

CLAIMS

1. A method of testing for pancreatic ductal adenocarcinoma comprising determining the level of expression or concentration of a protein selected from the group consisting of LYVE1, REG1 and TFF1, or a combination thereof, in a biological sample.
2. The method according to claim 1, wherein the method comprises determining the level of expression or concentration of two proteins selected from the group consisting of LYVE1, REG1 and TFF1, in a biological sample.
3. The method according to claim 1, wherein the method comprises determining the level of expression or concentration of each of LYVE1, REG1 and TFF1 in a biological sample.
4. The method according to any preceding claim, wherein the REG1 protein is REG1A and/or REG1B.
5. The method according to any preceding claim, wherein the determining step is carried out using a binding molecule or binding molecules specific for the protein or proteins whose level of expression or concentration is being determined.
6. The method according to claim 5 wherein the binding molecule is an antibody or an antibody fragment, a protein, or an aptamer.
7. The method according to any preceding claim wherein the biological sample is a urine, whole blood, serum or pancreatic tissue sample.
8. The method according to any preceding claim wherein the sample is from a human.
9. The method according to any preceding claim, wherein the pancreatic ductal adenocarcinoma is stage I or stage II pancreatic ductal adenocarcinoma.
10. The method of any preceding claim, wherein the method provides differential diagnosis distinguishing between stage I PDAC and a healthy patient, between stage I PDAC and chronic pancreatitis (CP), or between stage I PDAC and a later stage of PDAC.
11. The method of any preceding claim, further comprising the step of comparing the level of expression or concentration of one or more miRNAs with a reference.

12. The method of claim 11, wherein the reference is a biological sample from a healthy patient.
- 5 13. The method of any preceding claim, wherein the biological sample is from a patient having or suspected of having PDAC.
14. The method of any preceding claim, further comprising determining the level of expression or concentration of CA19.9 protein.
- 10 15. A protein selected from the group consisting of LYVE1, REG1 and TFF1, or a combination thereof, for use in diagnosing pancreatic ductal adenocarcinoma.
16. A combination of two proteins selected from the group consisting of LYVE1, REG1 and TFF1 for use in diagnosing pancreatic ductal adenocarcinoma.
- 15 17. The combination of each of LYVE1, REG1 and TFF1 proteins for use in diagnosing pancreatic ductal adenocarcinoma.
- 20 18. The protein or combination of proteins for use according to any one of claims 15 to 17, wherein the REG1 protein is REG1A and/or REG1B.
19. The protein or combination of proteins for use as claimed in any one of claims 15 to 18, wherein the proteins are urinary proteins.
- 25 20. The protein or combination of proteins for use as claimed in any one of claims 15 to 19, wherein the level of expression or concentration is measured using a binding molecule or binding molecules specific for the protein or proteins being analysed.
- 30 21. The protein or combination of proteins for use as claimed in claim 20 wherein the binding molecule is an antibody or an antibody fragment, a protein, or an aptamer.
- 35 22. The protein or combination of proteins according to any one of claims 15 to 21, wherein the pancreatic ductal adenocarcinoma is stage I or stage II pancreatic ductal adenocarcinoma.
23. A kit for testing for pancreatic ductal adenocarcinoma comprising a means for measuring the expression or concentration of LYVE1, REG1 or TFF1, or combinations thereof, in a biological sample.

24. The kit for testing for pancreatic ductal adenocarcinoma of claim 23 comprising a means for measuring the expression or concentration of two of LYVE1, REG1 or TFF1.
- 5 25. The kit for testing for pancreatic ductal adenocarcinoma of claim 23 comprising a means for measuring the expression or concentration of each of LYVE1, REG1 or TFF1.
- 10 26. The kit for testing for pancreatic ductal adenocarcinoma according to any one of claims 23 to 25, wherein the REG1 protein is REG1A and/or REG1B.
- 15 27. The kit of any one of claims 23 to 26, wherein the means for measuring is a biosensor.
28. The kit of claim 27, wherein the biosensor is an electrochemical, electronic, piezoelectric, gravimetric, pyroelectric biosensor, ion channel switch, evanescent wave, surface plasmon resonance or biological biosensor
- 20 29. The kit of claim 27, wherein the means for detecting comprises a dipstick coated with a membrane, wherein the dipstick comprises:
- (a) a first section to which is bound an unlabelled binding molecule with specific affinity for the protein whose expression or concentration is being measured;
- (b) a second section that is blocked with a non-reactive protein; and
- (c) a third section to which is bound the protein whose expression or concentration is being measured.
- 25 30. The kit according to any one of claims 23 to 29, wherein the kit further comprises one or more vessels for containing the biological sample.
- 30 31. The kit according to any one of claims 23 to 30, wherein the kit further comprises one or more solvents for extracting LYVE1, REG1 and/or TFF1 proteins from the biological sample.
- 35 32. The kit of any one of claims 23 to 31, wherein the means for detecting the amount of expression or concentration of the one or more biomarkers is a microarray.