CLAIMS

1. A method of assessing a subject for pre-Diabetes, Diabetes and/or a Diabetes related condition comprising measuring at least one biomarker in a sample from the subject, wherein said at least one biomarker is selected from the list of biomarkers in Table 1 or 2.

2. A method according to claim 1 wherein the at least one biomarker is at least two, three or four of the biomarkers in Table 1 or 2.

3. A method of assessing a subject for pre-Diabetes, Diabetes and/or a Diabetes related condition comprising measuring at least one biomarker in a sample from the subject, wherein said at least one biomarker is Peroxiredoxin-2, Complement C1q subcomponent subunit B, Sulfhydryl oxidase 1 or Apolipoprotein A-IV.

4. A method of assessing a subject for pre-Diabetes, Diabetes and/or a Diabetes related condition comprising measuring at least one biomarker in a sample from the subject, wherein said at least one biomarker is one or more of Peroxiredoxin-2, Protein AMBP and Complement C1q subcomponent.

5. A method of assessing a subject for pre-Diabetes, Diabetes and/or a Diabetes related condition comprising measuring at least one biomarker in a sample from the subject, wherein said at least one biomarker is one or more of Complement C1q subcomponent subunit B, Protein AMBP, Adiponectin and Complement Factor H-related protein 2.

6. A method of assessing a subject for pre-Diabetes, Diabetes and/or a Diabetes related condition comprising measuring at least one biomarker in a sample from the subject, wherein said at least one biomarker is Peroxiredoxin-2, Protein AMBP and Complement C1q subcomponent subunit B.

7. A method according to any one of the preceding claims wherein the step of measuring at least one biomarker in a sample from the subject comprises the use of mass spectrometry.

8. A method according to claim 7 wherein the mass spectrometry comprises measuring a peptide of the at least one biomarker.

9. A method according to claim 8 where the peptide is selected from the list of:

(i) a 10-15 amino acid peptide of a protein from Table 1 or 2;

(ii) a 5-25 amino acid peptide of a protein from Table 1 or 2;

(iii) a 5-20 amino acid peptide of a protein from Table 1 or 2;

(iv) a 10-20 amino acid peptide of a protein from Table 1 or 2; or

(v) a peptide in Table 3.

10. A method according to any one of claims 7 to 9 wherein the mass spectrometry comprises multiple reaction monitoring (MRM) mass spectrometry.

11. A method according to any one of the preceding claims wherein the subject is asymptomatic for or only exhibits non-specific indicators of pre-Diabetes, Diabetes and/or a Diabetes related condition.

12. A method according to any one of claims 1 to 10 wherein the subject has been diagnosed with pre-Diabetes, Diabetes and/or a Diabetes related condition.

13. A method according to any of the preceding claims wherein the subject has kidney disease.

14. A method according to any one of the preceding claims wherein the subject has microalbuminuria, macroalbuminuria or end stage renal disease.

15. The method according to any of the preceding claims wherein the sample comprises a blood sample.

16. A kit comprising reagents for measuring at least one biomarker in a sample from a subject, wherein said at least one biomarker is selected from the list of biomarkers in Table 1 or 2.

17. The kit of claim 16, wherein at least one of the reagents comprises a detectable label.

18. The kit of claim 16 or 17, further including a tool for evaluating the risk of an individual developing kidney disease from measurements of the at least one biomarker.

19. A computer readable medium having computer executable instructions for assessing a subject for pre-Diabetes, Diabetes and/or a Diabetes related condition, the computer readable medium comprising: a routine, stored on the computer readable medium and adapted to be executed by a processor, to store biomarker measurement data representing at least one biomarker selected from the list of biomarkers in Table 1 or 2.

20. A method of assessing a treatment for pre-Diabetes, Diabetes and/or a Diabetes related condition in a subject comprising measuring at least one biomarker, in a sample from the subject undergoing the treatment, selected from the list of biomarkers in Table 1 or 2, at least twice over the course of the treatment.

21. A method according to claim 20 wherein the biomarker is measured at at least two time points and the data from the two time points is compared over time.

22. A method of assessing the risk of a subject developing pre-Diabetes, Diabetes and/or a Diabetes related condition comprising measuring at least one biomarker, in a sample from the subject, selected from the list of biomarkers in Table 1 or 2.

