

CLAIMS

1. A method for determining whether a subject has a disease or condition or is at risk of developing a disease or condition, wherein the method comprises

5 determining in a biological sample obtained from the subject a quantitative value of at least one biomarker relative to a quantitative value of albumin in the biological sample; and
comparing the quantitative value(s) of the at least one biomarker to a control sample or to a control value;

10 wherein an increase or a decrease in the quantitative value(s) of the at least one biomarker, when compared to the control sample or to the control value, is/are indicative of the subject having the disease or condition or having an increased risk of developing the disease or condition.

15 2. The method according to claim 1, wherein the biological sample is a dry blood sample, a dry sample obtainable from blood, or obtainable from a dry blood sample.

3. The method according to claim 1 or 2, wherein the quantitative value of the at least one biomarker relative to the quantitative value of the albumin in the biological sample is
20 determined by calculating a ratio of an initial quantitative value of the at least one biomarker and the quantitative value of the albumin in the biological sample.

4. The method according to any one of claims 1 - 3,
25 wherein the dry blood sample is a dried blood spot.

5. The method according to any one of claims 1 - 4, wherein the dry blood sample or the dry sample obtainable from blood is obtainable from a fingertip of the subject, sampling of capillary blood from the upper arm of the subject, and/or by
30 venepuncture of the subject.

6. The method according to any one of claims 1 - 5, wherein the biological sample is obtainable from the dry blood sample or from the dry sample obtainable from blood by extracting at least a part of the blood or one or more
35 components thereof from the dry blood sample or from the dry sample obtainable from blood into a solvent.

7. The method according to any one of claims 1 - 6, wherein the method comprises determining in the biological

sample quantitative values of a plurality of biomarkers, such as two, three, four, five or more biomarkers.

8. The method according to any one of claims 1 - 7, wherein the method comprises determining in a biological sample obtained from the subject a quantitative value of at least one biomarker of the following relative to the quantitative value of the albumin in the biological sample:

- glycoprotein acetyls,
- omega-6 fatty acids,
- 10 - monounsaturated fatty acids,
- saturated fatty acids,
- omega-3 fatty acids,
- apolipoprotein A1 (ApoA1),
- docosahexaenoic acid (DHA),
- 15 - leucine,
- acetate,
- alanine,
- apolipoprotein B (ApoB),
- glutamine,
- 20 - isoleucine,
- linoleic acid,
- phenylalanine,
- tyrosine,
- degree of unsaturation of fatty acids,
- 25 - valine,
- histidine,
- cholesterol in HDL (HDL-C),
- glucose,
- acetoacetate,
- 30 - 3-hydroxybutyrate,
- cholesterol in LDL (LDL-C),
- lactate,
- triglycerides in LDL (LDL-TG),
- pyruvate, or
- 35 - cholesterol in VLDL (VLDL-C).

9. The method according to any one of claims 1 - 8, wherein the at least one biomarker comprises or is glycoprotein acetyls.

10. The method according to any one of claims 1 - 9, wherein the method comprises determining in the biological sample obtained from the subject a quantitative value of at least one biomarker of the following relative to the quantitative value of the albumin in the biological sample:

- omega-6 fatty acids,
- monounsaturated fatty acids,
- saturated fatty acids, or
- omega-3 fatty acids; and/or

10 a quantitative value of at least one biomarker of the following relative to the quantitative value of the albumin in the biological sample:

- apolipoprotein A1 (ApoA1),
- docosahexaenoic acid (DHA),
- 15 - leucine,
- acetate,
- alanine,
- apolipoprotein B (ApoB),
- glutamine,
- 20 - isoleucine,
- linoleic acid,
- phenylalanine,
- tyrosine,
- degree of unsaturation of fatty acids,
- 25 - valine,
- histidine; and/or

a quantitative value of at least one biomarker of the following relative to the quantitative value of the albumin in the biological sample:

- 30 - cholesterol in HDL (HDL-C),
- glucose,
- acetoacetate,
- 3-hydroxybutyrate,
- cholesterol in LDL (LDL-C),
- 35 - lactate,
- triglycerides in LDL (LDL-TG),
- pyruvate, or
- cholesterol in VLDL (VLDL-C).

