1. 'IMMUNOASSAY RAPID DIAGNOSTIC TEST UNIVERSAL ANALYSIS DEVICE, SYSTEM, METHOD AND COMPUTER READABLE MEDIUM'

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The following specification (particularly) describes the nature of the invention (and the manner in which it is to be performed):

WE CLAIM:

1.   A device for analysis of various test cassettes for immunoassay rapid diagnostic tests, the device comprising:

one or more walls defining an enclosed chamber which is adapted to selectively receive the various cassettes one at a time, each as a loaded cassette, in selectively removable relation;

two or more light emitting diodes (LEDs) within the chamber, which comprise at least one reflection light emitting diode (LED) adapted to illuminate the loaded cassette when lit, and at least one fluorescent LED adapted to fluoresce the loaded cassette when lit;

an imaging element inside the chamber which automatically captures a first image of the loaded cassette when at least one of the LEDs is lit; and

at least one processor which, with reference to the first image and to a database that comprises at least one test protocol associated with each of the various test cassettes, automatically identifies an applicable one said test protocol for the loaded cassette;

wherein the processor automatically, after incubation of the loaded cassette and depending on the applicable one said test protocol:

(i)   determines when the first image captures a post-incubation test signal from the loaded cartridge; and otherwise

(ii)   lights the fluorescent LED to generate the test signal by emission, or the reflection LED to generate the test signal by reflection, from the loaded cassette and uses the imaging element to capture a second image of the loaded cassette and of the test signal; and

wherein the processor automatically provides the test signal, in the first image or the second image, for analysis of the loaded cassette.

2. A device according to claim 1, wherein the processor automatically analyzes the test signal with reference to the applicable one said test protocol for the loaded cassette.

3. A device according to claim 2, wherein the test signal comprises a test line signal corresponding to a test line present on the loaded cassette after incubation, and the processor automatically measures an intensity of the test line signal.

4. A device according to any one of claims 2 to 3, wherein the test signal comprises a control line signal corresponding to a control line present on the loaded cassette after incubation, and the processor automatically measures an intensity of the control line signal.

5. A device according to any one of claims 2 to 4, wherein the applicable one said test protocol comprises a predetermined assay threshold value, and wherein the processor analyzes the test signal with reference to the assay threshold value to automatically determine a diagnostic test result associated with the loaded cassette.

6. A device according to claim 5, further comprising an output device which automatically presents the diagnostic test result to a user of the device.

7. A device according to any one of claims 2 to 6, further comprising a memory onboard the device which stores one or more sets of executable instructions to encode the processor to automatically analyze the test signal as aforesaid.

8. A device according to any one of claims 1 to 6, further comprising a memory onboard the device which stores one or more sets of executable instructions to encode the processor to automatically identify the applicable one said test protocol as aforesaid.

9. A device according to any one of claims 1 to 6, further comprising a memory onboard the device which stores the database.

10. A device according to any one of claims 1 to 8, further comprising a communications element onboard the device which the processor automatically uses to remotely reference the database as aforesaid.

11. A device according to any one of claims 1 to 10, further comprising at least one optical filter, and wherein (i) the processor automatically ensures the optical filter is moved to an engaged position between the loaded cassette and the imaging element, before lighting a corresponding one said emission LED, and the imaging element then captures the test signal through the optical filter, and (ii) the processor automatically ensures the optical filter is moved to a disengaged position clear of the imaging element, before lighting the reflection LED, and the imaging element then captures the test signal clear of the optical filter.

12. A device according to claim 11, wherein the optical filter is mounted on a sliding switch which slides the optical filter between the engaged position and the disengaged position.

13. A device according to claim 11, wherein the optical filter is mounted on a rotatable mechanism which rotates the optical filter between the engaged position and the disengaged position.

14. A device according to any one of claims 11 to 13, wherein the optical filter is an optical band pass filter.

15. A device according to any one of claims 1 to 10, further comprising an optical long pass filter positioned between the loaded cassette and the imaging element, and wherein the imaging element captures the test signal through the optical long pass filter.

16. A device according to any one of claims 1 to 15, wherein said at least one reflection LED comprises at least one white LED.

17.   A device according to any one of claims 1 to 16, wherein said at least one fluorescent LED comprises at least one ultraviolet LED.

18.   A device according to any one of claims 1 to 17, wherein said at least one fluorescent LED comprises at least one colored LED.

