United States Patent Application Publication 20250251417
Kind Code A1
Publication Date August 07, 2025
Inventor(s) CHANG; Ronald et al.

## Sample Processing Module Array Handling System and Methods

### Abstract

A handling system for high throughput processing of a large volume of biological samples is provided herein. Such systems can include an array support assembly that supports multiple diagnostic assay modules in an array having at least two dimensions, a loader that loads multiple diagnostic assay cartridges within the multiple diagnostic assay modules. The array support assembly can be movable relative the loader to facilitate loading and unloading so as to provide more efficient processing.

**Inventors:** **CHANG; Ronald (Sunnyvale, CA), MONTGOMERY; Steven (Sunnyvale, CA), MOTE; Gregory (Sunnyvale, CA), BLIVEN; Brian (San Jose, CA)**

**Applicant:** **Cepheid** (Sunnyvale, CA)

**Family ID:** **60703022**

**Appl. No.:** **19/045946**

**Filed:** **February 05, 2025**

### Related U.S. Application Data

parent US continuation 16953870 20201120 parent-grant-document US 12235279 child US 19045946
parent US division 15816960 20171117 parent-grant-document US 10871498 child US 16953870
us-provisional-application US 62424313 20161118

### Publication Classification

**Int. Cl.:** **G01N35/02** (20060101); **G01N35/00** (20060101); **G01N35/04** (20060101)

**U.S. Cl.:**

CPC **G01N35/025** (20130101); **G01N35/00029** (20130101); **G01N35/00732** (20130101); **G01N35/00871** (20130101); **G01N35/04** (20130101); G01N2035/00148 (20130101); G01N2035/00158 (20130101); G01N2035/00326 (20130101); G01N2035/00356 (20130101); G01N2035/00445 (20130101); G01N2035/00881 (20130101); G01N2035/0425 (20130101); G01N2035/0427 (20130101); G01N2035/0451 (20130101); G01N2035/0453 (20130101); G01N2035/0465 (20130101)

---

## Background/Summary

CROSS-REFERENCES TO RELATED APPLICATIONS [0001] This application is a continuation of U.S. application Ser. No. 16/953,870, filed Nov. 20, 2020, which is a divisional of U.S. application Ser. No. 15/816,960, filed Nov. 17, 2017 which claims the benefit of priority to U.S. Provisional Application No. 62/424,313 filed Nov. 18, 2016, the entire contents of which are incorporated herein by reference. [0002] This application is generally related to U.S. patent application Ser. No. 15/217,920 entitled “Molecular Diagnostic Assay System,” filed Jul. 22, 2016 which is incorporated herein by reference in its entirety for all purposes.

BACKGROUND OF THE INVENTION
[0003] The present invention relates to the field of fluidic devices for carrying out multiplex chemical or biochemical reactions and for performing multiplex chemical and/or biochemical assays. More particularly, this invention relates to a handling system for devices configured for carrying out multiplex chemical and/or biochemical reactions, and detecting a plurality of chemical and/or biochemical compounds.
[0004] Modern disease diagnosis, pathogen detection, gene discovery, drug development, and various genetic-related technologies and research increasingly rely on processing a large number of biological samples. Traditional methods of processing the samples one at a time have become increasingly inadequate and the demand for performing assays on a large volume of samples simultaneously has steadily increased, particularly in recent years. Hence, there is a need for chemical/biochemical reaction systems and devices that perform high-throughput assays.
[0005] Conventional high throughput methods can include the use of microarrays, such as a DNA microarray, which is typically a two-dimensional array of DNA molecules attached to a solid substrate on its surface. A DNA microarray can provide a useful platform as a multiplexing detection device. For example, each element of the array has a unique DNA sequence that is used to recognize or detect a unique complementary DNA sequence in a prepared fluid sample. These DNA microarrays have fundamentally changed conventional approaches of observing one or a few genes or molecules at a time to observing pathways, networks, and a large collection of genes and pools of molecules. Such DNA microarray chips available today typically operate based on the hybridization of target DNA or RNA molecules from the fluid sample in a solution phase with probe DNA (e.g. oligonucleotides or cDNA) molecules immobilized on solid substrates of the array. The arrays do not however provide for a rapid cost-effective way of detecting low abundance targets that can indicate the presence of an infectious disease or other pathogenic state, which is more typically detected using sensitive methods such as real-time PCR. A real-time PCR system detects PCR products as they accumulate during a PCR process and allows for improved speed and efficiency in performing assay, but these systems are typically hindered by the need to process the samples as a “batch” thus resulting in a delay of processing some samples until enough have been collected to make the overall process more cost effective, but this leads to increased turn-around-time. Such delays and increased cost lead to less efficiency and overall increase in health care costs.
[0006] Sample preparation is another typical problem that hinders the speed at which large volumes

of diagnostic assays can be performed. Although many such systems require separate processing of the fluid sample before introduction into a real-time PCR diagnostic assay device, there are advances in recent years that provide automated sample preparation that is coordinated with real-time PCR analysis within a single analytical device or system. One such device is the GeneXpert device developed by Cepheid as described in, e.g., U.S. Pat. Nos. 8,048,386; 6,374,684, and U.S. patent applications Ser. Nos. 13/843,739 and 15/217,920, each incorporated herein by reference.

[0007] The current Cepheid systems are provided to an end-user as individual modules, or a small system of grouped modules, or large scale systems. Currently available small systems provide an enclosure that includes a small number of modules, e.g. 2, 4, 8 or 16 modules, while the large scale systems can provide 48 or 80 modules. The small systems are well suited for small-scale operations, but cannot provide the high throughput demands of a large-scale operation, such as a laboratory or testing facility.

