Abstract: The present invention provides compositions, devices and methods suitable for the increased sensitivity and selectivity of binding assays thereby reducing false positive results without little or no reduction in the detection of true positives. The present invention is based on the novel discovery that an oxidative agent in the context of the device of the present invention results in decreased false positive reactivity with little or no reduction in true positive reactivity. The devices, compositions and methods of the present invention may be used, for example, to detect pathogens giving rise to endogenous urine antibodies include those organisms known to be causative agents in sexually-transmitted diseases and other diseases. The devices and methods of the present invention are also useful for various diagnostic procedures.
AMENDED CLAIMS
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Claims

1. A method for detecting the presence or absence of a target ligand in a sample, the method comprising:
   a. providing a labeled binding agent characterized by the ability to bind a target ligand;
   b. contacting the labeled binding agent of step a) with a sample suspected of containing the target ligand under conditions suitable for binding the target ligand to the labeled binding agent, wherein contact of the labeled binding agent with the sample occurs in the presence of an oxidizing agent; and
   c. assessing the binding of the target ligand to the labeled binding agent by i) comparing the false positive reactivity in the sample to an essentially identical control sample wherein the contact of the labeled binding agent with the sample does not occur in the presence of an oxidizing agent wherein a decreased number of false positives of the sample as compared to the control sample is indicative of a decrease in false positive reactivity and ii) in samples with a decrease in false positive reactivity detecting the presence or absence of the target ligand in the sample.

2. The method of Claim 1 wherein the sample is a biological sample.

3. The method of Claim 2 wherein the biological sample comprises a biological fluid selected from the group consisting of urine, blood, and oral fluid.

4. The method of Claim 1, wherein the target ligand is a protein.

5. The method of Claim 4, wherein the protein is an antibody.

6. The method of Claim 4, wherein the protein is a hormone.

7. The method of Claim 1, wherein the target ligand is a non-protein.

8. The method of Claim 7, wherein the non-protein is a lipid.

9. The method of Claim 7, wherein the non-protein is a carbohydrate.
10. The method of Claim 1 wherein the target ligand is an antibody to an HIV antigen.

11. The method of Claim 1 wherein the labeled binding agent is attached to a solid support suitable for binding the target ligand to the labeled binding agent on said support.

12. The method of Claim 1 wherein the labeled binding agent is movably supported on a surface.

13. The method of Claim 12 wherein a chromatographic test strip comprises said surface.

14. The method of Claim 12 wherein an immunochemical sampling device comprises said surface.

15. The method of Claim 13 wherein a lateral flow device comprises the chromatographic strip.

16. The method of Claim 13 wherein the sample is applied to the chromatographic test strip at a sample site and transported by sorption or capillary action along said strip prior to contact of the labeled binding agent with the sample at a conjugation site.

17. The method of Claim 1 wherein the oxidizing agent is selected from the group consisting of hydrogen peroxide, urea hydrogen peroxide, potassium chlorate, thimerosal, potassium iodate, potassium superoxide, potassium permanganate, sucrose containing glucose oxidase, calcium bromate, potassium chromate, potassium nitrate, potassium perchlorate and potassium permanganate.

18. The method of Claim 17 wherein the oxidizing agent is hydrogen peroxide and the source of the hydrogen peroxide is urea hydrogen peroxide.

19. The method of Claim 1 wherein contact of the labeled binding agent with the sample further occurs in the presence of a stabilizing agent.

20. The method of Claim 19 wherein the stabilizing agent comprises potassium stannate.
21. The method of Claim 1 wherein the labeled binding agent comprises a colloidal gold conjugate.

22. The method of Claim 1 wherein the labeled binding agent comprises a Protein A conjugate.

23. The method of Claim 1 wherein the oxidizing agent is solubilized from a solid dried on the test strip.

24. The method of Claim 23 wherein the oxidizing agent is dried on the test strip at the conjugation site prior to applying said sample.

25. The method of Claim 23 wherein the oxidizing agent is dried on the test strip at the sample site prior to applying said sample.

