

Claims

1. A method for detecting bladder cancer, comprising:
 - (i) providing a urine sample;
 - (ii) detecting the levels of the human neutrophil marker gene interleukin 8 receptor B (IL8Rb) in association with bladder cancer marker (BTM) genes in said sample wherein the BTM genes comprise cell division cycle 2, G1 to S and G2 to M (CDC2), midkine (neurite growth-promoting factor 2) (MDK), Homeo Box A13 (HOXA13), and insulin-like growth factor binding protein 5 (IGFBP5); and
 - (iii) wherein the presence of cancer is established by comparing the levels of IL8Rb and the BTM genes with the levels in normal patients, and/or patients having bladder cancer, and/or patients having an inflammatory bladder condition, and establishing if the patient has bladder cancer,

wherein an increase in the levels of the BTM genes, without an increase in the level of IL8Rb, is indicative of the patient having bladder cancer, and wherein an increase in the level of IL8Rb is indicative of the patient having an inflammatory bladder condition.
2. The method of claim 1, wherein:
 - (a) the likelihood of the presence of cancer is determined by establishing a diagnostic threshold based on the known expression levels of IL8Rb and the BTM genes with the levels in normal patients, and/or patients having bladder cancer, and/or patients having an inflammatory bladder condition, optionally wherein the threshold is established using a statistical method and optionally wherein the statistical method is any one of Linear Discriminant Analysis (LDA), Logistic Regression (LogReg), Support Vector Machine (SVM), K-nearest 5 neighbors (KN5N), and Partition Tree Classifier (TREE); and/or
 - (b) the BTM genes includes at least one additional marker gene selected from Figure 6 or Figure 7.
3. The method of any one of the preceding claims, wherein:
 - (a) said step of detecting is carried out by detecting the levels of mRNA; or
 - (b) said step of detecting is carried out by detecting the levels of cDNA, optionally using an oligonucleotide complementary to at least a portion of said cDNA, or using qRT-PCR method using a forward primer and a reverse primer.

4. The use of a device for detecting a bladder cancer in a urine sample, the device comprising:

a substrate having a IL8Rb gene capture reagent and capture reagent for bladder tumour marker (BTM) genes thereon wherein the BTM genes comprise cell division cycle 2, G1 to S and G2 to M (CDC2), midkine (neurite growth-promoting factor 2) (MDK), Homeo Box A13 (HOXA13), and insulin-like growth factor binding protein 5 (IGFBP5); and

a detector associated with said substrate, said detector capable of detecting the expression associated with said capture reagent, wherein an increase in the levels of the BTM genes, without an increase in the level of IL8Rb, is indicative of the patient having bladder cancer, and wherein an increase in the level of IL8Rb is indicative of the patient having an inflammatory bladder condition.

5. The use of claim 4, wherein the BTM genes includes at least one additional marker selected from Figure 6 or Figure 7.

6. The use of any one of claims 4 to 5, wherein:

- (a) said capture reagent is an oligonucleotide; or
- (b) said capture reagent is an antibody specific for either a oligonucleotide, a protein or a peptide.

7. The use of a kit for detecting bladder cancer in a urine sample, the kit comprising:

a substrate having a IL8Rb gene capture reagent and a capture reagent for bladder tumour marker (BTM) genes thereon wherein the BTM comprise cell division cycle 2, G1 to S and G2 to M (CDC2), midkine (neurite growth-promoting factor 2) (MDK), Homeo Box A13 (HOXA13), and insulin-like growth factor binding protein 5 (IGFBP5);

a means for visualizing a complex of said capture agent and a marker; reagents; and instructions for use,

wherein an increase in the levels of the BTM genes, without an increase in the level of IL8Rb, is indicative of the patient having bladder cancer, and wherein an increase in the level of IL8Rb is indicative of the patient having an inflammatory bladder condition.

8. The use of claim 7, wherein:

- (a) said capture reagent is an oligonucleotide; or
- (b) said capture reagent is an antibody selective for a oligonucleotide, a protein or a peptide.

- 9.** A method for screening for bladder cancer, comprising the steps of:
- providing a test urine sample from a test subject;
 - measuring the presence of the IL8Rb gene and bladder tumour marker (BTM) genes in said test urine sample wherein the BTM genes comprise cell division cycle 2, G1 to S and G2 to M (CDC2), midkine (neurite growth-promoting factor 2) (MDK), Homeo Box A13 (HOXA13), and insulin-like growth factor binding protein 5 (IGFBP5); and
 - comparing the amount of markers present in said test urine sample with a value obtained from a control urine sample from a subject not having bladder cancer, and/or with a control sample with a subject having an inflammatory condition of the bladder and establishing if bladder cancer is present,
- wherein an increase in the levels of the BTM genes, without an increase in the level of IL8Rb, is indicative of the presence of bladder cancer, and wherein an increase in the level of IL8Rb is indicative of the presence of an inflammatory bladder condition.
- 10.** The method of claim 9, wherein:
- (a) said marker detected is an oligonucleotide, optionally DNA or RNA; and/or
 - (b) said step of measuring uses an ELISA assay.