[0008] Although commercially available large systems, including Cepheid's Infinity 48 and 80 systems, provide a higher throughput of diagnostic assay testing, such systems are 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.

[0009] 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

[0010] The present invention relates 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.

[0011] 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 has a shape other than cylindrical, for example, the array can be elliptical, hexagonal, octagonal, or other geometrical configurations suitable for use with the invention. Each diagnostic assay module includes a diagnostic assay system adapted for receiving a diagnostic assay cartridge and performing a diagnostic assay on a biological sample within the cartridge. The system can further include a loader adapted to load each of the plurality of diagnostic assay cartridges within a diagnostic assay module within the array. The array support assembly is movable relative the loader such that the cartridge is loadable in any of the modules within the array by moving the loader relative the array. In some embodiments, the

array is a cylindrical array that rotates along its longitudinal axis and the loader mechanism translates vertically in an elevator adjacent the cylindrical array.
[0012] In some embodiments, the invention provides methods of handling a plurality of biological samples with a high throughput processing system. Such methods can include: receiving multiple 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 module includes 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. Loading can include 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 in combination with the loader. In some embodiments, the array is a cylindrical array enclosed by an outer shell and the methods can further include cooling a microenvironment of the array by forcing air upwards through an open central column and directing the cooling air through each row of the array with one or more baffles between rows of the array within the outer shell.

---

## Description

BRIEF DESCRIPTION OF THE DRAWINGS
[0013] FIG. **1**A provides an overview of a high throughput handling system for performing processing and diagnostic assays of a high-volume stream of samples, in accordance with some embodiments of the invention.
[0014] FIG. **1**B shows a schematic illustrating the diagnostic assay module and diagnostic assay cartridge(s) within the high throughput handling system of FIG. **1**A, in accordance with some embodiments.
[0015] FIG. **1**C shows an exploded view of the high throughput handling system of FIG. **1**A, in accordance with some embodiments.
[0016] FIG. **1**D shows a diagnostic assay modules assembly insertable into a circular level of the array of the high throughput handling system of FIG. **1**A, in accordance with some embodiments.
[0017] FIG. **1**E shows a support assembly and rotation actuators to facilitate rotation of a circular level of the array of the high throughput handling system of FIG. **1**A, in accordance with some embodiments.
[0018] FIG. **1**F shows an exploded view of the support assembly of FIG. **1**E, in accordance with some embodiments.
[0019] FIG. **1**G shows an exploded view of an elevator assembly of the high throughput handling system of FIG. **1**A, in accordance with some embodiments.
[0020] FIG. **1**H shows an exploded view of a base and loading tracking of the high throughput handling system of FIG. **1**A, in accordance with some embodiments.
[0021] FIGS. **2**A-**2**B depict a lab technician placing diagnostic assay cartridges in queue for processing within a high throughput handling system having an array of diagnostic assay modules, in accordance with some embodiments.
[0022] FIG. **2**C shows a pair of diagnostic assay cartridges held within a grasper being lifted in an elevator of the system to facilitate placement of one of the cartridges within a diagnostic assay module of the array, in accordance with some embodiments.
[0023] FIG. **2**D shows a pair of diagnostic assay cartridges held within a grasper being lowered in the elevator to discard a spent cartridge, in accordance with some embodiments.
[0024] FIG. **2**E depicts a technician placing a diagnostic assay cartridge in queue in the loading track and removing a waste receptacle from a base of the system filled with spent cartridges, in

accordance with some embodiments.
[0025] FIG. **3**A-**3**C depict top and side views illustrating the relative dimensions of the array assembly and base that allows for transport of the array assembly with countertop removed through a standard sized doorway, in accordance with some embodiments.
[0026] FIG. **3**D shows an overhead view of the array assembly with the counter removed, in accordance with some embodiments.
[0027] FIGS. **3**E and **3**F show an overhead and side view, respectively, of a high throughput handling system with a cartridge preparer that prepares and automatically loads prepared diagnostic assay cartridges onto the loading track, in accordance with some embodiments.
[0028] FIG. **4** illustrates a high throughput handling system with an adjustable height transport cart supporting the removable array assembly from the base of the system, in accordance with some embodiments.
[0029] FIGS. **5-6** illustrate detail view of the elevator and loader for grasping a pair of diagnostic assay cartridges to facilitate loading and/or unloading from the diagnostic assay modules of the array, in accordance with some embodiments.
[0030] FIG. **7** illustrates a specialized waste receptacle adapted for use with a high throughput handling system to collect spent cartridges that includes an optional lid and diverter, in accordance with some embodiments.
[0031] FIG. **8**A illustrates a cross-sectional view of the high throughput handling system to illustrate an integrated cooling system to control heat transfer through the array of diagnostic assay modules during operation, in accordance with some embodiments.
[0032] FIG. **8**B illustrates a cross-sectional view of the high throughput handling system with a cooling system with intake fans integrated within the base, in accordance with some embodiments.
[0033] FIG. **8**C shows a high throughput handling system with an external air cooler connected to the air intake of the base, in accordance with some embodiments.
[0034] FIG. **9** illustrates a cross-sectional view of the high throughput handling system to illustrate the modular construction of each level of the array, in accordance with some embodiments.
[0035] FIG. **10** illustrates an ultra-high throughput handling system with diagnostic assay module array, in accordance with some embodiments.
[0036] FIGS. **11-12** illustrates methods of performing sample processing using a high throughput handling system, in accordance with some embodiments.
[0037] FIG. **13** shows a comparison of throughput times for systems in accordance with embodiments of the invention as compared to commercially available systems
[0038] FIGS. **14**A-**14**D show alternative embodiments of module arrays and loading tracks utilized in high throughput handling systems, in accordance with some embodiments.

