CLAIMS

1. A microbe-binding molecule comprising:

(i) at least one microbe surface-binding domain;

(ii) a substrate-binding domain adapted for orienting the microbe surface-binding domain away from the solid substrate surface; and

(iii) at least one linker between the microbe surface-binding domain and the substrate-binding domain; and

(iv) a detectable label.

2. A microbe-binding molecule according to Claim 1, in which the microbe surface-binding domain comprises a carbohydrate recognition domain derived from at least one carbohydrate-binding protein selected from the group consisting of lectin, collectin, ficolin, mannose-binding lectin (MBL), maltose-binding protein, arabinose-binding protein, glucose-binding protein, *Galanthus nivalis* agglutinin, peanut lectin, lentil lectin, DC-SIGN, C-reactive protein, and any combinations thereof.

3. A microbe-binding molecule according to Claim 1 or 2, in which the microbe surface-binding domain comprises a carbohydrate recognition domain derived from mannose-binding lectin (MBL).

4. A microbe-binding molecule according to Claim 3, in which the carbohydrate recognition comprises an amino acid sequence selected from SEQ ID NOs: 1-4.

5. A microbe-binding molecule according to any preceding claim, in which the detectable label is selected from the group consisting of biotin, a fluorescent dye or particle, a luminescent or bioluminescent marker, a radiolabel, an enzyme, a microbial enzyme substrate, a quantum dot, an imaging agent, and any combinations thereof.

6. A microbe-binding molecule according to Claim 5, in which the detectable label comprises an enzyme which causes a colour change in the presence of an enzyme substrate.

7. A microbe-binding molecule according to Claim 5 or 6, in which the detectable label is a horseradish peroxidase or alkaline phosphatase.

8. A microbe-binding molecule according to any preceding claim, in which the linker comprises a portion of a Fc region of an immunoglobulin.

9. A microbe-binding molecule according to Claim 8, in which the portion of the Fc region comprises a hinge region, a CH2 region, a CH3 region, or any combinations thereof.

10. A microbe-binding molecule according to Claim 8 or 9, in which the portion of the Fc region comprises a mutation selected to increase half-life of the microbe-binding molecule, to modulate antibody-dependent cell-mediated cytotoxicity, to modulate complement-dependent cytotoxicity, or any combinations thereof.

11. A microbe-binding molecule according to any preceding claim, in which the substrate-binding domain comprises at least one oligopeptide comprising an amino acid sequence of Alanine-Lysine-Threonine (AKT).

12. A microbe-binding molecule according to any preceding claim for use in a method of diagnosing an infection in a subject, the method comprising administering to the subject the microbe-binding molecule and detecting binding of a microbe or microbial matter to the microbe-binding molecule.

13. A microbe-binding molecule according to Claim 12 for a use as specified therein, in which the method further comprises collecting a test sample from the subject for detecting the binding of a microbe or microbial matter to the microbe-binding molecule.

14. A microbe-binding molecule according to Claim 13 for a use as specified therein, in which the test sample is a body fluid or a tissue sample.

15. A method of detecting a microbe or microbial matter in a test sample comprising contacting *in vitro* or *ex-vivo* a test sample with a microbe-binding molecule according to any of Claims 1 to 11 and detecting binding of a microbe or microbial matter to the microbe-binding molecule.

16. An assay comprising:

(a) contacting a test sample with microbe-binding molecules, in which the microbe-binding molecules are conjugated to a surface of a solid substrate, and in which the engineered microbe-binding molecules each comprises:

(i) at least one microbe surface-binding domain;

(ii) a substrate-binding domain adapted for orienting the microbe surface-binding domain away from the solid substrate surface; and

(iii) at least one linker between the microbe surface-binding domain and the substrate-binding domain; and

(b) detecting binding of a microbe or microbial matter to at least a portion of the microbe-binding molecules.

17. An assay according to Claim 16, in which the detecting is performed by spectroscopy, electrochemical detection, polynucleotide detection, fluorescence anisotropy, fluorescence resonance energy transfer, electron transfer, enzyme assay, magnetism, electrical conductivity, isoelectric focusing, chromatography, immunoprecipitation, immunoseparation, aptamer binding, filtration, electrophoresis, use of a CCD camera, immunoassay, ELISA, Gram staining, immunostaining, microscopy, immunofluorescence, western blot, polymerase chain reaction (PCR), RT-PCR, fluorescence in situ hybridization, sequencing, mass spectroscopy, or any combination thereof.

18. An assay according to Claim 16 or 17, further comprising contacting the bound microbe or microbial matter with a labelling molecule prior to the detecting step.

19. An assay according to Claim 18, in which the labelling molecule comprises wheat germ agglutinin, lectins, antibodies, antigen binding fragments of antibodies, aptamers, or ligands of cell-surface receptors.

20. An assay according to Claim 18 or 19, in which the labelling molecule binds to a specific microbial class, strain or species.

21. An assay according to Claim 18, 19 or 20 in which the labelling molecule is conjugated to an enzyme that produces a colour change in the presence of an enzyme substrate.

