# Bladder EpiCheck® Included in 2022 European Association of Urology (EAU) Clinical Guidelines on Non-Muscle Invasive Bladder Cancer (NMIBC)

*Clinical Guidelines Support Adoption of Urinary Biomarker Tests with High Sensitivity and Negative Predictive Values for High-Grade Disease to Replace and/or Postpone Cystoscopies in Low- and Intermediate-Risk NMIBC*

*Publication of Meta-Analysis in European Urology Oncology Showed Bladder EpiCheck has Best Performance Amongst Guideline-Recommended Urinary Biomarker Tests*

**SAN DIEGO and REHOVOT, ISRAEL – March 16, 2022 –** Nucleix, a liquid biopsy company revolutionizing cancer treatment by detecting the disease earlier, today announced its Bladder EpiCheck® test has been included in the 2022 European Association of Urology (EAU) Clinical Guidelines for non-muscle invasive bladder cancer (NMIBC). The EAU guidelines aim to provide practical recommendations on the clinical management of NMIBC, to assist physicians in making informed treatment decisions with available scientific data.

The EAU guidelines state that urinary biomarker tests with high sensitivity and negative predictive values for high-grade disease, including a specific reference to Bladder EpiCheck, might be used to replace and/or postpone cystoscopies in low- and intermediate-risk NMIBC, and reduce the number of cystoscopies in this patient population.

Bladder cancer is the fifth most common cancer in the western world, but the costliest to care for, due to the need for prolonged surveillance. Because of high recurrence rate of the disease, patients undergo up to four follow-ups each year, which usually include cystoscopies that are invasive and painful.

“In follow up, many cystoscopies are negative, meaning the procedure was unnecessary. Apart from that, even when there is a high-grade recurrence, sensitivity of cystoscopies is certainly not 100%. The updated EAU guidelines illustrate that clinicians can improve NMIBC monitoring by replacing some of the cystoscopies with high-performing, non-invasive urinary markers,” said Professor Fred Witjes, Professor of Medical Sciences at Radboud University Medical Center and chair of the MIBC EAU guidelines. “In our hospital we have implemented such an alternating schedule with Bladder EpiCheck which benefits the patients and is cost effective.”

A comprehensive meta-analysis, entitled “Diagnostic Accuracy of Novel Urinary Biomarker Tests in Non-Muscle Invasive Bladder Cancer: A Systematic Review and Network Meta-Analysis,” was recently published in *European Urology Oncology*. Pooled data from five studies on Bladder EpiCheck reported an overall specificity of 85%, and a sensitivity of 91% and negative predictive value (NPV) of 99% for high grade disease. Importantly, Bladder EpiCheck demonstrated the best performance out of the guideline-recommended markers as measured by diagnostic odds ratios.

“Inclusion in the European Association of Urology’s guidelines for NMIBC will revolutionize patient care and drive adoption of Bladder EpiCheck, a non-invasive measure for surveilling the disease, which is a significant milestone for the Nucleix technology,” said Aharona Shuali, M.D., vice president of medical affairs at Nucleix.

**About Bladder EpiCheck®**

Bladder EpiCheck® provides patients and clinicians with a simple, objective urine test to detect recurrence of bladder tumors. The test analyzes subtle disease-specific changes in DNA methylation markers, allowing for the detection of 91% of high-grade cancers. Bladder EpiCheck® demonstrated negative predictive value (NPV) of 99% for high-grade cancer, meaning that when receiving a negative Bladder EpiCheck® result, there is 99% chance that no high-grade cancer is present[1]. Overall specificity of Bladder EpiCheck® is 85%, ensuring a low rate of false positive results. Bladder EpiCheck® is intended for use as a non-invasive method for monitoring of tumor recurrence in conjunction with cystoscopy in patients previously diagnosed with bladder cancer. Bladder EpiCheck® is CE-marked and available in Europe. The test is not available for sale in the United States.

**About Nucleix**

Nucleix is a liquid biopsy company revolutionizing cancer treatment with earlier disease detection at a time when intervention can bring the greatest impact for patients. Leveraging NGS and PCR-based epigenetics, the Company's pioneering testing approach uses methylation-based identification for early-stage and recurring cancer detection. The Company's non-invasive EpiCheck® platform delivers highly accurate and sensitive results, all while providing a seamless testing option for patients and the healthcare system. The Company is building an EpiCheck franchise, beginning with the Bladder EpiCheck® testing kit, marketed in Europe for bladder cancer recurrence. The Company is advancing a Lung EpiCheck test toward commercialization for high-risk individuals, while advancing additional tests for high-risk diseases. For more information, please visit: https://www.nucleix.com.

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[1] Laukhtina et al. Eur Urol Oncol 2021 Dec;4(6):927-942; and corrigendum at Eur Urol Oncol. 2022 Jan 19;S2588-9311(22)00004-9. doi: 10.1016/j.euo.2022.01.003