MACHINE READABLE DIAGNOSTIC TEST DEVICES AND METHODS AND APPARATUS TO MAKE AND/OR PROCESS THE SAME

RELATED APPLICATIONS

[0001] This patent claims priority to U.S. Provisional Patent Application Serial No. 63/129,375, which was filed on December 22, 2020 and to U.S. Provisional Patent Application Serial No. 63/032,093, which was filed on May 29, 2020. U.S. Provisional Patent Application Serial No. 63/129,375 and U.S. Provisional Patent Application Serial No. 63/032,093 are hereby incorporated herein by reference in their entireties.

FIELD OF THE DISCLOSURE

[0002] This disclosure relates generally to biosensors, and, more particularly, to a machine readable diagnostic test devices and methods and apparatus to make and/or process the same.

BACKGROUND

[0003] A biosensor (e.g., a lateral flow device, such as a lateral flow assay (LFA)) is a device that is capable of detecting a condition, disease, etc., in a human or animal based on a sample (e.g., a blood sample, a saliva sample, a urine sample, etc.) from the human or animal. LFAs have been used to detect the presence of a target analyte to determine pregnancy, presence of HIV, presence of Ebola, presence of different toxins, etc.

SUMMARY

[0003a] According to a first aspect of the present invention, there is provided a lateral flow assay device comprising:

a conjugate pad including conjugates corresponding to a target analyte in a biological sample, the conjugates labeled with an enzyme;

a porous media including a first zone and a second zone,

the first zone including at least one of immobilized antigens corresponding to the target analyte or immobilized antibodies corresponding to the target analyte,

the second zone laterally displaced from the first zone along a longitudinal axis of the lateral flow assay device,

the porous media to propagate a flow of the biological sample, the conjugates with the enzyme, and a liquid buffer along the porous media, and

a first electrode to contact the porous media in the first zone;

a second electrode to contact the porous media in the second zone, the first and second electrodes to detect an electrical signal when the target analyte is present in the biological sample and the enzyme reacts with the liquid buffer; and

a positionable flow arrestor to impede the flow in the second zone.

[0003b] According to a second aspect of the present invention, there is provided an apparatus for use with a fluid sample, the apparatus comprising:

a porous media;

a wicking pad in contact with the porous media; and

a switch including a flow arrestor to at least one of compress or shear the porous media to at least one of reduce or stop flow of liquid toward the wicking pad.

BRIEF DESCRIPTION OF THE DRAWINGS

[0004] FIG. 1A is an example environment including an example machine readable lateral flow immunoassay generator to generate a machine readable lateral flow immunoassay described in conjunction with examples disclosed herein.

[0005] FIG. 1B is a side view of the example machine readable lateral flow immunoassay of FIG. 1A.

[0006] FIG. 2A illustrates an example implementation of part the machine readable lateral flow immunoassay of FIG. 1A.

What Is Claimed Is:

1. A lateral flow assay device comprising:

a conjugate pad including conjugates corresponding to a target analyte in a biological sample, the conjugates labeled with an enzyme;

a porous media including a first zone and a second zone,

the first zone including at least one of immobilized antigens corresponding to the target analyte or immobilized antibodies corresponding to the target analyte,

the second zone laterally displaced from the first zone along a longitudinal axis of the lateral flow assay device,

the porous media to propagate a flow of the biological sample, the conjugates with the enzyme, and a liquid buffer along the porous media, and

a first electrode to contact the porous media in the first zone;

a second electrode to contact the porous media in the second zone, the first and second electrodes to detect an electrical signal when the target analyte is present in the biological sample and the enzyme reacts with the liquid buffer; and

a positionable flow arrestor to impede the flow in the second zone.

2. The lateral flow assay device of claim 1, further including a wicking pad coupled to the porous media, wherein the flow arrestor is to at least one of compress or shear the porous media to at least one of reduce or stop the flow toward the wicking pad.

3. The lateral flow assay device of claim 2, wherein the flow arrestor includes a switch that is movable from a first position to a second position to at least one of compress or shear the porous media.

4. The lateral flow assay device of claim 3, wherein movement of the switch to the second position causes the first electrode and the second electrode to contact the porous media.

5. The lateral flow assay device of claim 3, wherein the switch is spaced a first distance from the porous media in the first position and spaced a second distance from the porous media in the second position, the second distance less than the first distance.

6. The lateral flow assay device of claim 3, further including a circuit board, the first electrode and the second electrode coupled to the circuit board, the switch to move at least a portion of the circuit board proximate to the porous media.

