



# CellDetect® Improves the Sensitivity for Detecting Bladder Cancer in Voided Urine Specimens

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## ABSTRACT

### BACKGROUND

In the United States and Europe, bladder cancer accounts for 5%-10% of all malignancies in men. The risk of developing bladder cancer at < 75 years of age is 0.5-4%, and the prevalence of bladder cancer increases to 10% in a screening population with hematuria and/or a history of bladder cancer. In those cases, the initial work up typically involves the use of urinary tract cytology (UTC). However, UTC has relatively poor sensitivity, and a high frequency of cases are given indeterminate diagnoses, which limits the utility of UTC. CellDetect® is a novel chemical stain which adds color discrimination to cytomorphology in an attempt to increase the sensitivity of UTC specimens. We evaluated the performance of CellDetect® stain in routine screening of patients with hematuria and/or a history of bladder cancer.

### DESIGN

Consecutive voided urine specimens with sufficient volume were split. For each sample, one slide was processed as a SurePath specimen and stained with the Papanicolaou stain; a second slide was stained with CellDetect®. The CellDetect® smears were blindly reviewed by two pathologists. After adjudication, the results were compared to the clinical diagnosis made on the Pap-stained specimen. When cystoscopy or biopsy results were available, they were also compared.

### RESULTS

The study included 62 patients: 48 with history of bladder cancer; 9 with hematuria; and 5 with other urinary tract symptoms. Samples included 56 negative and 6 positive cases by cytomorphological assessment alone. CellDetect® correctly identified 100% of the positive cases while standard cytology only identified only 50% of the cases. The specificity of CellDetect® was 80.5% and for standard cytology 98%. 10 cases were categorized as atypical by standard cytology; within these cases, CellDetect® identified 2 true positive cases and 4 true negative cases, resulting in 100% sensitivity and 81.5% specificity.

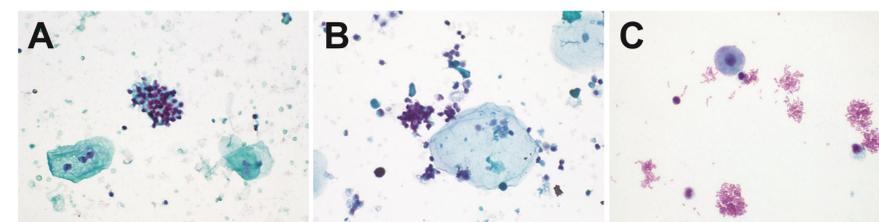
### CONCLUSIONS

The use of CellDetect® in conjunction with cytomorphology increased the sensitivity of detecting bladder cancer in both surveillance and hematuria screening cohorts. The performance of CellDetect requires further evaluation over a larger scale study.

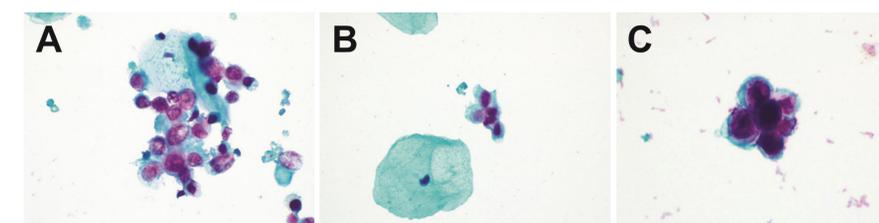
## RESULTS

	CellDetect, Pathologist #1	CellDetect, Pathologist #2	Cytology
Uninterpretable	11	9	0
TN	35	40	55
TP	6	5	3
FN	0	0	3
FP	10	8	1
Total	62	62	62
Sensitivity	100%	100%	50%
Specificity	78%	83%	98%

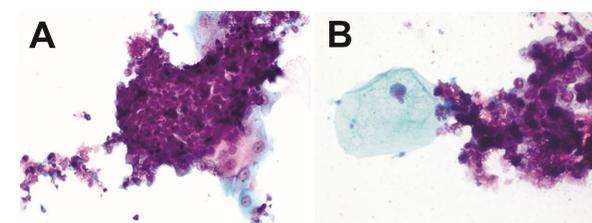
Performance of the CellDetect test by individual pathologist, prior to adjudication, as compared to the performance of cytology. Abbreviations: TN, true negative; TP, true positive; FN, false negative; FP, false positive.