22. The assay according to Claim 21, in which the enzyme comprises a beta-galactosidase, a peroxidase, a catalase, an alkaline phosphatase.

23. The assay according to any of Claims 16 to 22, in which the detecting further comprises identifying the microbe or microbial matter bound to the microbe-binding molecules based on a microbe signature determined by mass spectrometric analysis.

24. The assay according to Claim 23, further comprising, prior to the mass spectrometric analysis, detaching the bound microbe or microbial matter from at least a portion of the microbe-binding molecules.

25. An assay according to Claim 24, in which the detaching comprises incubating the microbe-binding molecules comprising the bound microbe or microbial matter in a buffer (i) having an acidic pH or (ii) comprising an ion which forms a salt with Ca^{2+} ion, and in which the salt is insoluble in the buffer.

26. An assay according to any of Claims 16 to 25, in which the surface of the solid substrate further comprises at least one reference area for comparison with a readout signal determined upon contact of the test sample with the microbe-binding molecules.

27. An assay according to any of Claims 16 to 26, in which the solid substrate is a dipstick, a test strip, or a microtiter plate.

28. An assay according to any of Claims 16 to 27, further comprising subjecting the bound microbe to at least one antibiotic.

29. An assay according to Claim 28, further comprising evaluating a response of the bound microbe to the at least one antibiotic.

30. An assay according to Claim 29, further identifying a treatment of an infection caused by the microbe.

31. A kit comprising:

(a) one or more containers containing a population of microbe-binding microparticles; in which the engineered microbe-binding microparticles each comprises on its surface at least one microbe-binding molecule, in which the at least one microbe-binding molecule comprises:

(i) at least one microbe surface-binding domain;

(ii) a substrate-binding domain adapted for orienting the microbe surface-binding domain away from the solid substrate surface; and

(iii) at least one linker between the microbe surface-binding domain and the substrate-binding domain; and

(b) one or more containers containing a population of labelling molecules, in which the labelling molecules are conjugated to an enzyme; and

(c) one or more containers containing an enzyme substrate that produces a colour change in the presence of the enzyme.

32. A kit according to Claim 31, in which the population of engineered microbe-binding molecules are pre-loaded in one or more blood collection tubes.

33. A kit according to Claim 32, in which the blood collection tube further comprises an anti-coagulant agent.

34. A kit according to Claim 31, 32 or 33, in which the population of engineered microbe-binding microparticles comprises a first subset having on their surfaces a first density of the microbe-binding molecules and a second subset having on their surfaces a second density of the microbe-binding molecules, in which the second density is different from the first density.

CLAIMS

1. A microbe-binding molecule comprising:

(i) at least one microbe surface-binding domain;

(ii) a substrate-binding domain adapted for orienting the microbe surface-binding domain away from the solid substrate surface; and

(iii) at least one linker between the microbe surface-binding domain and the substrate-binding domain; and

(iv) a detectable label,

in which the microbe surface-binding domain is linked to the C-terminal of the linker.

2. A microbe-binding molecule according to Claim 1, in which the microbe surface-binding domain comprises a carbohydrate recognition domain derived from at least one carbohydrate-binding protein selected from the group consisting of lectin, collectin, ficolin, mannose-binding lectin (MBL), maltose-binding protein, arabinose-binding protein, glucose-binding protein, *Galanthus nivalis* agglutinin, peanut lectin, lentil lectin, DC-SIGN, C-reactive protein, and any combinations thereof.

3. A microbe-binding molecule according to Claim 1 or 2, in which the microbe surface-binding domain comprises a carbohydrate recognition domain derived from mannose-binding lectin (MBL).

4. A microbe-binding molecule according to Claim 3, in which the carbohydrate recognition comprises an amino acid sequence selected from SEQ ID NOs: 1-5.

5. A microbe-binding molecule according to any preceding claim, in which the detectable label is selected from the group consisting of biotin, a fluorescent dye or particle, a luminescent or bioluminescent marker, a radiolabel, an enzyme, a microbial enzyme substrate, a quantum dot, an imaging agent, and any combinations thereof.

6. A microbe-binding molecule according to Claim 5, in which the detectable label comprises an enzyme which causes a colour change in the presence of an enzyme substrate.

7. A microbe-binding molecule according to Claim 5 or 6, in which the detectable label is a horseradish peroxidase or alkaline phosphatase.

8. A microbe-binding molecule according to any preceding claim, in which the linker comprises a portion of a Fc region of an immunoglobulin.

9. A microbe-binding molecule according to Claim 8, in which the portion of the Fc region comprises a hinge region, a CH2 region, a CH3 region, or any combinations thereof.

10. A microbe-binding molecule according to any preceding claim, in which the substrate-binding domain comprises at least one oligopeptide comprising an amino acid sequence of Alanine-Lysine-Threonine (AKT).

11. A microbe-binding molecule according to any preceding claim for use in a method of diagnosing an infection in a subject.

12. A microbe-binding molecule according to Claim 11 for a use as specified therein, in which the method comprises administering to the subject the microbe-binding molecule and detecting binding of a microbe or microbial matter to the microbe-binding molecule.

