

exceedingly large and typically require large rooms that are accessible through oversized doors that allow for delivery of such systems. These types of rooms are typically found in a clean setting of a hospital or laboratory and often must be specially built or modified to allow the system to be delivered and installed. This can require tremendous capital costs, in addition to the considerably high costs of the system, which can put installation of high throughput analytical systems beyond the reach of some diagnostic testing centers and laboratories. Such systems are also exceedingly large and since floor space in such facilities can be difficult and costly to obtain without displacing existing equipment or personnel, some facilities rely on undersized systems or multiple smaller systems, which often cannot meet the high throughput demands of the facility. These issues can result in a backlog or excessive wait times for analytical results. For example, such facilities may take one to three days (or more) to report a requested diagnostic test to the patient or physician from when the sample is first collected, even though the associated diagnostic assay may take only a few hours. Similar delay problems are faced by systems that use “batch” processing. Such delays are troubling, particularly when attempting to diagnose life threatening illnesses or screening individuals exposed to an outbreak of a pathogen or disease where unnecessary delays or isolation can cost lives and increases overall healthcare costs.

[0001] Thus, there is a need for a high throughput handling system that allows for processing of a large volume of samples in a more efficient and expedient manner. There is further need for such high throughput handling systems that are amenable to being incorporated into existing testing facilities where access, space and costs are of particular concern.

BRIEF SUMMARY OF THE INVENTION

[0002] Embodiments of the present invention relate to high throughput handling systems, devices and methods for processing of large volumes of biological samples, and in particular systems for performing diagnostic assays as detailed in the various embodiments as described herein.

[0010a] According to a first aspect of the present invention, there is provided a handling system for high throughput processing of a plurality of biological samples, each being within a respective diagnostic assay cartridge of a plurality of diagnostic assay cartridges, the system

including: a plurality of diagnostic assay modules, each diagnostic assay module comprising a diagnostic assay system adapted for receiving a diagnostic assay cartridge of the plurality and performing a diagnostic assay on the biological sample within the respective cartridge; an array support assembly supporting the plurality of diagnostic assay modules in an array having at least two dimensions; and a loader that is movable relative the array support assembly, wherein the loader is adapted to load the plurality of diagnostic assay cartridges within the plurality of diagnostic assay modules while supported within the array support assembly, wherein the array support assembly is configured to move relative the loader such that the diagnostic assay cartridge is loadable in any of the diagnostic assay modules within the array by moving the array support structure relative the loader in combination with movement of the loader relative the array support assembly.

[0010a] According to a second aspect of the present invention, there is provided a method of handling a plurality of biological samples with a high throughput processing system, each of the plurality of biological samples being within a diagnostic assay cartridge of a plurality of diagnostic assay cartridges, the method including: receiving the plurality of diagnostic assay cartridges in a high throughput processing system; and loading, with a loader, each of the plurality of diagnostic assay cartridges into a respective diagnostic assay module of a plurality of diagnostic assay modules within an array support defining an array having at least two dimensions, each diagnostic assay module comprising a diagnostic assay system adapted for receiving a diagnostic assay cartridge of the plurality and performing a diagnostic assay on a biological sample within the respective cartridge, wherein loading comprises moving the array support relative the loader such that the diagnostic assay cartridge is loadable in any of the diagnostic assay modules within the array by moving the array support structure relative the loader in combination with moving the loader relative the array support structure.

[0003] In some embodiments, the invention provides a handling system for high throughput processing of a plurality of biological samples, each sample being within a respective cartridge of a plurality of diagnostic assay cartridges. The system can include an array support assembly adapted to support a plurality of diagnostic assay modules in an array having at least two dimensions, typically a cylindrical array. In some embodiments, the array

