0.95 centimeters and a length of 1.3 centimeters was placed into the pre-cut area on the top strip using tape.

EXAMPLE 2

[0076] Laminated assay devices were formed in the manner described in Example 1. Thereafter, test samples were applied to the sample pad of the devices in an amount ranging from 10 to 100 microliters. The test sample contained an LH antigen in a concentration of 100 nanograms per milliliter in PBS buffer (pH of 7.42). The assay was allowed to develop until the wicking pad had absorbed almost all of the fluid from the test sample, which occurred in about 2 to about 15 minutes. A TMB substrate solution was then applied to the working electrode in an amount ranging from 10 to 30 microliters. Thereafter, a potential of about 0.1 to 0.3 volts was applied using a multi-channel VMP potentiostat commercially available from Perkin-Elmer, Inc. of Wellesley, Mass. The current was recorded after about 20 seconds, and effectively indicated the presence of the LH antigen.

[0077] While the invention has been described in detail with respect to the specific embodiments thereof, it will be appreciated that those skilled in the art, upon attaining an understanding of the foregoing, may readily conceive of alterations to, variations of, and equivalents to these embodiments. Accordingly, the scope of the present invention should be assessed as that of the appended claims and any equivalents thereto.

1. An assay device for detecting the presence or quantity of an analyte residing in a test sample, said assay device comprising a first substrate defining a first surface on which is disposed a detection working electrode, said assay device further comprising a second substrate defining a second surface on which is disposed an auxiliary electrode, said first substrate and said second substrate being at least partially laminated together so that said first surface faces said second surface, wherein said detection working electrode is capable of generating a measurable detection current that is proportional to the amount of the analyte within the test sample.

2. An assay device as defined in claim 1, wherein said first substrate, said second substrate, or combinations thereof, are formed from an insulative material.

3. An assay device as defined in claim 1, wherein said auxiliary electrode is a counter electrode, reference electrode, or combinations thereof.

4. An assay device as defined in claim 1, wherein both a counter electrode and a reference electrode are disposed on said second surface of said second substrate.

5. An assay device as defined in claim 1, wherein said detection working electrode is treated with an affinity reagent.

6. An assay device as defined in claim 5, wherein said detection working electrode is treated with said affinity reagent before said first substrate and said second substrate are at least partially laminated together.

7. An assay device as defined in claim 5, wherein said affinity reagent comprises a specific binding capture ligand for the analyte.

8. An assay device as defined in claim 7, wherein said specific binding capture ligand is selected from the group consisting of antigens, haptens, aptamers, antibodies, and complexes thereof.

9. An assay device as defined in claim 5, wherein said affinity reagent comprises a redox mediator.

10. An assay device as defined in claim 9, wherein said redox mediator is selected from the group consisting of oxygen, ferrocene derivatives, quinones, ascorbic acids, redox polymers with metal complexes, glucose, redox hydrogel polymers, and organometallic complexes.

11. An assay device as defined in claim 1, wherein a redox label is incorporated into the assay device for directly or indirectly binding to the analyte.

12. An assay device as defined in claim 11, wherein said redox label is an enzyme selected from the group consisting of alkaline phosphatase, horseradish peroxidase, glucose oxidase, beta-galactosidase, urease, and combinations thereof.

13. An assay device as defined in claim 11, wherein said redox label is used in conjunction with a particle modified with a specific binding member for the analyte.

14. An assay device as defined in claim 1, wherein a sample channel is formed on said first substrate, said second substrate, or combinations thereof.

15. An assay device as defined in claim 1, wherein the assay device comprises a porous membrane capable of being placed in fluid communication with the test sample.

16. An assay device as defined in claim 1, wherein a calibration working electrode is also disposed on said first surface of said first substrate.

17. An assay device for detecting the presence or quantity of an analyte residing in a test sample, said assay device comprising a first substrate defining a first surface on which is disposed a detection working electrode treated with an affinity reagent, said assay device further comprising a second substrate defining a second surface on which is disposed a counter electrode, a reference electrode, or combinations thereof, said first substrate and said second substrate being at least partially laminated together so that said first surface faces said second surface, wherein said detection working electrode is capable of generating a measurable detection current that is proportional to the amount of the analyte within the test sample.

18. An assay device as defined in claim 17, wherein said first substrate, said second substrate, or combinations thereof, are formed from an insulative material.

19. An assay device as defined in claim 17, wherein both a counter electrode and a reference electrode are disposed on said second surface of said second substrate.

20. An assay device as defined in claim 17, wherein said affinity reagent comprises a specific binding capture ligand for the analyte, a redox mediator, or combinations thereof.

21. A method for forming an assay device, said method comprising:

treating a detection working electrode disposed on a first surface of a first substrate with an affinity reagent; and

thereafter, at least partially laminating said first substrate to a second substrate, said second substrate defining a second surface on which is disposed an auxiliary electrode, wherein said first surface of said first substrate faces said second surface of said second substrate.

22. A method as defined in claim 21, wherein said first substrate, said second substrate, or combinations thereof, are formed from an insulative material.