Claims

1. A device for detecting a target analyte in a fluid sample, the device comprising:

a reaction chamber, wherein the reaction chamber comprises internal surfaces, a binding agent and a probe agent, the probe agent comprising a binding partner and a vehicle, wherein the binding partner is bound to the vehicle, wherein the target analyte in the fluid sample can react with the binding agent or the binding partner;

a detection chamber; and

a fluid passageway between the reaction chamber and the detection chamber,

wherein the device is adapted to move the reacted fluid sample from the reaction chamber to the detection chamber through the fluid passageway via capillary action, and

wherein the presence of the target analyte in the fluid sample at a concentration results in a change in the amount of probe agent that moves with the reacted fluid sample to the detection chamber, wherein the change is detectable in the detection chamber and dependent on at least a threshold of the concentration.

2. The device of claim 1, further comprising a fill chamber, wherein the fill chamber comprises internal surfaces.

3. The device of claim 1 or claim 2, wherein the internal surfaces comprise internal walls.

4. The device of claim 1 or claim 2, wherein the internal surfaces comprise surfaces of at least one supporting material.

5. The device of claim 1 or claim 2, wherein the reaction chamber comprises an opening to the atmosphere.

6. The device of claim 1, wherein the reaction chamber comprises a blocking agent, wherein the blocking agent is capable of preventing non-specific binding of proteins or lipidic particles to the internal surfaces of the reaction chamber.

7. The device of claim 2, wherein the fill chamber comprises a blocking agent, wherein the blocking agent is capable of preventing non-specific binding of proteins or lipidic particles to the internal surfaces of the fill chamber.

8. The device of claim 6 or claim 7, wherein the blocking agent comprises at least one selected from a surfactant and a blocking protein.

9. The device of claim 8, wherein the blocking protein comprises bovine serum albumin.

10. The device of claim 1, wherein the binding agent and the probe agent are bound to different internal surfaces of the reaction chamber.

11. The device of claim 1, wherein the binding agent comprises at least one magnetic bead.

12. The device of claim 11, further comprising a magnetic field to serve to confine the binding agent in the reaction chamber.

13. The device of claim 1, wherein the vehicle comprises at least one copy of an activating agent.

14. The device of claim 1, wherein the vehicle comprises from about 10 to about 100000 copies of an activating agent.

15. The device of claim 13 or 14, wherein the activating agent is encapsulated within the vehicle.

16. The device of claim 15, wherein the vehicle comprises at least one lipidic particle.

17. The device of claim 13 or 14, wherein the activating agent is bound to the vehicle.

18. The device of claim 17, wherein the vehicle comprises at least one polymer.

19. The device of claim 18, wherein the polymer is a dendrimer.

20. The device of any one of claims 13-19, wherein an unactivated agent is immobilized in the reaction chamber, wherein the unactivated agent can bind to an unbound or unencapsulated activating agent.

21. The device of claim 20, wherein the unactivated agent comprises at least one magnetic bead.

22. The device of any one of claims 13-21, wherein the detection chamber comprises a liberating agent, wherein the liberating agent can liberate the activating agent from the vehicle.

23. The device of claim 22, wherein the liberating agent comprises at least one agent selected from a mild detergent, a lytic peptide, an enzyme, heating, cooling, ultrasonication and a light source together with a photochemically activated lysing agent which is incorporated into the vehicle.

24. The device of claim 23, wherein the mild detergent comprises one detergent selected from n-octyl-B-D-glucopyranoside, tween 20, brij 35 and triton X-100.

25. The device of claim 23, wherein the lytic peptide comprises one peptide selected from mellitin, and one of a class of phospholipases, a component of the complement system.