19.   A device according to any one of claims 1 to 18, wherein the processor identifies the applicable one said test protocol with reference to one or more of the following which are captured in the first image, and stored in the database, for the loaded cassette: one or more cassette dimensions, one or more cassette shapes, one or more detection line dimensions, one or more control line dimensions, one or more detection areas, one or more membrane areas, one or more control line positions, one or more test line positions, one or more cassette colors, one or more line colors, manufacturer indicia, product indicia, brand name indicia, application indicia, disease indicia, test type indicia, incubation time indicia, expected results indicia, barcodes, two-dimensional barcodes, labels, and other printed and written indicia.

20.   A device according to any one of claims 1 to 19, wherein the processor additionally identifies the applicable one said test protocol with reference to one or more of the following which are received from the loaded cassette, and stored in the database for the loaded cassette: magnetically stored data, fluorescence data, and radioactive signal data.

21.   A device according to any one of claims 1 to 20, adapted for analysis of various lateral flow cassettes as the test cassettes.

22.   A device according to any one of claims 1 to 21, adapted for use with a cellular telephone to provide at least one of said imaging element and said processor.

23.   A device according to claim 22, wherein left and right channel audio signals from the cellular telephone are adapted to turn the reflection LED and the fluorescent LED on and off.

24.   A device according to any one of claims 1 to 21, wherein the imaging element comprises one or more scanning heads.

25.   A system for analysis of various test cassettes for immunoassay rapid diagnostic tests, the system comprising:

one or more walls defining an enclosed chamber which is adapted to selectively receive the various cassettes one at a time, each as a loaded cassette, in selectively removable relation;

two or more light emitting diodes (LEDs) within the chamber, which comprise at least one reflection light emitting diode (LED) adapted to illuminate the loaded cassette when lit, and at least one fluorescent LED adapted to fluoresce the loaded cassette when lit;

a database that comprises at least one test protocol associated with each of the various test cassettes;

a cellular telephone received by the walls of the chamber, with the cellular telephone comprising: a camera inside the chamber which automatically captures a first image of the loaded cassette when at least one of the LEDs is lit; and at least one processor which, with reference to the first image and in communication with the database, automatically identifies an applicable one said test protocol for the loaded cassette;

wherein the processor automatically, after incubation of the loaded cassette and depending on the applicable one said test protocol:

(i)   determines when the first image captures a post-incubation test signal from the loaded cartridge; and otherwise

(ii)   lights the fluorescent LED to generate the test signal by emission, or the reflection LED to generate the test signal by reflection, from the loaded cassette and uses the imaging element to capture a second image of the loaded cassette and of the test signal; and

wherein the processor automatically provides the test signal, in the first image or the second image, for analysis of the loaded cassette.

26. A system according to claim 25, wherein left and right channel audio signals from the cellular telephone are adapted to turn the reflection LED and the fluorescent LED on and off.

27. A method for analysis of various test cassettes for immunoassay rapid diagnostic tests, the method comprising:

a receiving step of selectively receiving the various cassettes one at a time, each as a loaded cassette, in selectively removable relation within an enclosed chamber which is defined by one or more walls;

a light emitting diode (LED) step of providing two or more LEDs within the chamber, which comprise at least one reflection LED adapted to illuminate the loaded cassette when lit, and at least one fluorescent LED adapted to fluoresce the loaded cassette when lit;

an imaging step of automatically capturing a first image of the loaded cassette, when at least one of the LEDs is lit, using an imaging element inside the chamber;

a database step of providing a database which comprises at least one test protocol associated with each of the various test cassettes; and

a processing step of using at least one processor, with reference to the first image and to the database, automatically identifying an applicable one said test protocol for the loaded cassette;

wherein in the processing step, the processor automatically, after incubation of the loaded cassette and depending on the applicable one said test protocol:

(i) determines when the first image captures a post-incubation test signal from the loaded cartridge; and otherwise

(ii)   lights the fluorescent LED to generate the test signal by emission, or the reflection LED to generate the test signal by reflection, from the loaded cassette and uses the imaging element to capture a second image of the loaded cassette and of the test signal; and

wherein in the processing step, the processor automatically provides the test signal, in the first image or the second image, for analysis of the loaded cassette.

28.   A method according to claim 27 wherein, in the processing step, the processor automatically analyzes the test signal with reference to the applicable one said test protocol for the loaded cassette.

29.   A method according to claim 28 wherein, in the processing step, the test signal comprises a test line signal corresponding to a test line present on the loaded cassette after incubation, and the processor automatically measures an intensity of the test line signal.

30.   A method according to any one of claims 28 to 29 wherein, in the processing step, the test signal comprises a control line signal corresponding to a control line present on the loaded cassette after incubation, and the processor automatically measures an intensity of the control line signal.

31.   A method according to any one of claims 28 to 30 wherein, in the processing step, the applicable one said test protocol comprises a predetermined assay threshold value, and the processor analyzes the test signal with reference to the assay threshold value to automatically determine a diagnostic test result associated with the loaded cassette.