configuration allows for a substantially reduced footprint, which allows the system to be used in a variety of locations since it does not require an inordinate amount of floor space, as do many conventional systems. In some embodiments, the system 100 (without the counter) has a width of about 86.36 cm or less and a height of about 187.96 cm or less. These dimensions substantially maximize the capacity of the array assembly while still allowing the system to be easily transported through a standard doorway, typically 203.2 cm high by 91.44 cm wide, even when lifted off the floor by 2.54 cm - 5.08 cm such as by a wheeled transport cart. The dimensions of base 160 are well within suitable limits for transport through a standard doorway. The circular counter 114 that sits between base 160 and array 130 can be removed and transported vertically if needed, for example, to reduce the overall width to allow passage through a standard doorway. In some embodiments, the internal crate and packaging used to support the instrument during shipping can be used as a transport cart to move the instrument to its final destination in the laboratory or hospital setting. In some embodiments, the internal crate and packaging that is also used as a transport cart is constructed of wood. Exemplary size dimensions can be further understood by referring to FIGS. 3A-3D below.

[0001] FIG. 3A-3C depict top and side views illustrating the relative dimensions of the array assembly. As seen in FIG. 3A, the system 100 with the counter attached has a minimum width, w . In this exemplary embodiment, w is about 114.3 cm. As can be seen in FIG. 3B, the maximum width, W , occurs along the counter 114. In this embodiment, W is about 51”129.54 cm. As can be seen in FIG. 3C, the system 100 has an overall height, h . In this embodiment, h is about 187.96 cm. As described previously, the counter can be removed to facilitate shipping and transport of system 100 through a standard sized doorway. As can be seen in FIG. 3D, in this embodiment, the system 100 with the counter removed has a reduced width, w' . In this embodiment, w' is about 86.36 cm which allows the system 100 to easily fit through a standard sized doorway. Although advantages of certain dimensions have been described herein, it is appreciated that other embodiments could include a similar system or components with various other dimensions in accordance with any of the concepts described herein. Advantageously, the counter 114 and loading track are such that the system can be accessed from all sides (e.g. 360 degrees) such that cartridges can be loaded by one or more personnel approaching from multiple directions. It is appreciated that in other embodiments, the counter 114 and loading track can be configured such that access is from less than 360 degrees (e.g. 270 degrees, 180 degrees, or less). As shown, in FIGS. 3A and 3D, the countertop 114 and system 100 can be configured with a generally circular shape with one

and an air filter 50f. In some embodiments, for example systems having between 50 and 200 modules, this configuration allows an optimal temperature range to be maintained in the microenvironment of the array so long as the air intake is about 21.11°C or less. Thus, in a room with an ambient temperature of about 21.11°C, an air intake open to the ambient room may be sufficient to maintain a suitable temperature controlled environment for the array, assuming the room has sufficient temperature control (e.g., air conditioning) to maintain an air supply of a consistent temperature. In other embodiments, such as that shown in FIG. 8C, an external cool air supply 50g can be connected to cool air intake 50c, so as to ensure a sufficiently cool air supply regardless of the ambient temperature. Such a configuration may be particularly useful in high temperature or uncontrolled environments.

[0002] Since heated air tends to accumulate in the uppermost portion of the array assembly, cooling system 150 can further include baffles 51, 52, 53, 54, 55 between row levels, that are adapted to direct and control air flow 56 through the assembly. Lower-most baffle 51 extends to the inside of the exterior shell so that the air flow is directed through the open central column and through the modules of the first row. Baffles 52, 53, 54 separate each of the four rows above the first level so that cool air supplied through the open central column is supplied directly to each row via the open central column. In some embodiments, baffles 52, 53, 54 are smaller and do not extend entirely to the outer shell 135 so as to allow flow of heated air passed through lower rows to travel upwards along an inside of the outer shell 135 towards the top most opening. Any of baffles 51-55 can include one or more holes to facilitate passage of air flow through the baffle as needed. In some embodiments, the baffles can be configured for level stratification and air management between levels. Top-most baffle 55 blocks the open central column but allows air flow through the inside of the outer shell to direct air flow to exit the system from one or more opening along the top of system 100. A top vent 151 can allow air to exit around the edges and top vents 152 on elevators 120, which allows each elevator to act as a chimney drawing heated air from each of the levels of the array.