7. The lateral flow assay device of claim 6, wherein the circuit board is pivotable, the switch to pivot the circuit board when the switch is moved.

8. The lateral flow assay device of any of claims 2-7, wherein the flow arrestor includes a first flow arrestor and a second flow arrestor.

9. The lateral flow assay device of claim 8, wherein the first flow arrestor is to at least one of compress or shear the porous media in the first zone and the second flow arrestor is to at least one of compress or shear the porous media in the second zone.

10. The lateral flow assay device of claim 9, wherein the first electrode and the second electrode are positioned between the first flow arrestor and the second flow arrestor.

11. The lateral flow assay device of any of claims 1-10, wherein the flow arrestor includes a chemical substance that is to form a barrier when wetted.

12. The lateral flow assay device of any of claims 1-11, further including an antenna in circuit with the first electrode and the second electrode, the antenna to transmit a wireless signal representative of the electrical signal to an external device.

13. The lateral assay device of any of claims 1-12, further including:

an antenna in circuit with the first electrode and the second electrode, the antenna is to receive a power signal from the external device;

a sensor to measure at least one of a voltage or a current between the first electrode and the second electrode, the sensor operable based on the power signal, the at least one of the voltage or the current being the electrical signal; and

a processor operable based on the power signal, the processor to:

compare the at least one of the voltage or the current to a threshold; and

when the at least one of the voltage or the current is more than the threshold, identify that the target analyte is present in the biological sample,

the antenna to wirelessly transmit results to the external device.

14. The lateral assay device of any of claims 1-13, wherein the electrical signal is generated by an enzymatic reaction.

15. The lateral assay device of any of claims 1-14, wherein the lateral assay device is batteryless.

16. An apparatus for use with a fluid sample, the apparatus comprising:

a porous media;

a wicking pad in contact with the porous media; and

a switch including a flow arrestor to at least one of compress or shear the porous media to at least one of reduce or stop flow of liquid toward the wicking pad.

17. The apparatus of claim 16, wherein the switch is moveable between a first position and a second position to at least one of compress or shear the porous media.

18. The apparatus of claim 17, further including an electrode, the switch to cause the electrode to contact the porous media while the switch is in the second position.

19. The apparatus of claims 17 or 18, wherein the switch is spaced a first distance from the porous media in the first position and spaced a second distance from the porous media in the second position, the second distance less than the first distance.

20. The apparatus of any of claims 16-19, further including a reservoir including a liquid buffer, the switch to cause the reservoir to release the liquid buffer onto the porous media.

21. The apparatus of any of claims 16-20, wherein the flow arrestor is to shear the porous media by cutting a portion of a depth of the porous media.

~~22. A non-visual indicating biosensor comprising:~~

~~a conjugate pad including conjugates to attach to a target analyte in a biological sample, the conjugates labeled with an enzyme;~~

~~a porous media having a first end and a second end, the conjugate pad coupled to a first end of the porous media;~~

~~at least one of immobilized antigens corresponding to the target analyte or immobilized antibodies corresponding to the target analyte coupled to porous media between the first end and the second end;~~

~~the porous media implementing a bioelectrochemical cell between the first end and the second end downstream from the at least one of immobilized antigens or immobilized antibodies, the bioelectrochemical cell to generate an electrical signal based on a reaction between a buffer and the enzyme when the target analyte is present in the biological sample;~~

~~a wicking pad to draw fluid along the porous media; and~~

~~an antenna to generate a wireless signal to communicate a presence of the electrical signal.~~

~~23. The non-visual indicating biosensor of claim 22, further a circuit board selectively engageable with the porous media, the circuit board including:~~

~~a first electrode; and~~

~~a second electrode downstream from the first electrode, the electrical signal generated based on at least one of a voltage differential between the first electrode and the second electrode or a current between the first electrode and the second electrode.~~

~~24. The non-visual indicating biosensor of claim 23, further including a processor to:~~

~~compare a magnitude of the voltage differential or the current to a threshold; and~~

~~identify that the target analyte is present in the biological sample when the magnitude satisfies the threshold.~~

~~25. The non-visual indicating biosensor of claim 24, wherein the antenna is to receive a power signal to operate the antenna and the processor.~~

~~26. The non-visual indicating biosensor of any of claims 22-25, further including a switch moveable between a first position and a second position, wherein movement of the switch from the first position to the second position changes the non-visual indicating biosensor from a first operating mode to a second operating mode.~~

27. The non-visual indicating biosensor of claim 26, wherein the switch includes a flow arrestor to at least one of cut or compress the porous media when the switch is in the second position, liquid flowable to the wicking pad in the first operating mode, and liquid flow arrested in the second operating mode.

