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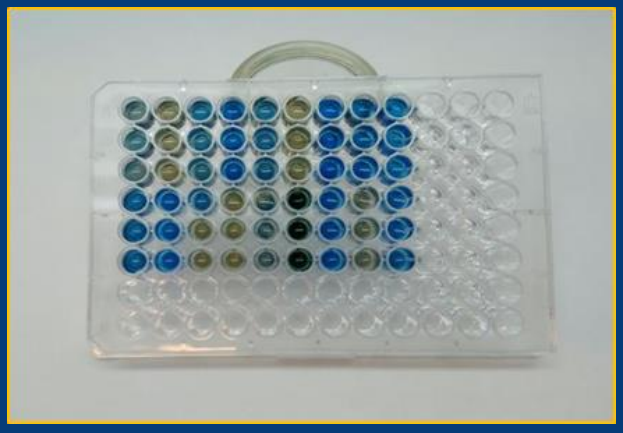
DIAGNOSTIC MARKER FOR BLADDER CANCER DETECTION

Technology



Bladder cancer is a disease affecting a constantly growing group of people around the world. Urinary epithelial carcinoma may be detected by specular and scanning tests, or by microscopic analysis of cells present in the urine. During the formation of a cancer within the urinary epithelium, increased activity of proteolytic enzymes is observed, causing the breakdown of proteins. The proposed diagnostic marker detects the presence of these enzymes. A very strong correlation between the presence of protease activity in human urine and the occurrence of bladder cancer have been observed. The diagnostic procedure with the use of the above mentioned marker takes no more than one hour, calculating from the moment of taking a patient's urine sample up to receiving the result. The effectiveness of describing detection method for bladder epithelial carcinoma has been confirmed during tests carried out on a group of 661 persons, including almost 200 patients with diagnosed bladder epithelial cancer. The occurrence of the disease has been confirmed not only by the use of proposed marker but also by histopathological examinations and during the medical treatment of patients as well.

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The proposed diagnostic marker shows qualities that make it competitive in relation to products with a similar range of activity which are available on the market.
Main advantages:

- non-invasive,
- requires only a small sample of the patient's urine to be tested, approximately 1 ml,
- short waiting time for the final result - less than 60 minutes,
- effective even in the initial phase of the disease,
- based on the study of protein activity, not its concentration as in case of markers currently available on the market,
- the method is significantly cheaper than other similar products on the market,
- the detection method does not require specialized knowledge, diagnostics is simple and easy to carry out,
- high diagnostic effectiveness of the marker at ca. 80,5%

Statistical Study results:
The study population consisted of 661 patients. The sensitivity of the diagnostic test, i.e. the probability of a positive test result vs. the histopathology report is 80.5% and the specificity is 77.1%. Positive predictive value, i.e. the probability that the disease really occurs in people with a positive test result vs. the histopathology report is 45.0%. On the other hand, the negative predictive value, or the probability that the disease does not really occur in people with a negative test result vs. the histopathology report is 94.4%.

	Group (N=661)
Sensitivity	80.5%
Specificity	77.1%
Positive predictive value	45.0%
Negative predictive value	94.4%

IP Status

Filed requests for the grants of a patent:

- Polish Patent Office: P.422233, P.426332
- European Patent Office: EP18183815
- Patent Cooperation Treaty: PCT/PL2019/050004

Implementation progress

TRL 7
Demonstration of the prototype under operating conditions

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