[0003] In some embodiments, the system includes a temperature controller configured to maintain the environment of the array assembly within range of temperatures suitable for processing of the samples within the modules of the array. In some embodiments, the temperature controller is configured to maintain the temperature of the ambient environment between about 10°C to about 40°C so as to be suitable for performing PCR with the diagnostic assay modules. Preferably, the temperature controller maintains the temperature

below 40°C. In some embodiments, the range of suitable temperatures is between about 18.33°C and 35°C. In some embodiments, the temperature controller maintains the temperature within a pre-defined delta (e.g. 2 degrees) from a target temperature. In some embodiments the temperature controller maintains the temperature within 1°C from a target temperature. This improves efficiency of analysis as well as consistency and predictability of analysis time. In some embodiments, the temperature controller is configured to adjust a temperature of an external air cooler that supplies air to the air intake. In some embodiments, the temperature controller is configured to adjust the air flow through the system by adjusting fan speed (e.g. speed up air flow/adjust air flow between levels), as needed in order to facilitate cooling, particularly as the system is nearing capacity. In some embodiments, the airflow through the system can be adjusted between levels such that more air is directed to the levels where temperature is exceeding optimal levels. In some embodiments, the system further includes diverters that can direct air from the open central column to each of the different rows of the array. For example, the diverters can be configured such that each of the four rows of the array each receive about 25% of the air flow from the open central column. In some embodiments, the diverters can be configured such that all of the air flow in the open central column is diverted to a particular row in the array. In some embodiments, each row of the array can receive anywhere from substantially none (0%) of the air flow in the open central column to receiving substantially all (100%) of the air flow from the open central column or anywhere in between. In some embodiments, the percentage of air flow allocated to a particular level increases with each level in an upwards direction. This allows the levels to be cooled in proportion to the amount of heat that accumulates. For example, in an exemplary four level configuration, the lowest level can receive between 0-10%, the next higher level can receive between 10-20%, the next higher level received between 20-50% and the highest level receives between 40-80% of the airflow. It is appreciated that various other allocations of airflow between levels could be realized. The temperature controllers can be communicatively coupled with one or more temperature sensors (e.g. thermocouples) disposed at one or more locations within the array to facilitate improved temperature control.

[0004] FIG. 9 shows a cross-sectional view illustrating the four circular frames defining the array assembly. Each of the circular frames are rotatably coupled within the assembly and operably coupled with a driver or drive mechanism controlled by the controller such that each frame can be rotatably driven so that each row of the array incrementally rotates. Typically, the structure is configured and controlled such that adjacent frames incrementally

CLAIMS:

1. A handling system for high throughput processing of a plurality of biological samples, each being within a respective diagnostic assay cartridge of a plurality of diagnostic assay cartridges, the system comprising:

a plurality of diagnostic assay modules, each diagnostic assay module comprising a diagnostic assay system adapted for receiving a diagnostic assay cartridge of the plurality and performing a diagnostic assay on the biological sample within the respective cartridge;

an array support assembly supporting the plurality of diagnostic assay modules in an array having at least two dimensions; and

a loader that is movable relative the array support assembly, wherein the loader is adapted to load the plurality of diagnostic assay cartridges within the plurality of diagnostic assay modules while supported within the array support assembly,

wherein the array support assembly is configured to move relative the loader such that the diagnostic assay cartridge is loadable in any of the diagnostic assay modules within the array by moving the array support structure relative the loader in combination with movement of the loader relative the array support assembly.

2. The system of claim 1, wherein each of the diagnostic assay modules is adapted to perform a diagnostic assay independent from each other.

3. The system of claim 1, wherein the array support assembly is configured so as to define a cylindrical array.

4. The system of claim 1, wherein the array comprises a plurality of horizontal rows and the loader is translatable along a substantially vertical axis so as to be movable between horizontal rows of the cylindrical array.

5. The system of claim 1, wherein the loader includes a grasper adapted to insert a cartridge supported by the grasper along a horizontal axis from a grasped position within the grasper to a loaded position within a diagnostic assay module of the array.

6. The system of claim 5, wherein the grasper is further adapted to unload a cartridge loaded in a diagnostic assay module within the array from the loaded position and transport the cartridge away from the respective module.