## DETAILED DESCRIPTION OF THE INVENTION

[0039] The present invention relates generally to systems, devices and methods for providing high throughput performance in the analysis/testing of biological samples, as detailed in the various embodiments described herein. The system utilizes an array of diagnostic assay modules that are movable relative a loader to allow concurrent processing of a large volume of biological fluid samples received in diagnostic assay cartridges within the array of modules. In some embodiments, the diagnostic assay modules are each capable of performing sample preparation as well as a diagnostic assay of a fluid sample within a diagnostic assay cartridge disposed therein. Typically, the diagnostic assay modules can be independently operable such that the processing in each module is performed separately from each other. Although in some embodiments the modules are identical, it is appreciated that the array can include differing types of modules as well. Such a configuration is advantageous as individual modules can be removed/replaced and serviced as needed without adversely affecting or require dismantling of other modules or mechanisms.
[0040] These and other aspects can be further understood by reference to the various embodiments shown in the following figures and described in the text.

[0041] FIG. **1**A depicts a high throughput handing system **100** having an array support assembly **130** that supports an array of diagnostic assay modules **30**. In this embodiment, each module is configured with the same function and capabilities for processing a fluid sample within a diagnostic assay cartridge **10** inserted and received therein. In this embodiment, the array is a cylindrical array having four circular rows, each row supporting 25 diagnostic assay modules **30** such that the entire system **100** includes 100 independent modules. Various other configurations, having more or fewer rows, or more or fewer modules per row could be utilized. System **100** includes two elevators **120** to facilitate loading and unloading of the cartridges **10** from the modules **30** of the array. Each elevator includes a loader **20** adapted to releasably hold a diagnostic assay cartridge and position the cartridge into any of the available modules **30** and/or to remove a spent cartridge **10** from any of the modules **30** after processing to be discarded. Although this embodiment includes two such elevators, more or fewer elevators could be utilized. Advantageously, the entire array of 100 cartridges can be loaded in about 10 minutes by a single elevator and can be loaded in less than seven minutes by use of two elevators. The above described configuration allows for throughput and processing speeds that are vastly improved as compared to conventional processing systems. Each cylindrical row is rotatable along a longitudinal axis of the array and the elevator travels between rows of the array, typically by translating vertically. In some embodiments, each cylindrical row rotates in steps such that a diagnostic assay cartridge receptacle bay of each diagnostic assay module is positioned adjacent the elevator for a time sufficient to facilitate loading and/or unloading of a cartridge, at least a second or more, typically a few seconds (e.g., 3-5 seconds), in some embodiments, about 10 seconds or more. Such a configuration allows for ready access to any of the modules by combined movement of the elevator and the array, such that the diagnostic assay cartridges can be loaded and unloaded from modules **30** considerably faster than a system having a planar rectangular array of receptacles for receiving such cartridges. In some embodiments, the rows of the array revolve separately from each other, for example, adjacent rows can travel in opposite directions, and in some embodiments, each row can travel in the same direction or the entire cylindrical array can be fixed and revolve as a single unit. In some embodiments, not all rows of the array rotate. For example, one row of the array can be held stationary, while the remaining rows of the array rotate (either together or in opposite directions).

[0042] In some embodiments, the modules of the array are independently operable and are electrically and communicatively coupled with a central power source and communication platform, which can be housed within a base **160** of the system. Base **160** includes two doors that house one or more waste receptacles into which spent diagnostic assay cartridges are automatically discharged after processing. A waste capacity indicator **162** (e.g. LED) indicates to a user that the receptacle is full. The indicator **162** can be lit in response to a determination that the receptacle is full, based on a diagnostic assay cartridge count or a weight of the receptacle. In some embodiments, the waste capacity indicator **162** can indicate differing states as the waste receptacle fills, for example, green/yellow/red corresponding to partly empty/near full/completely filled. In some embodiments, the indicator **162** is disposed on a central post on an interior of the base and the handles of the doors are translucent to allow a user to view the indicator LED through the handles. Base **160** can also include proximity sensor **163** that detects approach of personnel and initiates rotation of the loading track to receive cartridges to be loaded for analysis. Base **160** can further house various control, power and communication features or hubs to facilitate coordinated control of system components and automation of the system. As shown in FIG. **1**H, base can include controller **180**, automation computer **181**, power distributor **182** and communication hub **183** (e.g. ethernet hub). It is appreciated that the controller, automation computer and communication hub can include hardwired communication and/or wireless communication. Further, such features can be centralized or divided among multiple units. For example, controller **180** can initiate various control aspects of the overall system and communicate with individual controllers associated with each of the modules of the array.

