SUMMARY OF THE INVENTION

[0006] In one aspect, there is provided a test strip for a paper-based assay comprising, a substrate addition zone for receiving a substrate and a test zone, said test zone comprising a capture agent, wherein the substrate addition zone is located upstream of said test zone.

[0007] In one aspect, there is provided a paper-based enzyme assay comprising a test strip as described herein.

[0008] In one aspect, there is provided a method of detecting the presence of an analyte in a sample, said method comprising the steps of: a) contacting said sample onto said test zone of a test strip as described herein; b) dispensing a substrate onto the substrate addition zone; and c) detecting an emitted signal from said test zone to confirm the presence or absence of said analyte in said sample.

[0009] In one aspect, there is provided a method of detecting the presence of an analyte in a sample, said method comprising the steps of: a) contacting said sample onto said detector zone of a test strip as described herein; b) dispensing a substrate onto the substrate addition zone; and c) detecting an emitted signal from said test zone to confirm the presence or absence of said analyte in said sample.

[0009a] In one aspect, there is provided a test strip for a paper-based assay comprising, a substrate addition zone for receiving a substrate and a test zone, said test zone comprising a capture agent, wherein the substrate addition zone is located upstream of said test zone, wherein a detector agent is pre-dried onto an applicator, and wherein the applicator is applied onto the test zone.

DEFINITIONS

[0010] The term "antigen binding protein" as used herein refers to antibodies, antibody fragments and other protein constructs, such as domains, which are capable of binding to an antigen.

[0011] The term "antibody" is used herein in the broadest sense to refer to molecules with an immunoglobulin-like domain and includes monoclonal, recombinant, polyclonal, chimeric, humanised, bispecific and heteroconjugate antibodies; a single variable domain, a domain antibody, antigen binding fragments, immunologically effective fragments, single chain Fv, diabodies, Tandabs™, etc (for a summary of alternative "antibody" formats see Holliger and Hudson, Nature Biotechnology, 2005, Vol 23, No. 9, 1126-1136).

[0012] The phrase "single variable domain" refers to an antigen binding protein variable domain (for example, V_H, V_{HH}, V_L) that specifically binds an antigen or epitope independently of a different variable region or domain.

[0013] A "domain antibody" or "dAb" may be considered the same as a "single variable domain" which is capable of binding to an antigen. A single variable domain may be a

Claims

1. A test strip for a paper-based assay comprising, a substrate addition zone for receiving a substrate and a test zone, said test zone comprising a capture agent, wherein the substrate addition zone is located upstream of said test zone, wherein a detector agent is pre-dried onto an applicator, and wherein the applicator is applied onto the test zone.

2. The test strip according to claim 1, wherein the substrate addition zone and the test zone are in a spaced apart configuration.

3. The test strip according to claim 1, wherein the substrate addition zone and the test zone are in an adjacent configuration.

4. The test strip according to claim 1, wherein the substrate addition zone and the test zone are in an immediately adjacent configuration.

5. The test strip according to any one of claims 1 to 4, wherein the substrate addition zone and the test zone are not interposed by any other zone.

6. The test strip according to claim 1, wherein the substrate addition zone and the test zone are interposed by a detector zone.

7. The test strip according to any one of claims 1 to 6, wherein a sample is contacted with the test strip at the test zone.

8. The test strip according to any one of claims 1 to 7, wherein the detector agent is selected from the group consisting of antibodies, antigens, oligonucleotides and peptides, and wherein the detector agent is conjugated to an enzyme.

9. The test strip according to claim 8, wherein the enzyme is alkaline phosphatase, beta-galactosidase, glucose dehydrogenase and horseradish peroxidase.

10. The test strip according to any one of claims 1 to 9, wherein the test strip is a porous membrane.

11. The test strip according to claim 10, wherein the porous membrane is selected from the group consisting of nitrocellulose membrane, polyvinylidene fluoride (PVDF) membrane and filter paper.

12. The test strip according to claim 11, wherein the membrane is nitrocellulose membrane.

13. The test strip according to any one of claims 1 to 12, wherein the test zone is subdivided into two or more areas, each area comprising the same or different capture agent.

14. The test strip according to claim 13, wherein the two or more areas comprises an array.

15. The test strip according to claims 13 or 14, wherein the capture agent is selected from the group consisting of antibodies, antigens, oligonucleotides and peptides.

16. The test strip according to any one of claims 13 to 15, wherein the capture agent is mixed with a coloured marker to assist in the localization of the or each capture agent on said test strip.

17. The test strip according to any one of claims 1 to 16, wherein the test strip further comprises one or more control areas located within or without of the test zone.

18. The test strip according to any one of claims 1 to 17, wherein the test zone is marked on the test strip.

19. The test strip according to claim 18 wherein the test zone is marked on the test strip with a dye or outline.

20. The test strip according to claim 19, wherein the dye is a washable dye.

21. The test strip according to any one of claims 1 to 20, wherein the substrate is an enzymatic substrate.

22. The test strip according to claim 21, wherein the enzymatic substrate is BCIP, NBT or combined BCIP/NBT, TMB, DAB, glucose/potassium ferricyanide/Fe3+ or X-gal.

23. The test strip according to any one of claims 1 to 22, wherein the substrate is contacted with the test strip in an aqueous solution, polymer solution or a polymer gel.

24. The test strip according to any one of claims 1 to 23, wherein the substrate is dispensed on the underside of the test strip.

25. A paper-based enzyme assay comprising a test strip as defined in any of claims 1 to 24.

26. A method of detecting the presence of an analyte in a sample, said method comprising the steps of:
    a) contacting said sample onto said test zone of a test strip according to claim 7;
    b) dispensing a substrate onto the substrate addition zone; and
    c) detecting an emitted signal from said test zone to confirm the presence or absence of said analyte in said sample.

27. The method of claim 26, wherein the signal is a colourimetric signal.

28. The method according to claim 26, wherein the signal is a fluorescent signal.

29. The method according to claim 26, wherein the signal is a chemiluminescent signal.

30. The method according to claim 26, wherein the signal is an electrochemiluminescent signal.

31. The method according to claim 26, wherein the signal is an electrochemical signal.