26. The device of claim 23, wherein the enzyme comprises one enzyme selected from a protease and trypsin.

27. The device of any one of claims 13-26, wherein the activating agent comprises a cofactor for an enzyme.

28. The device of claim 27, wherein the detection chamber comprises an apoenzyme which can be activated by the cofactor.

29. The device of claim 27, wherein the enzyme comprises glucose oxidase.

30. The device of claim 29, wherein the cofactor comprises flavin adenine dinucleotide.

31. The device of claim 30, wherein the detection chamber comprises apo-glucose oxidase.

32. The device of claim 27, wherein the enzyme comprises a glucose dehydrogenase.

33. The device of claim 32, wherein the cofactor comprises pyrolloquinoline quinone.

34. The device of claim 33, wherein the detection chamber comprises apo-glucose dehydrogenase.

35. The device of claim 32, wherein the cofactor comprises flavin adenine dinucleotide.

36. The device of claim 27, wherein the detection chamber further comprises an enzyme substrate.

37. The device of claim 36, wherein the enzyme substrate comprises an oxidizable substrate.

38. The device of claim 37, wherein the oxidizable substrate comprises one substrate selected from galactose, maltose, xylose, and acetic acid.

39. The device of claim 37, wherein the enzyme substrate comprises glucose.

40. The device of claim 27, wherein the detection chamber further comprises at least one mediator.

41. The device of claim 40, wherein the mediator comprises one substance selected from dichlorophenolindophenol, phenazine ethosulphate, ferricyanide, ferrocene and complexes between transition metals and nitrogen-containing heteroatomic species.

42. The device of claim 27, wherein the device further comprising a buffer capable of adjusting the pH of the sample.

43. The device of claim 42, wherein the buffer comprises a substance selected from phosphate, citrate, citraconate, mellitate, tris, pipes, mops, hepes, phthalate, imadazole.

44. The device of claim 1, wherein the binding partner of the probe agent is adapted to bind to the binding agent.

45. The device of claim 1, wherein the binding partner of the probe agent is adapted to bind to the target analyte.

46. The device of claim 45, wherein the target analyte is bound to the binding agent.

47. The device of claim 1, wherein there is a vent in the distal end of the detection chamber.

48. The device of claim 47, wherein the vent can be opened by piercing an outer layer of the device.

49. The device of claim 47, wherein the vent can be opened by removing a portion of an outer layer of the device.

50. The device of claim 1, wherein the detection chamber comprises at least two electrodes for detecting an electrochemical reaction in the detection chamber.

51. The device of claim 50, wherein at least one of the electrodes is formed from an electrically conductive layer, and further wherein there is a break in the electrically conductive layer that serves to define at least one edge of the electrode in the detection chamber.

52. The device of claim 50, wherein at least one electrode comprises palladium, platinum, gold, iridium, carbon, carbon mixed with binder, indium oxide, tin oxide or a mixture thereof.

53. The device of claim 50, wherein a change in the amount of the probe agent in the detection chamber is detectable via an electrochemical reaction in the detection chamber.

54. A method of detecting a target analyte in a fluid sample, comprising:

delivering the fluid sample to a device, wherein the device comprises a reaction chamber and a detection chamber, the reaction chamber comprising a binding agent and a probe agent, the probe agent comprising a binding partner and a vehicle;

allowing a reaction to proceed in the reaction chamber between the binding agent and the probe agent, wherein the presence of the target analyte in the fluid sample at a concentration results in changes in the amount of probe agent bound in the reaction chamber and in the amount of unbound probe agent, wherein the changes are dependent on the concentration of the target analyte;

moving the reacted sample fluid from the reaction chamber into the detection chamber by capillary action such that the unbound probe agent moves to the detection chamber; and

detecting presence of the probe agent in the detection chamber via a detecting agent.

55. The method of claim 54, the delivering of the sample to the device comprising delivering the sample to the reaction chamber through a fill chamber of the device.

56. The method of claim 55, wherein the delivering the sample fluid to the fill chamber comprising a capillary action.

57. The method of claim 54, the detecting agent comprises an apo-enzyme.

58. The method of claim 54, the vehicle comprising at least one copy of an activating agent, wherein one copy of the activating agent can activate at least one copy of the detecting agent.

59. The method of claim 54, wherein the moving of the sample from the reaction chamber to the detection chamber comprising opening a vent.

60. The method of claim 54, further comprising quantifying electrical signals received from the detection chamber, wherein the magnitude of the electrical signals is dependent on the concentration of the target analyte in the sample fluid.