7. The system of claim 5, wherein the grasper is further adapted to concurrently support at least two cartridges of the plurality of cartridges to facilitate any of:
consecutive loading of the at least two cartridges,
consecutive unloading of the at least two cartridges from respective loaded positions,

unloading of one cartridge of the at least two cartridges from a given module and subsequent loading of another cartridge of the at least two cartridges within the same module,
and

unloading of one cartridge of the at least two cartridges from a given module and subsequent loading of another cartridge of the at least two cartridges within a different module.

8. The system of claim 1, wherein the array support structure comprises a stack of circular frames separated by slip rings configured to transmit power and communication data through a rotating union such that each module has a direct power and communication coupling.

9. The system of claim 8, wherein each of the diagnostic assay modules comprises a rechargeable power source that is wirelessly rechargeable by near-field energy transfer.

10. The system of claim 1, wherein the array support assembly includes one or more sensors associated with each module within the array, the one or more sensors being adapted to determine the location of the modules within the array.

11. The system of claim 7, further comprising:
a controller having an input and an output, the controller being configured to output a control command to the loader to load a diagnostic assay cartridge in a particular

diagnostic assay module of the plurality in response to an input received from the one or more sensors that the diagnostic assay module is available for loading.

12. The system of claim 11, wherein the controller is configured to determine a preferred diagnostic assay module from a plurality of available diagnostic assay modules based on any of: proximity, a temperature measurement, a load balance, a heat balance, a distribution among levels or within a respective level, a time length of assay, or any combination thereof.

13. The system of claim 11, wherein the one or more sensors are further configured to obtain a unique ID of each a diagnostic assay module and an associated cartridge loaded therein.

14. The system of claim 11, wherein each diagnostic assay module includes a wireless communication unit adapted to communicate with the controller.

15. The system of claim 12, wherein the wireless communication unit of each diagnostic assay module is configured to communicate to the controller that a diagnostic assay cartridge is associated with a particular diagnostic assay module of the plurality after loading of the cartridge in the respective module.

16. The system of claim 12, wherein the controller is adapted to track which diagnostic assay module of the plurality is associated with each diagnostic assay cartridge of the plurality.

17. The system of claim 12, wherein the controller is adapted to output a command to the loader to load a diagnostic assay cartridge within a diagnostic assay module that is not already associated with a diagnostic assay cartridge.

18. The system of claim 17, wherein the controller is further adapted to output to the loader a command to unload a particular diagnostic assay cartridge after receiving an input

that a diagnostic result has been received from the diagnostic assay module associated with the respective cartridge.

19. The system of claim 1, wherein the system further includes a waste receptacle disposed beneath the array support, wherein the loader is further adapted to unload spent diagnostic assay cartridges for collection and discarding within the waste receptacle.

20. The system of claim 1, wherein the system further comprises:
a loading track configured to convey a plurality of diagnostic assay cartridges to the loader.

21. The system of claim 20, wherein the loading track defines a plurality of recesses adapted to receive the plurality of diagnostic assay cartridges.

22. The system of claim 21 wherein each recess is configured to maintain each of the plurality of diagnostic assay cartridges in a particular position and/or orientation relative the loading track to facilitate loading with the loader when received.

23. The system of claim 20, wherein the loader includes a grasper adapted to grasp a diagnostic assay cartridge conveyed by the loading track when disposed at a particular loading position.

24. The system of claim 20, wherein the array support defines a cylindrical array and the loading track is a ring configured to rotate around the cylindrical array.

25. The system of claim 24, wherein the ring-shaped loading track and the cylindrical array are configured to rotate about a common longitudinal axis and the ring-shaped loading track is adapted to rotate independently from the cylindrical array.

26. The system of claim 20, wherein the loading track includes one or more sensors adapted to detect when one or more diagnostic assay cartridges are placed in the loading track.

27. The system of claim 26, wherein the loading track is adapted to transport the one or more diagnostic assay cartridges toward the loader in response to detection of the one or more cartridges.

28. The system of claim 1, further comprising:
an air cooling system that is configured to direct air through a central column of the array assembly and through each level of the array assembly so as to maintain the entire array assembly within a range of suitable temperatures.

