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## **Feasibility of the Epicheck test in upper urinary tract tumor: Interim analysis of a prospective trial**

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### Introduction & Objectives

In UTUC several studies reported the low specificity and sensitivity of urine cytology for both diagnosis and surveillance. Bladder EpiCheck™ (EpiCheck) is a urine test developed by Nucleix Ltd for monitoring the recurrence of bladder cancer based on analysis of 15 informative DNA methylation biomarkers. Epicheck has been demonstrated to have a high NPV 95% in bladder cancer and even 99% for high grade. Since UTUC shares many features with bladder cancer, Epicheck could have some important value in the diagnosis of UTUC. The objective was to assess the diagnostic accuracy of Epicheck in UTUC.

### Materials & Methods

Single center prospective study that plans to include 90 patients, who undergo ureteroscopy for primary, recurrent or surveillance of UTUC since June 1st 2018. For each patient, protocol includes collection of voided urine sample for urine cytology and bladder voided Epicheck (Nucleix/Israel), collection ureteral urine as the first step of ureteroscopy for both selective cytology and selective Epicheck test. Results were compared to pathology obtained from 3 forceps biopsy. Primary outcome was to calculate sensitivity, specificity, negative predictive value of voided and selective Epicheck. Secondary outcome was the accuracy of Epicheck in the detection of high grade UTUC.

### Results

In this interim analysis, a total of 47 patients were included: mean age 73 years, 83% male. 54 ureters were explored. 46 % (22/47) were positive UTUC that was confirmed by endoscopic biopsy. 50% of UTUC were of high grade. Sensitivity, specificity, negative predictive value (NPV) and positive predictive value (PPV) of bladder and ureteral cytology, bladder and ureteral Epicheck for the diagnosis of all UTUC are summarized in Table 1. Sensitivity, specificity, negative predictive value (NPV) and positive predictive value (PPV) of bladder and ureteral cytology, bladder and ureteral Epicheck for the diagnosis of high grade UTUC are summarized in Table 2. This interim analysis reported a significant higher sensitivity of Bladder epicheck compared to voided cytology (75 vs 39%,  $p=0.03$ ), Se of 89% and NPV of 95% for high grade UTUC.

### Table 1

	Detection of any UTUC			
	Bladder Epicheck	Bladder Cytology	Ureter Epicheck	Ureter Cytology
Sensitivity	75%	39%	67%	56%
Specificity	77%	96%	81%	96%
PPV	75%	90%	76%	93%
NPV	77%	63%	73%	69%

Table 2

	Detection of High Grade			
	Bladder Epicheck	Bladder Cytology	Ureter Epicheck	Ureter Cytology
Sensitivity	89%	64%	100%	64%
Specificity	65%	81%	76%	81%
PPV	42%	50%	55%	50%
NPV	95%	88%	100%	88%

## Conclusions

Bladder Epicheck was associate to better sensitivity in the diagnosis of UTUC compared to voided cytology and high Se and NPV for high grade UTUC. Therefore, negative Bladder Epicheck could be in favor of attempt for conservative treatment in UTUC considering.