Claims

1. A device for detecting a target analyte in a fluid sample, the device comprising:

a reaction chamber, wherein the reaction chamber comprises internal surfaces, a binding agent and a probe agent, the probe agent comprising a binding partner and a vehicle, wherein the binding partner is bound to the vehicle, wherein the target analyte in the fluid sample can react with the binding agent or the binding partner, wherein the vehicle comprises a plurality copies of a labeling molecules or an activating agent;

a detection chamber; and

a fluid passageway between the reaction chamber and the detection chamber,

wherein the device is adapted to move the reacted fluid sample from the reaction chamber to the detection chamber through the fluid passageway via capillary action, and

wherein the presence of the target analyte in the fluid sample at a concentration results in a change in the amount of probe agent that moves with the reacted fluid sample to the detection chamber, wherein the change is detectable in the detection chamber and dependent on at least a threshold of the concentration.

2. The device of claim 1, further comprising a fill chamber, wherein the fill chamber comprises internal surfaces.

3. The device of claim 1 or claim 2, wherein the internal surfaces comprise internal walls.

4. The device of claim 1 or claim 2, wherein the internal surfaces comprise surfaces of at least one supporting material.

5. The device of claim 1 or claim 2, wherein the reaction chamber comprises an opening to the atmosphere.

6. The device of any one of claims 1-5, wherein the reaction chamber comprises a blocking agent, wherein the blocking agent is capable of preventing non-specific

binding of proteins or lipidic particles to the internal surfaces of the reaction chamber.

7. The device of any one of claims 2-6, wherein the fill chamber comprises a blocking agent, wherein the blocking agent is capable of preventing non-specific binding of proteins or lipidic particles to the internal surfaces of the fill chamber.

8. The device of claim 6 or claim 7, wherein the blocking agent comprises at least one selected from a surfactant and a blocking protein.

9. The device of claim 8, wherein the blocking protein comprises bovine serum albumin.

10. The device of any one of claims 1-9, wherein the binding agent and the probe agent are bound to different internal surfaces of the reaction chamber.

11. The device of any one of claims 1-10, wherein the binding agent comprises at least one magnetic bead.

12. The device of claim 11, further comprising a magnetic field to serve to confine the binding agent in the reaction chamber.

13. The device of any one of claims 1-12, wherein the vehicle comprises from about 10 to about 100000 copies of an activating agent.

14. The device of any one of claims 1-13, wherein the activating agent is encapsulated within the vehicle.

15. The device of claim 14, wherein the vehicle comprises at least one lipidic particle.

16. The device of claim 14 or 15, wherein the activating agent is bound to the vehicle.

17. The device of claim 16, wherein the vehicle comprises at least one polymer.

18. The device of claim 17, wherein the polymer is a dendrimer.

19. The device of any one of claims 13-18, wherein an unactivated agent is immobilized in the reaction chamber, wherein the unactivated agent can bind to an unbound or unencapsulated activating agent.

20. The device of claim 20, wherein the unactivated agent comprises at least one magnetic bead.

21. The device of any one of claims 14-20, wherein the detection chamber comprises a liberating agent, wherein the liberating agent can liberate the activating agent from the vehicle.

22. The device of claim 21, wherein the liberating agent comprises at least one agent selected from a mild detergent, a lytic peptide, an enzyme, heating, cooling, ultrasonication and a light source together with a photochemically activated lysing agent which is incorporated into the vehicle.

23. The device of claim 23, wherein the mild detergent comprises one detergent selected from n-octyl-B-D-glucopyranoside, tween 20, brij 35 and triton X-100 ($C_{14}H_{22}O(C_2H_4O)_n$).

24. The device of claim 22, wherein the lytic peptide comprises one peptide selected from mellitin, and one of a class of phospholipases, a component of the complement system.