32.   A method according to claim 31, further comprising a presentation step, wherein the diagnostic test result is automatically presented using an output device.

33.   A method according to any one of claims 28 to 32 wherein, before the processing step, one or more sets of executable instructions are stored in a memory and, in the

processing step, the executable instructions encode the processor to automatically analyze the test signal as aforesaid.

34. A method according to any one of claims 27 to 32 wherein, before the processing step, one or more sets of executable instructions are stored in a memory and, in the processing step, the executable instructions encode the processor to automatically identify the applicable one said test protocol as aforesaid.

35. A method according to any one of claims 27 to 34 wherein, in the processing step, the processor automatically uses a communications element to remotely reference the database as aforesaid.

36. A method according to any one of claims 27 to 35, further comprising a filtering step of providing at least one optical filter, and wherein in the processing step, (i) the processor automatically ensures the optical filter is moved to an engaged position between the loaded cassette and the imaging element, before lighting a corresponding one said emission LED, and the imaging element then captures the test signal through the optical filter, and (ii) the processor automatically ensures the optical filter is moved to a disengaged position clear of the imaging element, before lighting the reflection LED, and the imaging element then captures the test signal clear of the optical filter.

37. A method according to any one of claims 27 to 35, further comprising a filtering step of providing an optical long pass filter positioned between the loaded cassette and the imaging element, and wherein in the processing step, the imaging element captures the test signal through the optical long pass filter.

38. A method according to any one of claims 27 to 37 wherein, in the LED step, at least one white LED is provided as said at least one reflection LED.

39.   A method according to any one of claims 27 to 38 wherein, in the LED step, at least one ultraviolet LED is provided as said at least one fluorescent LED.

40.   A method according to any one of claims 27 to 39 wherein, in the LED step, at least one colored LED is provided as said at least one fluorescent LED.

41.   A method according to any one of claims 27 to 40 wherein, in the processing step, the processor identifies the applicable one said test protocol with reference to one or more of the following which are captured in the first image, and stored in the database, for the loaded cassette: one or more cassette dimensions, one or more cassette shapes, one or more detection line dimensions, one or more control line dimensions, one or more detection areas, one or more membrane areas, one or more control line positions, one or more test line positions, one or more cassette colors, one or more line colors, manufacturer indicia, product indicia, brand name indicia, application indicia, disease indicia, test type indicia, incubation time indicia, expected results indicia, barcodes, two-dimensional barcodes, labels, and other printed and written indicia.

42.   A method according to any one of claims 27 to 41 wherein, in the processing step, the processor additionally identifies the applicable one said test protocol with reference to one or more of the following which are received from the loaded cassette, and stored in the database for the loaded cassette: magnetically stored data, fluorescence data, and radioactive signal data.

43.   A method according to any one of claims 27 to 42 wherein, in at least one of the imaging step and the processing step, a cellular telephone is provided as said imaging element and/or as said processor.

44.   A method according to claim 43 wherein, in at least one of the imaging step and the processing step, left and right channel audio signals from the cellular telephone turn the reflection LED and the fluorescent LED on and off.

45.   A method according to any one of claims 27 to 42 wherein, in the imaging step, one or more scanning heads are provided as at least part of said imaging element.

46.   A computer readable medium for analysis of various test cassettes for immunoassay rapid diagnostic tests, and for use with: one or more walls defining an enclosed chamber which is adapted to selectively receive the various cassettes one at a time, each as a loaded cassette, in selectively removable relation; two or more light emitting diodes (LEDs) within the chamber, which comprise at least one reflection light emitting diode (LED) adapted to illuminate the loaded cassette when lit, and at least one fluorescent LED adapted to fluoresce the loaded cassette when lit; an imaging element inside the chamber; and a database that comprises at least one test protocol associated with each of the various test cassettes;

with the computer readable medium comprising executable instructions which are physically stored thereon and which, upon execution, encode at least one processor to automatically:

capture a first image of the loaded cassette using the imaging element when at least one of the LEDs is lit;

identify, with reference to the first image and to the database, an applicable one said test protocol for the loaded cassette;

after incubation of the loaded cassette and depending on the applicable one said test protocol: (i) determine when the first image captures a post-incubation test signal from the loaded cartridge; and otherwise (ii) light the fluorescent LED to generate the test signal by emission, or the reflection LED to generate the test signal by reflection, from the loaded

cassette and uses the imaging element to capture a second image of the loaded cassette and of the test signal; and

provide the test signal, in the first image or the second image, for analysis of the loaded cassette.

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