[0043] In some embodiments, each diagnostic assay module **30** is configured to receive a diagnostic assay cartridge having a reaction vessel or tube extending from the cartridge configured for detection of a nucleic acid target in a nucleic acid amplification test (NAAT), e.g., Polymerase Chain Reaction (PCR) assay. Preparation of a biological fluid sample in such a cartridge generally involves a series of processing steps, which can include chemical, electrical, mechanical, thermal, optical or acoustical processing steps according to a specific protocol. Such steps can be used to perform various sample preparation functions, such as cell capture, cell lysis, purification, binding of analyte, and/or binding of unwanted material. In some embodiments, the diagnostic assay cartridge can include one or more chambers suited to perform the sample preparation steps. A diagnostic assay cartridge suitable for use with the invention is shown and described in U.S. Pat. No. 6,374,684, entitled “Fluid Control and Processing System” filed Aug. 25, 2000, and U.S. Pat. No. 8,048,386, entitled “Fluid Processing and Control,” filed Feb. 25, 2002, the entire contents of which are incorporated herein by reference in their entirety for all purposes. The arrays of modules described herein can include modules in accordance with those detailed in U.S. patent application Ser. No. 15/217,920 entitled “Molecular Diagnostic Assay System,” filed Jul. 22, 2016. It is appreciated, however, that the systems described herein can include various other types of modules and cartridges as well, as will be known to persons of skill in the art.
[0044] Non-limiting exemplary nucleic acid amplification methods suitable for use with the invention include, polymerase chain reaction (PCR), reverse-transcriptase PCR (RT-PCR), Ligase chain reaction (LCR), transcription mediated amplification (TMA), and Nucleic Acid Sequence Based Amplification (NASBA), and isothermal amplification. Additional nucleic acid tests suitable for use with the instant invention are well known to persons of skill in the art. Analysis of a fluid sample generally involves a series of steps, which can include any of: optical detection, electrical detection or chemical detection, according to a particular protocol.
[0045] FIG. **1**B shows such a diagnostic assay cartridge **10** adapted for use with a diagnostic assay module **30** within the array of modules supported by the array support assembly **130**. When using the module **30** separately from the array in system **100**, a user inserts the cartridge **10** directly into a receiving bay behind door **31**. The module **30** can be configured to open door **31** when the bay is empty and the module **30** is ready to perform sample processing or when sample processing is complete to facilitate removal of the spent cartridge. In system **100**, the diagnostic assay cartridges are placed in a queue within a loading track **110**, which revolves around the cylindrical array to transport each cartridge **10** to the elevator **120**. The loader **20** then picks up each cartridge to be processed and the loader translates vertically along the elevator to the appropriate row of the module in which the cartridge is loaded. The basic elements of system **100** can be seen in the exploded view shown in FIG. **1**C, which shows the four levels of the array support assembly **130**, each level having multiple diagnostic modules **30** mounted therein, the transparent shell **135** that encases the array to allow a clean temperature controlled environment to be maintained, two elevators **120**, counter **114** and base **160** with cartridge loading track **110**. Elevators **120** can be further understood by referring to the exploded view shown in FIG. **1**E. In some embodiments, loading track **110** is cylindrical, but it is appreciated that loading track **110** can be any geometrical shape as long as the track connects back on itself such that the track is continuous and recirculates.
[0046] FIG. **1**D shows an individual rotatable level of the array support **130** that supports multiple diagnostic assay modules **30** therein. Each diagnostic assay module **30** is contained within a carrier **141** having a carrier cover **142** with a front opening to allow access to the loading bay of a respective module **30**. The carrier **141** is securely attached to corresponding supports within the array support **130**, which can be further understood by referring to FIG. **1**E and the exploded view of the array support shown in FIG. **1**F. The support includes a slip ring, which includes a fixed slip ring portion **131** at its center, which carries power and data through a rotating union, and a rotating hub **137** which interfaces with an upper frame **136** that includes engineered cutouts for interfacing with and securely attaching multiple module carriers **141** therein to support the modules within the

level. A circuit board **139** (e.g. PCB) disposed near the bottom electrically interface with each of the modules when mounted therein. Upper frame **136** is coupled with a ring gear **132**, which is rotatably controlled by motor **134** via drive mechanism **133** to allow each level to be incrementally rotated, as described herein. Motor **134** can be a server motor, stepper motor or any suitable motor. Drive mechanism **133** can be a drive belt, cable, screw, gear or any suitable drive mechanism. Movement of the level of the array can be controlled by controller **138**. In some embodiments, controller **138** can include power control and motor motion control. Associated components can include a power transformer, power production distributer and various power distribution components. Baffle **52** interfaces with the bottom of the support and facilitates controlled airflow through each level. In some embodiments, the baffle along the bottom of each level differs between each level to provide graduated destratification of airflow between levels, providing more airflow where needed.

[0047] System **100** can include a controller that coordinates movements between the various components of the system described herein. For example, each module **30** can communicate, either directly or wirelessly, to the central controller such that the controller can identify which modules **30** are empty and can direct the elevator to the appropriate row to arrive at the identified module **30**. In some embodiments, each module communicates with a diagnostic assay cartridge **10** inserted therein by near field communication (NFC) by which an ID of the cartridge containing a biological fluid sample and an appropriate assay protocol is obtained by the module **30**. Likewise, the module **30** communicates when a sample processing is completed and the cartridge is ready to be removed such that the controller sends a command to the loader to translate along the elevator to the appropriate location to remove the spent cartridge. Although the elevator moves on command to a particular vertical location, the rows of the array support moves in regular increments (typically, a rotation sufficient to move the next adjacent column of diagnostic module of the array to the elevator) at regular intervals (typically, at least one second or more to allow loading/unloading of a diagnostic assay cartridge into a module or removal of spent cartridges from a module). In some embodiments, the array support is controlled to rotate in larger increments that skip one or more adjacent columns, which may promote more even distribution of loaded modules. The load/unload times for cartridges is short, given the large number of modules (typically 4 rows×25 modules/row), a module having an empty bay for loading or a module having a spent cartridge for unloading will arrive at one of the elevators in short order. Indeed, the entire array of 100 modules can be loaded in approximately 10 minutes.

