undergoing cystoscopic examination or TURBT were enrolled in this study. Voided urine samples were processed into two smears. Slides were stained automatically by CellDetect® and Papanicolaou (Pap). A Cytopathologist, blinded to the final diagnosis, first observed the Pap slide and subsequently the CellDetect® slide. The results were then compared to biopsy and/or cystoscopy.
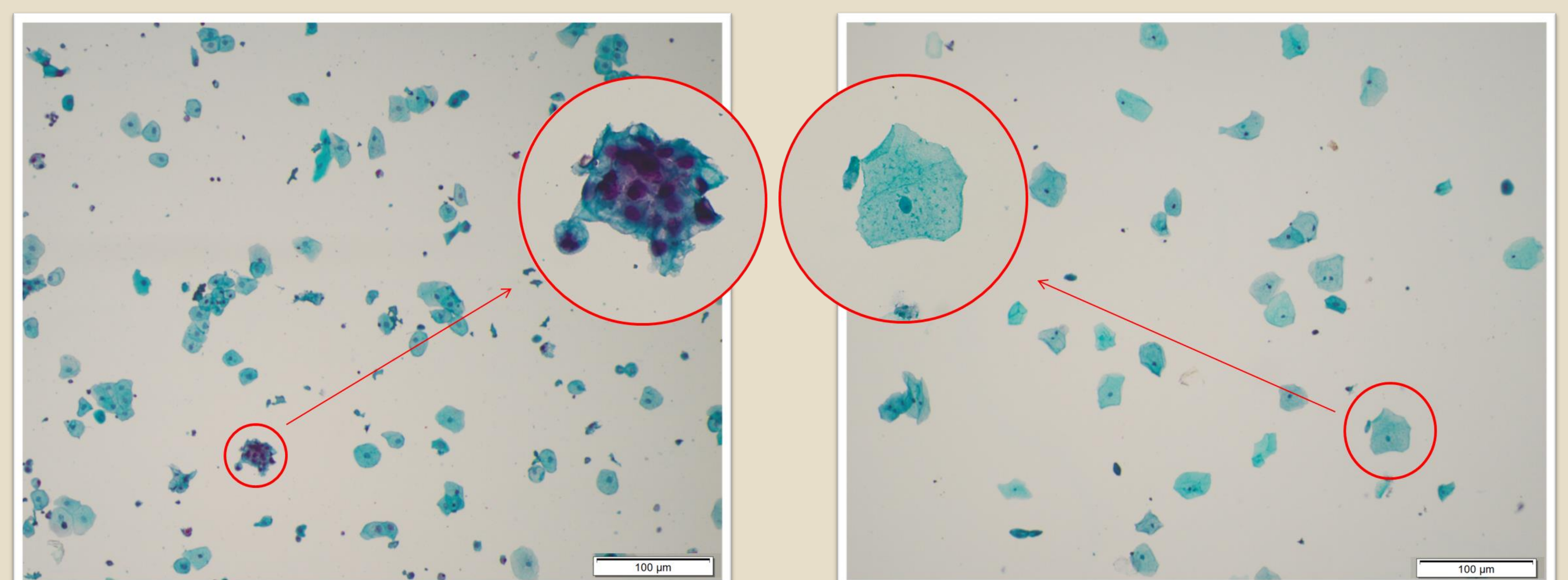
Results

A total of 90 sets of urine smears, including 57 negative and 33 positive cases, were prepared. The overall sensitivity and specificity of CellDetect® were 82% and 86% respectively compared to 58% and 95% for Pap staining. Notably, higher sensitivity of CellDetect® versus Pap was observed for both LG + PUNLMP (n=17, 71% versus 35%, $p < 0.04$) and high grade tumors (n=16, 94% versus 81%). When the patients were grouped by disease stage, higher sensitivity of CellDetect® versus Pap was observed for both NMIBC (n=24, 75% versus 50%) and MIBC (n=9, 100% versus 78%).

