Bladder EpiCheck

Epigenetic Bladder Cancer Detection with Superior Performance

A Test Urologists Can Act Upon

- Superior Results - very high sensitivity, specificity and NPV
- Panel of 15 Biomarkers
- Operator Independent

*Bladder EpiCheck® is not approved for clinical use
HOW IT WORKS

Methylation of the DNA is a set of ‘switches’ that activate or deactivate specific genes in order to allow different cell types to perform their role. It is therefore a powerful tool to distinguish between cell types. Cancer cells show changes in methylation pattern compared to healthy cells, and if one could “read” these methylation changes against a large background of healthy cells, one would be able to detect the presence of tumors in body fluids, such as urine and blood. This is exactly what Nucleix does.

TECHNOLOGY PLATFORMS

Nucleix’s products are based on 2 main technology platforms that are applied to Bladder EpiCheck:

BIOMARKER PANEL DISCOVERY TOOL

We have a unique capability of building biomarker panels based on our proprietary technology. There is a significant challenge in building biomarker panels who are highly informative, adding biomarkers does not necessarily increase specificity and sensitivity. We use an iterative process of empirical data analysis and panel composition refinement that leads us to best-in-class performance.

CLINICAL ASSAY TOOL

- Analyzes DNA from urine and detects subtle disease-specific DNA methylation changes
- Allowing detection of cancer DNA molecules in a noise of over 150,000 non-cancerous DNA molecules
- Requiring only small amounts of DNA
- Outputs yes/no + EpiScore (0-100) representing methylation levels at panel
- Simple laboratory assay
- Requires no bisulfite conversion
- Automatic software analysis for objective, repeatable and precise results

CLINICAL SAMPLE  METHYLATION PROFILE OF NOVEL BIOMARKERS  DIAGNOSIS

Proprietary Biochemical Assay  EpiCheck® Algorithm

Iterative process of re-selecting panel candidates until we achieve the wanted result
Performance Results:

- Sensitivity: 90%
- Specificity: 83%
- NPV: 97%

- Results are based on a clinical study performed at Meir Medical Center, Israel. The study included a cohort of 221 patients that were monitored for recurrence. Bladder EpiCheck results were compared to the gold standard - cystoscopy / pathology.
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Sensitivity by Stage:
- Ta: 81%
- T1: 100%
- T2: 100%
- CIS: 91%
- Unspecified: 100%

Sensitivity by Grade:
- LG: 84%
- HG: 95%
- Unspecified: 100%

- Multiplexing 15 biomarkers to ensure high sensitivity, specificity and NPV
- Objective results – operator independent
- Measurable result using our EpiScore – Potential ability to detect trends in disease evolution

Bladder EpiCheck

Nucleix.com
Nucleix Ltd. develops, manufactures and markets highly innovative and non-invasive molecular cancer diagnostic tests. Our highly sensitive and specific tests are based on identification of subtle changes in methylation patterns. Nucleix technology is based on a combination of a new biochemical platform in conjunction with sophisticated algorithms.

Our first product Bladder EpiCheck® is a urine test for monitoring of bladder cancer. This test has shown very high sensitivity and specificity, and it is expected to reach the market in Q2 2016. Nucleix pipeline includes diagnostic tests for lung and colorectal cancer detection from blood samples, using its proprietary and highly innovative technology.

Nucleix is backed up by leading investors including OrbiMed - one of the world’s largest bio-medical VC funds.