23. A method of monitoring pre-Diabetes, Diabetes and/or a Diabetes related condition in a subject comprising measuring at least one biomarker, in a sample from the subject, selected from the list of biomarkers in Table 1 or 2 and comparing the measurement obtained with another measure of the at least one biomarker.

24. A method of diagnosing or identifying pre-Diabetes, Diabetes and/or a Diabetes related condition in a subject comprising measuring at least one biomarker, in a sample from the subject, selected from the list of biomarkers in Table 1 or 2.

25. A method of differentially diagnosing kidney disease from other conditions that also cause proteinuria in a subject comprising measuring at least one biomarker, in a sample from the subject, selected from the list of biomarkers in Table 1 or 2.

26. A method of differentially diagnosing sub-classses or stages of pre-Diabetes, Diabetes and/or a Diabetes related condition in a subject comprising measuring at least one biomarker, in a sample from the subject, selected from the list of biomarkers in Table 1 or 2.

27. A test system comprising:

(i) means for obtaining test results data representing levels of at least one biomarker selected from the list of biomarkers in Table 1 or 2, in a sample from the subject;

(ii) means for collecting and tracking the test results data generated in step (i);

(iii) means for calculating a pre-Diabetes, Diabetes and/or a Diabetes related condition risk index value from the test results data, wherein said risk index value is representative of the risk of an individual developing or having pre-Diabetes, Diabetes and/or a Diabetes related condition; and

(iv) means for reporting said risk index value.

28. A method of ranking or grouping a population of individuals, comprising: obtaining pre-Diabetes, Diabetes and/or a Diabetes related condition risk index data for individuals in said population based on at least one biomarker in Table 1 or 2; and ranking individuals within the population relative to the remaining individuals in the population or dividing the population into at least two groups, based on factors comprising said obtained risk index data.

29. A method of evaluating a pre-Diabetes, Diabetes and/or a Diabetes related condition surrogate endpoint in a subject, the method comprising: measuring at least one biomarker from the list of biomarkers in Table 1 or 2; and evaluating a pre-Diabetes, Diabetes and/or a Diabetes related condition surrogate endpoint in the subject based on said measure.

30. The method of claim 29, where the surrogate endpoint is the amount of protein in the subject's urine.

31. The method of claim 29 or 30 wherein the surrogate endpoint is the albumin creatine ratio.

32. A method of evaluating the risk of a subject developing pre-Diabetes, Diabetes and/or a Diabetes related condition comprising measuring at least one biomarker in a sample from the subject, wherein said at least one biomarker is selected from the list of biomarkers in Table 1 or 2.

33. A method of monitoring the risk of a subject developing pre-Diabetes, Diabetes and/or a Diabetes related condition comprising measuring at least one

biomarker in a sample from the subject, wherein said at least one biomarker is selected from the list of biomarkers in Table 1 or 2.

34. A method of diagnosing or identifying a subject with pre-Diabetes, Diabetes and/or a Diabetes related condition comprising measuring at least one biomarker in a sample from the subject, wherein said at least one biomarker is selected from the list of biomarkers in Table 1 or 2.

35. A method of monitoring pre-Diabetes, Diabetes and/or a Diabetes related condition therapy or intervention comprising measuring at least one biomarker in a sample from the subject, wherein said at least one biomarker is selected from the list of biomarkers in Table 1 or 2.

36. A method of differentially diagnosing a disease state or sub-class of pre-Diabetes, Diabetes and/or a Diabetes related condition comprising measuring at least one biomarker in a sample from the subject, wherein said at least one biomarker is selected from the list of biomarkers in Table 1 or 2.

37. A method of treating pre-Diabetes, Diabetes and/or a Diabetes related condition in a subject comprising: evaluating risk, for the subject, of developing pre-Diabetes, Diabetes and/or a Diabetes related condition using at least one biomarker from Table 1 or 2 and treating the subject when identified as being at elevated risk for pre-Diabetes, Diabetes and/or a Diabetes related condition with a treatment regimen to delay or prevent the onset of pre-Diabetes, Diabetes and/or a Diabetes related condition.

38. A method of ranking or grouping a population of subjects, comprising: obtaining data representing a pre-Diabetes, Diabetes and/or a Diabetes related condition risk score for subjects comprised within said population, wherein said risk score is calculated using at least one biomarker from Table 1 or 2 and ranking subjects within the population relative to the remaining individuals in

the population or dividing the population into at least two groups, based on factors comprising said obtained risk score data.