[0048] In some embodiments, the diagnostic assay modules have a communications subsystem that can include a diagnostic component. A processor can be communicatively coupled with the communications subsystem and the diagnostic component. The processor can be configured to cause the diagnostic assay module to wirelessly receive, using the communications subsystem, a command from a mobile device. The processor can also be configured to wirelessly send, using the communications subsystem, a module command response to the mobile device. The processor can also be configured to conduct a test using the diagnostic module. The processor can also be configured to wirelessly send, using the communications subsystem, encrypted diagnostic information (e.g., medical information), indicative of a result of the test, to a remote server.

[0049] FIGS. **2**A-**2**E illustrates the process of a technician loading diagnostic assay cartridges **10** in a high throughput handling system **100** for processing within diagnostic assay modules **30** of the array and removing spent cartridges from the system **100**.

[0050] In FIG. **2**A, the technician places individual cartridges **10** to be processed within recesses of the loading track **110** of system **100** while the loading track incrementally rotates toward elevator **120**. Loader **20** is lowered along vertical elevator **120** and grasps a cartridge **10***a* to be tested. In some embodiments, the elevator includes a sensor that senses when a cartridge is ready to be picked up such that a central controller can direct the loader **20** to grasp and hold the cartridge **10***a* from the loading track **110**. If any of the modules **30** within any of array rows **130***a*, **130***b*, **130***c*,

**130***d*, are empty, the controller commands the loader **20** to translate along the elevator to any row having an empty module **30**. Loader **20** then loads the diagnostic assay cartridge **10***a* into the respective module. In this embodiment, the loader is configured to flip or rotate such that the loader can hold a pair of cartridges simultaneously. Such a configuration further improves speed and efficiency since after loading of cartridge **10***a*, the loader can flip to load the other cartridge, or could be used to remove a spent cartridge **10***b* before loading of cartridge **10***a*. To discard spent cartridge **10***b*, loader **20** lowers and releases spent cartridge **10***b* above waste chute **116** to be collected in a waste receptacle stored in base **160**. If there are no spent cartridges to remove, the dual sided loader **20** could be used to pick up two cartridges **10***a* to be loaded for sequential loading into empty modules **30** and/or the dual sided loader could be used to pick up two spent cartridges from two modules **30** for disposal.

[0051] In some embodiments, the controller commands the loader to translate to the nearest empty module, although in other embodiments, the controller commands the loader to translate to a module to distribute the cartridges more uniformly within the respective modules of the array. In some embodiments, the controller commands the loader to only pick up cartridges for a particular assay. In some embodiments, assays of a particular type are all loaded onto a particular row of the array. In some embodiments, the controller commands the loader according to a number of factors, which may be combined or weighted according to various differing objectives or combinations of objectives. Such objectives include, but are not limited to: proximity, temperature, load balance, heat balance, distribution among levels or within a respective level, time length of assay, or any combination thereof. In some embodiments, the system can determine a preferred module, a preferred level of a particular array, or a preferred array for loading of a cartridge based on one or more objectives or factors, including but not limited to any of those described herein.

[0052] FIG. **2**B shows another view of the technician loading diagnostic assay cartridges **10***a* to be processed onto the loading track **110**. In addition, a pair of emergency stop buttons **114***e* are disposed on the countertop **114**. It is appreciated that one or more emergency stop features could be included on various other portions of the system in the alternative or in addition. As can be seen, loading track **110** can include recesses **111** adapted to receive the cartridges. In any of the embodiments herein, the loading track can be continuous and/or recirculating. Loading track can be defined as multiple components that fit into a rotating ring **112** of main casting **113**, which can be seen in the exploded view of base shown in FIG. **1**H. Some embodiments could utilize any type of recirculating track configured to receive multiple cartridges. Such tracks could include a non-linear track, as shown, or a linear track having a recirculating surface (e.g. conveyor belt). Such tracks can include a cartridge receiving surface, which could include any of a recess, a protrusion, a coupling feature, a hook, magnet, or any feature suited to receive a cartridge and optionally maintain the cartridge in a particular orientation. Alternatively, the track could receive the multiple cartridges in any orientation, and the orientations are subsequently adjusted by an adjustment feature (e.g. gripper, orienting features, interfacing surfaces, or any suitable mechanism). In some embodiments, the loading track could include independently movable carts, each configured to support one or more cartridges. In some embodiments, the system includes at least one emergency stop button located on the counter, which shuts off power to the loading track and the elevators. In the embodiment shown in FIG. **1**H, loading track includes recesses **111**, each recess dimensioned to receive a respective cartridge. Recesses **111** are specially contoured so as to receive the cartridges in a proper location and orientation to facilitate grasping of the diagnostic assay cartridge by loader **20**. In some embodiments, this can be accomplished by use of interfacing features (e.g. hole/pegs), or protrusion or ridges that constrain the cartridges in the proper location and orientation. In some embodiments, the track is a continuous molded structure. In some embodiments, the holders for the cartridges are not connected and are individually separated, where each holder contains only a single cartridge. In some embodiments, the holders are arranged in small groups to hold a subset of cartridges (e.g. 2, 3, 4, 5, 6, 7, 8, 9, 10 or more cartridges). In some embodiments, the cartridge holders can be removed from the track for filling with cartridges away from the system and the filled rack can then be placed on the track for loading onto the array. In some embodiments, the system is configured to select certain cartridges from the recirculating track for loading into the array while allowing other cartridges to recirculate for one or more passes by the loader for subsequent loading into the array. Such selection can be determined based on data obtained from the cartridge so as to prioritize loading based on one or more factors, including but not limited to, any of: rush status, sample ID, type of sample, type of assay, and an assay length.