28. The non-visual indicating biosensor of claims 26 or 27, wherein an electrode moves from a disengagement with the porous media to engagement with the porous media as the switch moves from the first position to the second position.

29. The non-visual indicating biosensor of any of claims 22-28, wherein the antenna is to:
sense a first electromagnetic field from an external device at a first time;
provide identification data of the non-visual indicating biosensor to the external device in response to sensing the first electromagnetic field;
sense a second electromagnetic field from the external device at a second time; and
provide the wireless signal to communicate the presence of the electrical signal to the external device in response to sensing the second electromagnetic field.

30. The non-visual indicating biosensor of claim 29, wherein the antenna is to:
sense a third electromagnetic field from the external device at a third time, the third time between the first time and the second time; and
provide the identification data to the external device in response to sensing the third electromagnetic field.

31. The non-visual indicating biosensor of claims 22 or 26-30, wherein the antenna is to provide a signal corresponding to at least one of a voltage or a current generated at the porous media, the at least one of the voltage of the current caused by an enzymatic reaction between the enzyme and the buffer.

32. At least one non-transitory computer readable medium comprising instructions that, when executed, cause one or more processors to at least:
access identification information received from a lateral flow assay device at a first time;

implement a counter to monitor a first time period and a second time period, the first time period and the second time period based on the identification information;

order a change from a first operating mode of the lateral flow assay device to a second operating mode of the lateral flow assay device after the first time period and for the second time period;

access at least one of a voltage value or a current value received from the lateral flow assay device via a near field communication (NFC) at a second time, the second time after the second time period;

perform a comparison of the voltage value or the current value to a threshold, the threshold based on the identification information; and

identify a diagnostic test result based on the comparison.

33. The at least one non-transitory computer readable medium of claim 32, wherein the instructions cause the one or more processors to:

determine a geolocation of the lateral flow assay device; and

tag the geolocation of the lateral flow assay device with the diagnostic test result.

34. The at least one non-transitory computer readable medium of claim 32, wherein the lateral flow assay device is a first lateral flow assay device, the identification information is first identification information, the voltage value is a first voltage value, the current value is a first current value, the comparison is a first comparison, the threshold is a first threshold, and the diagnostic test result is a first diagnostic test result, the instructions to cause the one or more processors to:

access second identification information received from a second lateral flow assay device via the NFC at a third time;

use the counter to monitor a third time period and a fourth time period, the third time period and the fourth time period based on the second identification information;

order a change from a first operating mode of the second lateral flow assay device to a second operating mode of the second lateral flow assay device after the third time period and for the fourth time period;

access at least one of a second voltage value or a second current value received from the second lateral flow assay device via the NFC at a fourth time, the fourth time after the fourth time period;

perform a second comparison of the second voltage value or the second current value to a second threshold, the second threshold based on the second identification information; and

identify a second diagnostic test result based on the second comparison.

35. The at least one non-transitory computer readable medium of claim 34, wherein one or more of (1) the third time period at least partially overlaps with one or more of the first time period or the second time period, or (2) the fourth time period at least partially overlaps with one or more of the first time period or the second time period.

36. The at least one non-transitory computer readable medium of claim 32, wherein the identification information is first identification information and the lateral flow assay device is a first lateral flow assay device, the instructions to cause the one or more processors to prior to the ordering of the change from the first operating mode to the second operating mode, access second identification information received from a second lateral flow assay device via the NFC at third first time after the first time and before the second time.

37. The at least one non-transitory computer readable medium of claim 36, wherein the instructions cause the one or more processors to, when the first identification information matches the second identification information, order the change from the first operating mode to the second operating mode, the first lateral flow device being the second lateral flow device.

38. The at least one non-transitory computer readable medium of claim 36, wherein when the first identification information does not match the second identification information, the instructions cause the one or more processors to:
display an indication that the second lateral flow device is not the first lateral flow device; and
prompt a user to scan the first lateral flow device via the NFC.

39. The at least one non-transitory computer readable medium of claim 32, wherein the identification information is first identification information, the instructions to cause the one or more processors to, when second identification information that matches the first

identification information has not been obtained from the lateral flow assay device within the first time period, tag the diagnostic test result as void.