39. A method of identifying or assessing an agent for treating or reducing the risk of developing pre-Diabetes, Diabetes and/or a Diabetes related condition comprising:

(i) contacting cells expressing at least one biomarker from Table 1 or 2 with a putative agent; and

(ii) comparing expression and/or levels of at least one biomarker from Table 1 or 2 in the cells prior to contact with the putative agent to expression and/or levels of at least one biomarker from Table 1 or 2 in the cells after contact with the putative agent;

wherein a change in the level or expression identifies the agent as an agent for treating pre-Diabetes, Diabetes and/or a Diabetes related condition.

40. Use of at least one biomarker in Table 1 or 2 as a drug target for pre-Diabetes, Diabetes and/or a Diabetes related condition.

41. A method of treating or reducing the risk of developing pre-Diabetes, Diabetes and/or a Diabetes related condition in a subject comprising administering an effective amount of an agent adapted to change the expression or level of at least one biomarker in Table 1 or 2 to the subject.

42. Use of an agent adapted to change the expression or level of at least one biomarker in Table 1 or 2 for preparing a medication for treating or reducing the risk of developing pre-Diabetes, Diabetes and/or a Diabetes related condition.

CLAIMS

1. A method of assessing a subject for diabetic nephropathy comprising measuring at least one biomarker in a sample from the subject, wherein said at least one biomarker is CD5 antigen like.

2. A method according to claim 1 wherein the at least one biomarker further comprises a biomarker selected from the list of biomarkers comprising: peroxiredoxin-2, protein AMBP, complement C1q subcomponent subunit B, apolipoprotein C-III, insulin-like growth factor-binding protein 3, adiponectin, complement factor H-related protein 2, haemoglobin subunit beta, apolipoprotein B-100, sulfhydryl oxidase 1, complement component C8 beta chain and apolipoprotein A-IV.

3. A method according to claim 1 wherein the at least one biomarker further comprises a biomarker selected from the list of biomarkers comprising: insulin-like growth factor-binding protein 3 and apolipoprotein A-IV.

4. A method according to claim 1 wherein the at least one biomarker further comprises insulin-like growth factor-binding protein 3 and apolipoprotein A-IV.

5. A method according to any one of claims 1 to 4 wherein the step of measuring at least one biomarker in a sample from the subject comprises detecting a peptide fragment of said at least one biomarker.

6. A method according to claim 5 wherein the peptide fragment is a 5-25 amino acid peptide fragment.

7. A method according to claim 5 or 6 wherein the peptide fragment is selected from the group comprising SEQ ID NO's: 1-20.

8. A method according to any one of claims 5 to 7 wherein the peptide fragment is selected from the group comprising SEQ ID NO's: 2, 3, 4, 5, 16 and 17.

9. A method according to any one of claims 5 to 8 wherein the said peptide fragment is detected using mass spectrometry.

10. A method according to any one of the preceding claims wherein the subject is asymptomatic for or only exhibits non-specific indicators of diabetic nephropathy.

11. A method according to any one of claims 1 to 10 wherein the subject has been diagnosed with diabetic nephropathy.

12. A method according to any of the preceding claims wherein the subject has kidney disease.

13. A method according to any one of the preceding claims wherein the subject has microalbuminuria, macroalbuminuria or end stage renal disease.

14. The method according to any of the preceding claims wherein the sample comprises a blood sample.

15. A method of assessing a treatment for diabetic nephropathy in a subject comprising measuring CD5 antigen like, in a sample from the subject undergoing the treatment at least twice over the course of the treatment.

16. A method of assessing the risk of a subject developing diabetic nephropathy comprising measuring CD5 antigen like in a sample from the subject.

17. A test system comprising:

(i) means for obtaining test results data representing levels of CD5 antigen like in a sample from the subject;

(ii) means for collecting and tracking the test results data generated in step (i);

(iii) means for calculating a diabetic nephropathy risk index value from the test results data, wherein said risk index value is representative of the risk of an individual developing or having diabetic nephropathy; and

(iv) means for reporting said risk index value.

18. A method of monitoring a diabetic nephropathy therapy or intervention comprising measuring CD5 antigen like in a sample from the subject.

19. Use of CD5 antigen like as a drug target for diabetic nephropathy.