[0053] FIG. **2**C shows another view of the loader **20** grasping cartridges **10***a*, **10***b*. As can be seen, the loader **20** can be translated along elevator **120** to any row of the array **130** and can discard cartridge **10***b* by lowering and releasing the cartridge into waste chute **116**, as shown in FIG. **2**D. FIG. **2**E shows a technician loading cartridges **10** into the loading track **110** and in the process of removing waste receptacle **60** by opening base doors **161**, the waste receptacle **60** having been positioned beneath waste chute **116** within the base **160** to collect spent cartridges. Receptacle **60** can be easily removed for cleaning. In some embodiments, the base **160** includes a waste receptacle excluder **164** designed to prevent insertion of the waste receptacle **60** if the correct flap is not opened and snapped into place.

[0054] One particularly advantageous aspect of the above-described cylindrical array configuration is that the array support assembly **130** can be defined to have dimensions suitable for transporting the array through a standard sized doorway. This allows system **100** to be set up in virtually any suitable location and does not require an oversized entry, as do many conventional large-scale analysis systems. In addition, the cylindrical 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 34″ or less and a height of about 74″ 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 80″ high by 36″ wide, even when lifted off the floor by 1-2″ 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. **3**A-**3**D below.

[0055] FIG. **3**A-**3**C depict top and side views illustrating the relative dimensions of the array assembly. As seen in FIG. **3**A, the system **100** with the counter attached has a minimum width, w. In this exemplary embodiment, w is about 45.5″. As can be seen in FIG. **3**B, the maximum width, W, occurs along the counter **114**. In this embodiment, W is about 51″. As can be seen in FIG. **3**C, the system **100** has an overall height, h. In this embodiment, h is about 74″. 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. **3**D, in this embodiment, the system **100** with the counter removed has a reduced width, w′. In this embodiment, w′ is about 34″ 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. **3**A and **3**D, the countertop **114** and system **100** can be configured with a generally circular shape with one flattened side. This allows the system to be placed against a wall if needed. It is appreciated that the system and countertop, however, could be configured in any shape with or without a flattened side, including circular, polygonal (e.g. square, hexagonal, etc.) or any regular or irregular shape desired.

[0056] In some embodiments, the system can further include an automated cartridge preparer, which can be configured to perform one or more pre-analytic steps that can include such processes as adding the biological sample to be tested to the cartridge, closing the cartridge lid and preparing the cartridge for loading onto the array. By use of a cartridge preparer, wear and tear on the modules affixed within the array can be further reduced, as can technician time which is typically used for pre-analytic cartridge processing. The cartridge preparer can be further configured to position a diagnostic assay cartridge within the loading track of the system after performing the pre-analytic processing. FIG. **3**E shows an exemplary embodiment in which system **100** includes cartridge preparer **115** positioned adjacent the loading track **110**. As can be seen in FIG. **3**F, cartridge preparer **115** can include a cartridge loader for positioning a prepared cartridge **10** within loading track **110**. It is understood that the sample loader of the cartridge preparer **115** can include similar mechanisms as those described in the array elevators, or any suitable mechanisms as would be known to one of skill in the art.

[0057] In some embodiments, system **100** can include a transport cart **170** to facilitate transport and assembly of system **100** at a desired location. As shown in FIG. **4**, the transport cart **170** can include a lifter **171** controlled by crank **172**, multiple cranks or other such user control mechanisms, which may include hydraulic, electrical, pneumatic, control or lift mechanisms to allow the system **100** to be lifted off the ground and wheeled into a room. The transport cart **170** provides a more stable manner in which to move the system **100**, which may be preferable given the small footprint and relative height of the system. This approach is advantageous as it allows the array assembly **130** to be delivered and transported to its destination as a substantially assembled unit despite its considerable weight and dimensions. The removable counter can then be mounted to the system once it is delivered to its final destination. Typically, the base and array assembly are securely and fixedly attached one another. In some embodiments, the array assembly can be removed from the base to facilitate shipping or transport and can be assembled on-site. In some embodiments, the base can include wheels to allow the system to be moved or transported without any transport cart.

[0058] FIGS. **5-6** depict detailed views of the cartridge loader **20** in elevator **120**. As shown in FIG. **5**, elevator **120** includes a track **121** which guides vertical movement of a vertical carriage **122**, which is powered and controlled by the central controller in response to sensors and/or determination of empty modules **30** or spent cartridges based on communication with the modules **30**. In this embodiment, loader **20** includes two graspers **22**, each having a pair of contoured jaws that are spaced apart to grasp the outer edges along the front face under the automation flange of each cartridge **10**, as shown. The two graspers **22** extend from a central member or shaft **21** that is rotationally or pivotally coupled to a horizontal carriage **23** that translates along a pair of rods **123** extending from vertical carriage **122** towards the array **130**. Movement of the horizontal carriage in combination with movement of the grasping jaws allows the loader to pick up each diagnostic assay cartridge to be loaded as well as place the cartridge **10** within a receptacle bay of a respective module **30**. Movement of the horizontal carriage **23** towards track **121** also allows loader **20** to align any spent cartridges above the waste chute **116** to be discarded, as shown in FIG. **6**. These components can be further understood by referring to the exploded view in FIG. **1**G.