26. An immunochemical sampling device enabling detection of a target ligand in a biological sample, the device comprising a chromatographic test strip, the chromatographic test strip comprising:
   a. a sample application zone;
   b. a conjugate zone comprising a movably supported, labeled first binding agent that binds a target ligand of interest;
   c. an analysis zone comprising a second binding agent immobilized therein which specifically binds the target ligand of interest; and
   d. optionally, a control zone;

wherein, said sample application zone, conjugate zone, analysis zone, and control zone define a flow path for the sample and wherein, the chromatographic test strip comprises an oxidizing agent, or oxidizing agent source thereof, movably supported on the test strip so that contact of the labeled first binding agent with the sample occurs in the presence of the oxidizing agent and wherein the presence of said oxidizing agent results in the decrease of false positive reactions as compared to a control sample.
27. The immunochemical sampling device of Claim 26 wherein the biological sample comprises a biological fluid selected from the group consisting of urine, blood, and oral fluid.

28. The immunochemical sampling device of Claim 26 wherein the target ligand is an antibody to an HIV antigen.

29. The immunochemical sampling device of Claim 26 wherein a lateral flow device comprises the chromatographic strip.

30. The immunochemical sampling device of Claim 26 wherein the oxidizing agent is selected from the group consisting of hydrogen peroxide, potassium chlorate, potassium bromate, potassium iodate, potassium periodate, potassium superoxide, potassium permanganate, glucose oxidase, calcium bromate, potassium chromate, potassium nitrate, potassium perchlorate and potassium manganate.

31. The immunochemical sampling device of Claim 26 wherein the oxidizing agent is hydrogen peroxide and the source of the hydrogen peroxide is urea hydrogen peroxide.

32. The immunochemical sampling device of Claim 26 further wherein the oxidizing agent is dried on the chromatographic test strip.

33. The immunochemical sampling device of Claim 30 wherein the oxidizing agent further comprises a stabilizing agent.

34. The immunochemical sampling device of Claim 33 wherein the stabilizing agent comprises potassium stannate.

35. The immunochemical sampling device of Claim 26 wherein the labeled first binding agent comprises a colloidal gold conjugate.

36. The immunochemical sampling device of Claim 26 wherein the labeled first binding agent comprises a Protein A conjugate.
37. The immunochemical sampling device of Claim 26 wherein the sample application zone comprises the oxidizing agent, or oxidizing agent source thereof, dried on the test strip.

38. The immunochemical sampling device of Claim 26 wherein the conjugate zone comprises the oxidizing agent, or oxidizing agent source thereof, dried on the test strip.

39. The method of Claim 26, wherein the target ligand is a protein.

40. The method of Claim 39, wherein the protein is an antibody.

41. The method of Claim 39, wherein the protein is a hormone.

42. The method of Claim 26, wherein the target ligand is a non-protein.

43. The method of Claim 42, wherein the non-protein is a lipid.

44. The method of Claim 42, wherein the non-protein is a carbohydrate.

45. The immunochemical sampling device of Claim 28 wherein the test zone comprises an HIV-1 gp41 synthetic peptide.

46. The immunochemical sampling device of Claim 28 wherein the test zone comprises an HIV-1 gp41 recombinant protein.

47. The immunochemical sampling device of Claim 28 wherein the test zone comprises an HIV-2 gp36 synthetic peptide.

48. The immunochemical sampling device of Claim 28 wherein the test zone comprises an HIV-2 gp36 recombinant protein.

49. The immunochemical sampling device of Claim 26 wherein the control zone comprises Protein A.
50. The immunochemical sampling device of Claim 26 wherein the control zone comprises a goat anti-human IgG.
STATEMENT UNDER ARTICLE 19(1)

Applicant has elected to amend Claim 1 and 26 of the subject application to include better distinguish over the cited art.

Applicant has amended the claims to recite additional steps including the determining any decrease on false positive reactions as compared to a control sample. Support for this modification exists within the Specification at least at Example 1.

With regard to the references cited in the International Search Report and Written Opinion, Applicant respectfully submits that the claims as currently amended disclose a novel invention involving inventive step as required under Articles 33(2) and 33(3) PCT, respectively. Applicant respectfully submits that Claims Claim 1 – 50 are in condition for allowance. A replacement sheet for Claims 1 – 50 accompanies this paper per PCT Rule 46.