	n	CellDetect®	Papanicolaou Stain
Sensitivity	33	82%	58%
Specificity	57	86%	95%

Test Sensitivity

LG-Low Grade
PUNLMP-Papillary Urothelial Neoplasm of Low Malignant Potential
HG-High Grade
NMIBC-Non Muscle Invasive Bladder Cancer
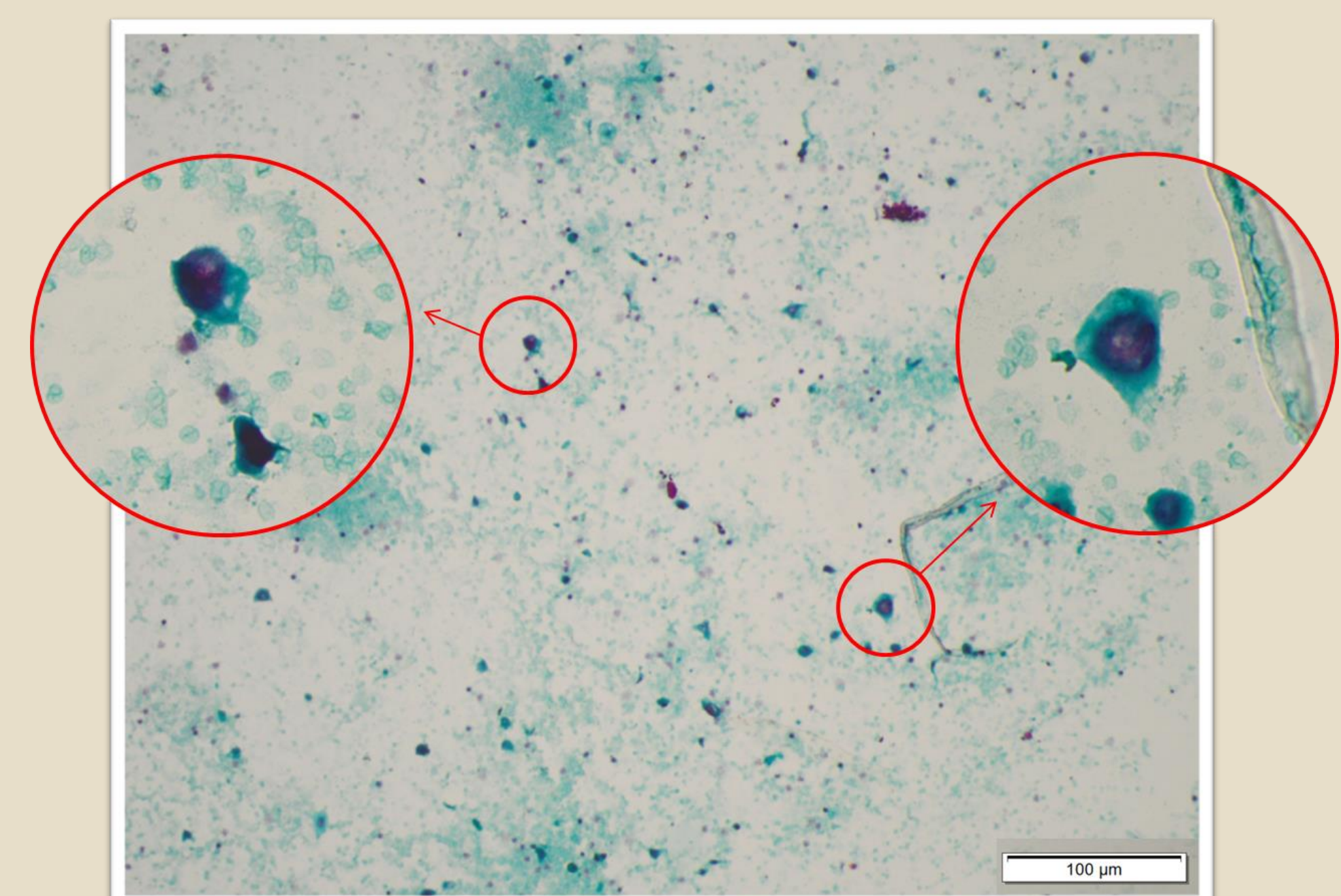MIBC-Muscle Invasive Bladder Cancer

Images of urine smears stained by CellDetect®

Low-grade urine smear

Negative urine smear

Images of urine smears stained by CellDetect®: Epithelial cells are stained in green while dysplastic cells exhibiting purple nuclei

High-grade urine smear

Conclusion

This study validates the use of CellDetect® in routine clinical settings and confirms its ability to accurately identify urothelial carcinoma throughout all cancer grades, particularly LGs. Additional study is underway to compare the performance of the test to that of FISH.