[0059] Elevator **120** can further include one or more sensors for detecting proximity of an approaching diagnostic assay cartridge in the loading track and obtaining data from the cartridge before loading. For example, as shown in FIG. **6**, a proximity sensor **125** disposed within the entry into elevator **120** detects the approaching cartridge, which signals to the elevator to pick up the cartridge. In addition, a data sensor (e.g. NFC sensor) detects an ID of the diagnostic assay cartridge and a diagnostic assay protocol for the cartridge, which in some embodiments, can be used to determine where the cartridge should be loaded onto the array. In some embodiments, an NFC sensor is used to identify a given cartridge. In some embodiments, the sensor used to detect the diagnostic assay cartridge can employ optical recognition technology (bar codes, QR codes), RFID tags, and infrared (IR) detection. Additional sensor detection methods will be well known to persons of skill in the art.

[0060] FIG. **7** depicts an exemplary waste receptacle **60** adapted for use with the above-described system. Waste receptacle **60** is specially shaped to fit within base **160** so that a narrowed portion extends under waste chute **116**. In some embodiments waste receptacle **60** includes a main receptacle body **61** that can be formed in various other shapes, e.g. square, round, oval, etc. Waste receptacle **60** is typically formed of a rigid polymer and can be formed so as to be suitable for reuse or to be disposable. In some embodiments, waste receptacle **60** further includes a lid **63** that includes end flaps **63***a* that are adapted to fold upward against main portion **63***b*. End flaps **63***a* can further include coupling feature **64***a* that interfaces with a corresponding coupling feature on **64***b* so as to hold the respective end flap in the upwardly folded position, which allows a sufficient opening for spent cartridges to be directed into the waste receptacle while the lid remains on top of the waste receptacle **60**. In some embodiments, a waste receptacle can include an excluder that prevents the waste receptacle from being inserted into base **160** if the correct flap is not opened. Such a lid is particularly useful since some diagnostic assays are performed on biological fluid samples that may contain biohazardous material (e.g. infectious waste or hazardous chemicals) such that contact with the spent cartridges should avoided or minimized.

[0061] After the waste receptacle **60** is sufficiently filled, it can be removed from base **160** and the end flap **63***a* can be folded downward and the entire lid secured and/or sealed against the outer edge opening of the waste receptacle so that the contents can be discarded within the sealed receptacle without having to empty the waste receptacle or transfer the contents. In some embodiments, the waste receptacle can include a diverter **62**, which can include angled portions **62***a*, **62***b* so as to direct any discarded cartridges into the waste receptacle. In some embodiments, the waste receptacle can include dividers or can use one or more disposable bags such that the diverter can keep spent cartridges deposited through a first opening separate from spent cartridges deposited through a second opening on the opposite end. Diverter **62** could further include a lip or ridge **62***c* along one or more sides so as to inhibit prevent any leakage or residue from spent the cartridges.

[0062] In performing assays, it is desirable and often necessary to maintain an ambient temperature within a suitable range to maintain hardware functionality, assay integrity and improve testing efficiency. In some embodiments, the ambient operating temperature range for the modules is from about 10° C. to about 40° C. In performing sample processing and diagnostic assays concurrently with a large number of modules (e.g. 100 or more), a considerable amount of heat can be created. Further, many such diagnostic assays utilize thermal cycling to amplify the target analyte in the fluid sample, which can further contribute to the overall heat being generated. Since heat rises this can result in a substantial temperature differential between the top-most row of the array **130** as compared to the bottom-most row. Thus, to maintain a suitable ambient temperature for each module of the array **130**, system **100** can include an integrated cooling system.

[0063] FIG. **8**A illustrates a cross-section of system **100**, which reveals the design of an internal cooling system **150** incorporated into the structure of the array assembly **130**, which is detailed further in FIG. **9**. Array assembly **130** is composed of four levels, each having a main circular frame, **130***a*, **130***b*, **130***c*, **130***d*. Each frame includes features for attaching and securing the module **30** to the respective frame. Each level is further designed such that each level is isolated or baffled from each other level with regard to air flow. The frames can define an open central column through which the longitudinal vertical axis of the frame extends with openings adjacent to each of the modules **30** attached to the frame. Cooling system **150** utilizes this open central column and openings adjacent the modules to force air through the array support assembly **130**. The array support assembly **130** is enclosed in an outer cylindrical, transparent outer shell **135**, which protects the modules **30** from dirt and debris and allows a microenvironment to be established and allows a positive pressure to be maintained around the array support assembly. In some embodiments, each of elevators **120** can be encased in an outer shell that merges with the outer cylindrical shell **135** such that the inside of each elevator is open to the interior of the cylindrical shell **135**. In some embodiments, the elevators are open to air flow on each level and act as “chimneys” for removing hot air from within the array assembly.

[0064] One or more cooling fans draw cool air in from the bottom of the array assembly through the open central column and outward through each of the modules **30** before the air travels upwards along the inside of outer shell **135**, and within the elevator columns, and outward through a top of the array assembly **135**. In some embodiments, positive pressure is maintained within the array assembly, as compared to an ambient environment. In some embodiments, the rate of air flow through the open central column is about 250 cubic feet per minute. The airflow path is shown by the dashed arrows in FIG. **8**A. As can be seen in FIG. **8**B, a single fan **50***a* is positioned beneath the open central column and one or more auxiliary fans **50***b* can be used to provide additional air flow through the lower level. In some embodiments, the first level **130***a* doesn't receive any air from the open central column since the first air exit holes in the column are above the first baffle **52**, thus auxiliary fans **50***b* can be used to direct air through the first level **130***a*. In some embodiments, the first exit air holes in the column are below the first baffle **52**, thus allowing the first level **130***a* to receive air from the open column (not shown). System **100** can include a cool air intake **50***c* that feeds column cooling fan **50***a* and auxiliary fans **50***b* with an air supply at a controlled temperature (not shown). Cool air intake **50***c* can include one or more fans, such as intake fans **50***d*, **50***e* and an air filter **50***f*. 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 70° F. or less. Thus, in a room with an ambient temperature of about 70° F., 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. **8**C, an external cool air supply **50***g* can be connected to cool air intake **50***c*, 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.