11. The method according to any one of claims 1 - 10, wherein the disease is an infectious disease or a complication thereof, such as sepsis, pneumonia, optionally severe pneumonia, or other lower respiratory infection; or
5 diabetes.

12. The method according to any one of claims 1 - 11, wherein the quantitative value of the at least one biomarker and/or the quantitative value of the albumin is/are measured using nuclear magnetic spectroscopy.

10 13. The method according to any one of claims 1 - 12, wherein the dry blood sample is a dried whole blood sample, a dried plasma sample, a dried serum sample, or a dried sample derived therefrom.

14. The method according to any one of claims 1 - 13,
15 wherein the method further comprises determining whether the subject has the disease or condition or is at risk of developing the disease or condition using a risk score, hazard ratio, and/or predicted absolute risk calculated on the basis of the quantitative value(s) of the at least one biomarker or of the
20 plurality of the biomarkers relative to the quantitative value of the albumin.

15. A method for determining whether a subject is at risk of developing an infectious disease or a complication thereof, wherein the method comprises
25 determining in a biological sample obtained from the subject a quantitative value of at least one biomarker of the following:

- glycoprotein acetyls,
- albumin,
- 30 - omega-6 fatty acids,
- monounsaturated fatty acids,
- saturated fatty acids,
- omega-3 fatty acids,
- apolipoprotein A1 (ApoA1),
- 35 - docosahexaenoic acid (DHA),
- leucine,
- acetate,
- alanine,
- apolipoprotein B (ApoB),

- glutamine,
 - isoleucine,
 - linoleic acid,
 - phenylalanine,
 - 5 - tyrosine,
 - degree of unsaturation of fatty acids,
 - valine,
 - histidine,
 - cholesterol in HDL (HDL-C),
 - 10 - glucose,
 - acetoacetate,
 - 3-hydroxybutyrate,
 - cholesterol in LDL (LDL-C),
 - lactate,
 - 15 - triglycerides in LDL (LDL-TG),
 - pyruvate, or
 - cholesterol in VLDL (VLDL-C); and
- comparing the quantitative value(s) of the at least one biomarker to a control sample or to a control value;
- 20 wherein an increase or a decrease in the quantitative value(s) of the at least one biomarker, when compared to the control sample or to the control value, is/are indicative of the subject having an increased risk of developing the infectious disease or the complication thereof.
- 25 16. The method according to claim 15, wherein the method comprises determining in a biological sample obtained from the subject a quantitative value of glycoprotein acetyls; and/or
- a quantitative value of at least one biomarker of the
- 30 following:
- omega-6 fatty acids,
 - monounsaturated fatty acids,
 - saturated fatty acids, or
 - omega-3 fatty acids; and/or
- 35 a quantitative value of at least one biomarker of the following:
- apolipoprotein A1 (ApoA1),
 - docosahexaenoic acid (DHA),
 - leucine,

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- acetate,
 - alanine,
 - apolipoprotein B (ApoB),
 - glutamine,
 - 5 - isoleucine,
 - linoleic acid,
 - phenylalanine,
 - tyrosine,
 - degree of unsaturation of fatty acids,
 - 10 - valine,
 - histidine; and/or
- a quantitative value of at least one biomarker of the following:
- cholesterol in HDL (HDL-C),
 - 15 - glucose,
 - acetoacetate,
 - 3-hydroxybutyrate,
 - cholesterol in LDL (LDL-C),
 - lactate,
 - 20 - triglycerides in LDL (LDL-TG),
 - pyruvate, or
 - cholesterol in VLDL (VLDL-C).

17. The method according to claim 15 or 16, wherein the infectious disease or the complication thereof is sepsis, pneumonia, optionally severe pneumonia, or other lower respiratory infection.

18. The method according to any one of claims 15 - 17, wherein the method further comprises determining whether the subject is at risk of developing the infectious disease or the complication thereof using a risk score, hazard ratio, and/or predicted absolute risk calculated on the basis of the quantitative value(s) of the at least one biomarker or of the plurality of the biomarkers.

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