25. The device of claim 22, wherein the enzyme comprises one enzyme selected from a protease and trypsin.

26. The device of any one of claims 1-25, wherein the activating agent comprises a cofactor for an enzyme.

27. The device of claim 26, wherein the detection chamber comprises an apoenzyme which can be activated by the cofactor.

28. The device of claim 26 or claim 27, wherein the enzyme comprises glucose oxidase.

29. The device of claim 28, wherein the cofactor comprises flavin adenine dinucleotide.

30. The device of claim 29, wherein the detection chamber comprises apo-glucose oxidase.

31. The device of claim 26 or claim 27, wherein the enzyme comprises a glucose dehydrogenase.

32. The device of claim 31, wherein the cofactor comprises pyrolloquinoline quinone.

33. The device of claim 32, wherein the detection chamber comprises apo-glucose dehydrogenase.

34. The device of claim 31, wherein the cofactor comprises flavin adenine dinucleotide.

35. The device of any one of claims 1-34,, wherein the detection chamber further comprises an enzyme substrate.

36. The device of claim 35, wherein the enzyme substrate comprises an oxidizable substrate.

37. The device of claim 36, wherein the oxidizable substrate comprises one substrate selected from galactose, maltose, xylose, and acetic acid.

38. The device of claim 36, wherein the enzyme substrate comprises glucose.

39. The device of any one of claims 1-38, wherein the detection chamber further comprises at least one mediator.

40. The device of claim 39, wherein the mediator comprises one substance selected from dichlorophenolindophenol, phenazine ethosulphate, ferricyanide, ferrocene and complexes between transition metals and nitrogen-containing heteroatomic species.

41. The device of claim any one of claims 1-40, wherein the device further comprising a buffer capable of adjusting the pH of the sample.

42. The device of claim 41, wherein the buffer comprises a substance selected from phosphate, citrate, citraconate, mellitate, tris, pipes, mops, hepes, phthalate, imadazole.

43. The device of claim any one of claims 1-42, wherein the binding partner of the probe agent is adapted to bind to the binding agent.

44. The device of claim any one of claims 1-43, wherein the binding partner of the probe agent is adapted to bind to the target analyte.

45. The device of claim 44, wherein the target analyte is bound to the binding agent.

46. The device of any one of claims 1-45, wherein there is a vent in the distal end of the detection chamber.

47. The device of claim 46, wherein the vent can be opened by piercing an outer layer of the device.

48. The device of claim 46, wherein the vent can be opened by removing a portion of an outer layer of the device.

49. The device of any one of claims 1-48, wherein the detection chamber comprises at least two electrodes for detecting an electrochemical reaction in the detection chamber.

50. The device of claim 49, wherein at least one of the electrodes is formed from an electrically conductive layer, and further wherein there is a break in the electrically conductive layer that serves to define at least one edge of the electrode in the detection chamber.

51. The device of claim 49 or claim 50, wherein at least one electrode comprises palladium, platinum, gold, iridium, carbon, carbon mixed with binder, indium oxide, tin oxide or a mixture thereof.

52. The device of any one of claims 49-51, wherein a change in the amount of the probe agent in the detection chamber is detectable via an electrochemical reaction in the detection chamber.

53. A method of detecting a target analyte in a fluid sample, comprising:

delivering the fluid sample to the device of any one of claims 1-52, allowing a reaction to proceed in the reaction chamber between the binding agent and the probe agent, wherein the presence of the target analyte in the fluid sample at a concentration results in changes in the amount of probe agent bound in the reaction chamber and in the amount of unbound probe agent, wherein the changes are dependent on the concentration of the target analyte;

moving the reacted sample fluid from the reaction chamber into the detection chamber by capillary action such that the unbound probe agent moves to the detection chamber; and

detecting presence of the probe agent in the detection chamber via a detecting agent.

54. The method of claim 53, the delivering of the sample fluidto the device comprising delivering the sample to the reaction chamber through a fill chamber of the device.

55. The method of claim 54, wherein the delivering the sample fluid to the fill chamber comprising a capillary action.

56. The method of, any one of claims 53-55, wherein the detecting agent comprises an apo-enzyme.

57. The method of any one of claims 53-57, wherein one copy of the activating agent can activate at least one copy of the detecting agent.

58. The method of any one of claims 53-57, wherein the moving of the sample from the reaction chamber to the detection chamber comprising opening a vent.

59. The method of any one of claims 53-58, further comprising quantifying electrical signals received from the detection chamber, wherein the magnitude of the electrical signals is dependent on the concentration of the target analyte in the sample fluid.

60. A device for detecting a target analyte in a fluid sample substantially as herein described with reference to any one of the embodiments shown in figures 1-7.

61. A method of detecting a target analyte in a fluid sample substantially as herein described with reference to the accompanying drawings.