13. A microbe-binding molecule according to Claim 11 for a use as specified therein, in which the method further comprises collecting a test sample from the subject for detecting the binding of a microbe or microbial matter to the microbe-binding molecule.

14. A microbe-binding molecule according to Claim 13 for a use as specified therein, in which the test sample is a body fluid or a tissue sample.

15. A method of detecting a microbe or microbial matter in a test sample comprising contacting *in vitro* or *ex-vivo* a test sample with a microbe-binding molecule according to any of Claims 1 to 11 and detecting binding of a microbe or microbial matter to the microbe-binding molecule.

16. An assay comprising:

(a) contacting a test sample with microbe-binding molecules, in which the microbe-binding molecules are conjugated to a surface of a solid substrate, and in which the engineered microbe-binding molecules each comprises:

(i) at least one microbe surface-binding domain;

(ii) a substrate-binding domain adapted for orienting the microbe surface-binding domain away from the solid substrate surface; and

(iii) at least one linker between the microbe surface-binding domain and the substrate-binding domain, in which the microbe surface-binding domain is linked to the C-terminal of the linker; and

(b) detecting binding of a microbe or microbial matter to at least a portion of the microbe-binding molecules.

17. An assay according to Claim 16, in which the detecting is performed by spectroscopy, electrochemical detection, polynucleotide detection, fluorescence anisotropy, fluorescence resonance energy transfer, electron transfer, enzyme assay, magnetism, electrical conductivity, isoelectric focusing, chromatography, immunoprecipitation, immunoseparation, aptamer binding, filtration, electrophoresis, use of a CCD camera, immunoassay, ELISA, Gram staining, immunostaining, microscopy, immunofluorescence, western blot, polymerase chain reaction (PCR), RT-PCR, fluorescence in situ hybridization, sequencing, mass spectroscopy, or any combination thereof.

18. An assay according to Claim 16 or 17, further comprising contacting the bound microbe or microbial matter with a labelling molecule prior to the detecting step.

19. An assay according to Claim 18, in which the labelling molecule comprises wheat germ agglutinin, lectins, antibodies, antigen binding fragments of antibodies, aptamers, or ligands of cell-surface receptors.

20. An assay according to Claim 18 or 19, in which the labelling molecule binds to a specific microbial class, strain or species.

21. An assay according to Claim 18, 19 or 20 in which the labelling molecule is conjugated to an enzyme that produces a colour change in the presence of an enzyme substrate.

22. An assay according to Claim 21, in which the enzyme comprises a beta-galactosidase, a peroxidase, a catalase, an alkaline phosphatase.

23. An assay according to any of Claims 16 to 22, in which the detecting further comprises identifying the microbe or microbial matter bound to the microbe-binding molecules based on a microbe signature determined by mass spectrometric analysis.

24. An assay according to Claim 23, further comprising, prior to the mass spectrometric analysis, detaching the bound microbe or microbial matter from at least a portion of the microbe-binding molecules.

25. An assay according to Claim 24, in which the detaching comprises incubating the microbe-binding molecules comprising the bound microbe or microbial matter in a buffer (i) having an acidic pH or (ii) comprising an ion which forms a salt with Ca^{2+} ion, and in which the salt is insoluble in the buffer.

26. An assay according to any of Claims 16 to 25, in which the surface of the solid substrate further comprises at least one reference area for comparison with a readout signal determined upon contact of the test sample with the microbe-binding molecules.

27. An assay according to any of Claims 16 to 26, in which the solid substrate is a dipstick, a test strip, or a microtiter plate.

28. An assay according to any of Claims 16 to 27, further comprising subjecting the bound microbe to at least one antibiotic.

29. An assay according to Claim 28, further comprising evaluating a response of the bound microbe to the at least one antibiotic.

30. An assay according to Claim 29, further identifying a treatment of an infection caused by the microbe.

31. A kit comprising:

(a) a population of microbe-binding microparticles; in which the engineered microbe-binding microparticles each comprises on its surface at least one microbe-binding molecule, in which the at least one microbe-binding molecule comprises

(i) at least one microbe surface-binding domain;

(ii) a substrate-binding domain adapted for orienting the microbe surface-binding domain away from the solid substrate surface; and

(iii) at least one linker between the microbe surface-binding domain and the substrate-binding domain, in which the microbe surface-binding domain is linked to the C-terminal of the linker; and

(b) containing a population of labelling molecules, in which the labelling molecules are conjugated to an enzyme; and

(c) containing an enzyme substrate that produces a colour change in the presence of the enzyme.

32. A kit according to Claim 31, in which the population of engineered microbe-binding molecules are pre-loaded in one or more blood collection tubes.

33. A kit according to Claim 32, in which the blood collection tube further comprises an anti-coagulant agent.

34. A kit according to Claim 31, 32 or 33, in which the population of engineered microbe-binding microparticles comprises a first subset having on their surfaces a first density of the microbe-binding molecules and a second subset having on their surfaces a second density of the microbe-binding molecules, in which the second density is different from the first density.