40. The at least one non-transitory computer readable medium of claim 32, wherein the instructions cause the one or more processors to tag the diagnostic test result as void when a confirmation of the change from the first operating mode to the second operating mode has not been obtained within the second time period.

41. The at least one non-transitory computer readable medium of any of claims 32-40, wherein the at least one of the voltage or the current is wirelessly detected by the NFC.

42. The at least one non-transitory computer readable medium of claim 32, wherein the instructions cause the one or more processors to wirelessly transmit the diagnostic test result and corresponding patient data to at least one of a remote database or a remote server.

43. At least one non-transitory computer readable medium comprising instructions that, when executed, cause one or more processors to at least:

access first identification information received from a lateral flow assay device via a near-field communication (NFC) scan at a first time;

implement a counter to monitor a first time period, the first time period based on the identification information;

before the first time period ends, access second identification information via a second NFC scan at a second time after the first time;

compare the first identification information to the second identification information;

when the first identification information matches the second identification information, access at least one of a voltage value or a current value received from the lateral flow assay device via a third NFC scan at a third time, the third time after the second time; and

identify a diagnostic test result based on the at least one of the voltage value of the current value.

44. At least one non-transitory computer readable medium comprising instructions that, when executed, cause one or more processors to at least:

access identification information corresponding to a lateral flow assay device;

~~implement a counter to monitor a time period;~~

~~instruct a user to scan the lateral flow assay using a near field communication (NFC) after the time period;~~

~~access at least one of a voltage value or a current value received from the lateral flow assay device via the scan;~~

~~perform a comparison of the voltage value or the current value to a threshold, the threshold based on the identification information; and~~

~~determine a diagnostic test result based on the comparison.~~

~~45. The at least one non-transitory computer readable medium of claim 44, wherein the instructions cause the one or more processors to guide the user to:~~

~~apply at least one of a sample or a buffer to the lateral flow assay device; and~~

~~implement the counter after the user has confirmed that the at least one of the sample or the buffer was applied.~~

~~46. The at least one non-transitory computer readable medium of claim 44, wherein the instructions cause the one or more processors to instruct the user to scan the lateral flow assay using the NFC to obtain the identification information.~~

~~47. The at least one non-transitory computer readable medium of claim 44, wherein the instructions cause the one or more processors to instruct a user to scan the lateral flow assay using the NFC at a time prior to the access of the at least one of the voltage value or the current value.~~

~~48. The at least one non-transitory computer readable medium of claim 47, wherein the identification information is first identification information, the instruction to cause the one or more processors to:~~

~~access second identification information via the NFC in response to the scan at the second time;~~

~~compare the second identification information to the first identification information; and~~

~~alert a user to an error when the second identification does not match the first identification information.~~

49. A method for determining a presence or absence of a target analyte in a biological sample, the method comprising:

instructing a user via an interface of a user device to apply the biological sample to a lateral flow device;

generating, by executing instructions with a processor of the user device, a test result by determining whether the target analyte is present in the biological sample based on an electrical signal wirelessly received from the lateral flow device; and

transmitting, from the user device, the test result to at least one of an external server or an external database.

50. The method of claim 49, wherein the electrical signal corresponds to an enzymatic reaction on the lateral flow device.

51. The method of claim 49, further including instructing the user via the interface to take an action to arrest flow on the lateral flow device.

52. The method of claim 51, wherein arresting the flow strengthens the electrical signal.

53. The method of claim 51, further including implementing a timer via the user device, wherein the instructing of the user to take the action to arrest flow is based on an output of the timer.

54. The method of claim 49, wherein the generating the test result includes comparing, by executing instructions with the processor, the electrical signal to a threshold, the electrical signal being at least one of a voltage or a current generated at a porous membrane of the lateral flow device.

55. The method of claim 49, further including preventing display the test results on the interface of the user device to preserve privacy of a patient.

56. The method of claim 49, further including obtaining, by executing instructions with the processor, a first identifier from the lateral flow device at a first time prior to instructing the user to apply the biological sample and obtaining, by executing instructions with the

~~processor, a second identifier from the lateral flow device prior to obtaining the electrical signal.~~

~~57. The method of claim 56, further including identifying, by executing instructions with the processor, an algorithm based on the first identifier, the determining whether the target analyte is present in the biological sample being based on the algorithm.~~

~~58. The method of claim 56, further including validating, by executing instructions with the processor, that the electrical signal corresponds to the lateral flow device when the first identifier matches the second identifier.~~

~~59. The method of claim 49, wherein the transmitting of the test result includes transmitting the test result in conjunction with patient information and geolocation information.~~