29. The system of claim 28, wherein the range of suitable temperatures is between 18.33°C and 35°C to facilitate a PCR analysis.

30. The system of claim 28, wherein the air cooling system includes a baffle between each level of the array assembly such that air flow is, at least partly, separated between levels.

31. The system of claim 28, wherein the air cooling system includes an external air cooler communicatively coupled with one or more sensors in one or more levels of the array assembly.

32. The system of claim 1, wherein each of the diagnostic assay modules is fixedly secured within the array support assembly yet remains removable to allow repair and/or replacement.

33. The system of claim 1, wherein the array support assembly defines a cylindrical array having a diameter of 86.36 cm or less and a height of 203.2 cm or less when

secured within the assembled system so as to facilitate transport of the system through a standard-sized doorway.

34. The system of claim 1, wherein the array support assembly comprises a plurality of stacked circular frames defining an open central column.

35. The system of claim 31, wherein the system further includes an integrated cooling system that includes:

one or more cooling fans that are configured to draw a cool air intake upward from a bottom of the open central column toward a top of the open central column.

36. The system of claim 32, wherein the system further includes circular baffles between each row so as to direct cooling air from the open central column directly to each row of modules within the cylindrical array.

37. The system of claim 1, wherein the array support assembly is a cylindrical array that supports at least 50 modules and includes at least two stacked rows.

38. The system of claim 1, wherein the array support assembly is a cylindrical array, each row supporting 25 modules, and having at least 4 rows such that the array support assembly supports at least 100 modules.

39. The system of claim 1, wherein the array support assembly comprises two cylindrical arrays, each row supporting 25 modules, and each cylindrical array having at least 4 rows such that the system supports 200 modules.

40. The system of claim 20, further comprising:

a cartridge preparer configured to perform one or more sample processes on a fluid sample within a diagnostic assay cartridge before analysis and to subsequently load the prepared diagnostic assay cartridge within the loading track.

41. A method of handling a plurality of biological samples with a high throughput processing system, each of the plurality of biological samples being within a diagnostic assay cartridge of a plurality of diagnostic assay cartridges, the method comprising:

receiving the plurality of diagnostic assay cartridges in a high throughput processing system; and

loading, with a loader, each of the plurality of diagnostic assay cartridges into a respective diagnostic assay module of a plurality of diagnostic assay modules within an array support defining an array having at least two dimensions, each diagnostic assay module comprising a diagnostic assay system adapted for receiving a diagnostic assay cartridge of the plurality and performing a diagnostic assay on a biological sample within the respective cartridge, wherein loading comprises moving the array support relative the loader such that the diagnostic assay cartridge is loadable in any of the diagnostic assay modules within the array by moving the array support structure relative the loader in combination with moving the loader relative the array support structure.

42. The method of claim 41 wherein loading each of the plurality of diagnostic assay modules comprises positioning each cartridge within a receptacle of a given diagnostic assay module within the array.

43. The method of claim 41 further comprising:
detecting a presence of each of the plurality of diagnostic modules within the array support.

44. The method of claim 41 wherein loading comprises:
determining availability of a given diagnostic module of the plurality of diagnostic modules within the array support, with a controller of the system, based on an output wirelessly received from the given diagnostic module.

45. The method of claim 44 further comprising:
determining a preferred diagnostic assay module from a plurality of available diagnostic assay modules based on any of: proximity, a temperature measurement, a load

balance, a heat balance, a distribution among levels or within a respective level, a time length of assay, or any combination thereof; and

loading a diagnostic assay cartridge of the plurality into the preferred diagnostic assay module determined.

46. The method of claim 42, further comprising:
performing a diagnostic assay in at least one of the plurality of diagnostic assay modules within the array.

47. The method of claim 42 wherein each of the plurality of diagnostic assay modules within the array operates independently from each other.

48. The method of claim 41 further comprising:
obtaining a unique ID associated with each diagnostic assay module and associated diagnostic assay cartridge upon loading of the respective cartridge into the respective module.