Examples of CellDetect® staining in benign specimens. A-B, Negatively staining squamous cells and positively staining inflammatory cells. C, Negatively staining benign urothelial cell in a background of positively staining bacteria.



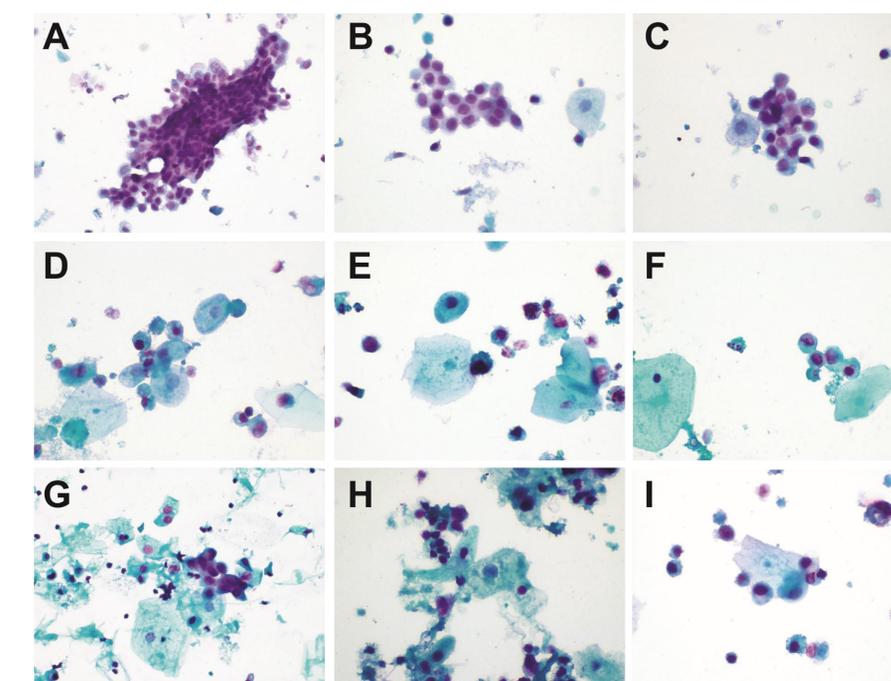
Examples of CellDetect® staining in a specimen diagnosed as high grade urothelial carcinoma on conventional Pap-stained cytology.



Examples of CellDetect® staining in a specimen diagnosed as Negative for High Grade Urothelial Carcinoma (NHGUC), demonstrating a positively-staining tissue fragment. The patient had low grade urothelial carcinoma on a subsequent tissue biopsy.

	CellDetect, Pathologist #1	CellDetect, Pathologist #2
Uninterpretable	3	2
TN	4	5
TP	2	2
FN	0	0
FP	1	1
Total	10	10
Sensitivity	100%	100%
Specificity	80%	83%

Performance of CellDetect test by individual pathologist, prior to adjudication, on specimens diagnosed as Atypical Urothelial Cells by cytology. Abbreviations: TN, true negative; TP, true positive; FN, false negative; FP, false positive.



Examples of CellDetect® staining in different specimens diagnosed as Atypical Urothelial Cells in which the patient had high grade urothelial carcinoma or carcinoma in situ on follow up tissue biopsy.

## CONCLUSIONS

The use of CellDetect® in conjunction with cytomorphology increased the sensitivity of detecting bladder cancer in both surveillance and hematuria screening cohorts. The performance of CellDetect requires further evaluation over a larger scale study.