49. The method of claim 48 further comprising:
associating a diagnostic assay result from the particular diagnostic assay module with the biological sample of the respective cartridge loaded into the module based on the unique IDs.

50. The method of claim 41 wherein each of the plurality of diagnostic assay modules are removable from the array support assembly, the method further comprising:
removing one or more diagnostic assay modules from the array support and replacing with one or more replacement diagnostic assay modules.

51. The method of claim 41 wherein the loader includes a grasper such that loading comprises:
grasping, with the grasper, a diagnostic assay cartridge of the plurality received;

transporting the diagnostic assay cartridge supported with the grasper to an available diagnostic assay module in the array by one or both of: translating the grasper and moving the array support relative the grasper; and

loading the grasped diagnostic assay into the available diagnostic assay module.

52. The method of claim 51 wherein determining the available diagnostic assay module comprises wirelessly communicating with each of the plurality of diagnostic assay modules in the array.

53. The method of claim 51 wherein transporting the diagnostic assay cartridges with the grasper of the loader comprises translating the grasper along a first axis of the array.

54. The method of claim 53 wherein transporting the diagnostic assay cartridges further comprises moving the array support along a second axis of the array, the second axis being transverse to the first axis.

55. The method of claim 54 wherein the first axis has a substantial vertical component and the second axis is substantially horizontal.

56. The method of claim 54 wherein the array is a cylindrical array having a plurality of horizontal rows and a plurality of vertical columns and moving the array support comprises rotating the support about a longitudinal axis of the array.

57. The method of claim 41 wherein receiving the plurality of diagnostic assay cartridges comprises receiving each of the plurality in a loading track that moves the received plurality of diagnostic assay cartridges toward the loader mechanism for loading in the array.

58. The method of claim 57 wherein the loading track comprises a plurality of recesses for receiving the plurality of diagnostic cartridges, each recess configured for receiving one diagnostic cartridge of the plurality, the method further comprising:

sensing one or more of the plurality of diagnostic cartridges received in the loading track and moving the one or more sensed modules toward the loader in response.

59. The method of claim 57 wherein the array support is a cylindrical array and the loading track is a ring that extends about the cylindrical array such that moving the one or more sensed diagnostic cartridges comprises rotating the ring about a common longitudinal axis of the cylindrical array and the ring-shaped loading track.

60. The method of claim 41, further comprising:

unloading a respective diagnostic assay cartridge after a diagnostic assay is performed on the biological sample therein from a respective diagnostic assay module of the plurality.

61. The method of claim 60, wherein unloading the diagnostic assay cartridge comprises moving the loader to the diagnostic assay module in response to an output from the associated module that is indicative of completion of the diagnostic assay on the biological sample performed by the respective module.

62. The method of claim 61, wherein the output is received wirelessly from the diagnostic assay module with a controller that controls movement of the array support and the loader.

63. The method of claim 60, further comprising:

concurrently supporting with the loader at least two diagnostic assay cartridges that include a first diagnostic assay cartridge for loading in the array and a second diagnostic assay cartridge having been unloaded from the array.

64. The method of claim 63, further comprising:

loading the first diagnostic assay cartridge support in the loader into a respective diagnostic module from which the second diagnostic assay cartridge has been unloaded.

65. The method of claim 60, further comprising:
transporting one or more spent diagnostic cartridges having been unloaded from the array by the loader towards a waste receptacle.

66. The method of claim 41 further comprising:
maintaining a temperature in each level of the array assembly within a range of suitable temperatures for sample processing within the system.

67. The method of claim 66 further comprising:
a suitable temperature range of 18.33°C to 35°C.

68. The method of claim 66 wherein maintaining the temperature comprises running one or more fans of a cooling system that directs air flow through a central column of the array of modules and through each level of the array of modules.

69. The method of claim 69 wherein air flow through each level is, at least partly, separated by a baffle such that the air flow varies between levels.

70. The method of claim 41 further comprising:
preparing one or more diagnostic assay cartridges in a sample preparer that automatically transports the one or more prepared diagnostic assay cartridges into a loading track of the system for subsequent analysis.