[0065] Since heated air tends to accumulate in the uppermost portion of the array assembly, cooling system **150** can further includes 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 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.

[0066] 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 65 and 95 degrees Fahrenheit. 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.

[0067] 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 rotate in opposite directions (e.g. **130***a* rotates clockwise, **130***b* rotates counterclockwise, **130***c* rotates clockwise, **130***d* rotates counterclockwise or vice versa). It is appreciated, however, that various other configurations and movement schemes are within the scope of the invention. Power and communication is supplied to each of the modules **30** in each frame through power and communication cables that extend through the central column and between each rotating frame through slip rings, which allow passage of power and data through a rotating union. In some embodiments, the slip rings include holes to further facilitate passage of air from the central column into each of the levels of the array assembly. Thus, the modules **30** of the array **130** remain electrically and communicatively coupled to a common power source and communication unit of the central control during the differential rotational movement of the array.

[0068] FIG. **10** illustrates an embodiment showing an ultra-high throughput handling system **200**, which includes two systems **100′** substantially similar to those described herein, which are integrated into a single system. The system can be defined by same or similar structures as the previously described embodiments with minor modification, such as a modified countertop **114** that extends between two columnar arrays. In some embodiments, the two arrays share a single loading track that can be in the shape of an oval circulating around both arrays. Such a configuration provides ever further improvements in speed and efficiency for processing extremely high-volume streams of diagnostic assay cartridges.

[0069] FIGS. **11** and **12** depict methods of loading and unloading diagnostic assay cartridges from a high throughput system in accordance with the invention. FIG. **11** shows a method of automatically loading a diagnostic assay cartridge into an available diagnostic assay module in a circular array of a high throughput handling system. FIG. **12** shows a methods of unloading and discarding a spent diagnostic assay cartridge from a diagnostic assay module in a circular array after processing is complete.

[0070] As depicted in FIG. **11**, such a method can include a step of sensing a diagnostic assay cartridge to be analyzed in a loading track of a high throughput handling system having an array of diagnostic assay modules. Sensing can include detecting proximity of the cartridge and/or reading information from the cartridge (e.g. ID, assay type, etc.). Next, the system can facilitate loading of the cartridge into the array. Typically, loading includes grasping the cartridge with a loader and loading into an available module. The method can further include identifying a diagnostic assay module within the array that is empty and available to perform sample processing based on communication with the module. Optionally, the method can include determining a preferred diagnostic module in which to load the sample from multiple available modules. Determination of a preferred module can be based on any of: proximity, temperature, load balance, heat balance, distribution among levels or within a respective level, time length of assay, or any combination thereof or any factor desired. The loader then moves the cartridge to the array until the loader is adjacent the identified module in the array and loads the cartridge into the empty bay of the identified or preferred module.

[0071] As depicted in FIG. **12**, such methods can include a step of receiving a communication from a diagnostic assay module in an array of a high throughput handling system that sample processing is complete. Next, the method can entail identifying a location of the module within the array, then moving a loader/unloader relative the array until adjacent the identified module. This can include waiting until the array is moved to an appropriate position so that the loader can intercept the identifying module when the respective column is moved adjacent the loader. Next, the spent cartridge is removed from the module and moved away from the identified module and released or discarded into a waste receptacle.

[0072] FIG. **13** illustrates throughput of samples on the **100** module system of FIG. **1**A (Omega 100) and the **200** module system of FIG. **10** (Omega 200) as compared to conventional high throughput systems (Cepheid Infinity-80, Roche Cobas 4800, BD Viper XTR, Hologic Panther, and Abbott M2000). Throughput data for the Omega system was modeled based on simulation models of the Omega 100 and Omega 200 systems and utilizing available data from each of the commercial systems noted. The data for the commercial systems was obtained from the study by Jang et al. (Sexually Transmitted Disease (June 2016) Vol 43(6):377-381. This data is also provided in Table 1 below. As can be seen, the time required to process a large number of samples with the Omega system is considerably lower than any of the other commercially available systems as shown, for example analysis of 192 sample in the Omega 200 system can be performed in less than half the time required by other commercially available systems.

TABLE-US-00001 TABLE 1 Time Comparison of High Throughput Systems Sam- Omega Omega Cobas Viper ples 200 100 Infinity 4800 XTR Panther M2000 1 1:30 1:30 1:31 3:15 3:42 4:05 4:35 10 1:34 1:34 1:40 3:16 4:06 4:11 5:04 24 1:40 1:40 2:03 3:36 4:08 4:32 5:21 48 1:50 1:50 2:13 3:49 4:13 5:01 5:48 96 2:10 2:10 3:54 5:03 5:13 5:55 7:15 192 2:50 4:04 6:45 7:47 7:25 7:43 12:07

[0073] FIGS. **14**A-**14**D illustrate alternative embodiments of a high throughput processing systems,

in accordance with aspects of the invention. FIG. **14**A shows system **300**, which includes a circular array of modules **301** and loading track **310**. Similar to other embodiments, loading track **310** is a recirculating track that transports diagnostic assay cartridges to a loader, however, track **310** includes movable cartridge carriers **311** (e.g., carriages or "boats") that circulate within the track. In some embodiments, each cartridge support can be independently movable within the loading track and can be removed and replaced as needed. Each carrier **311** can include a support feature, such as a contoured recess or other suitable feature for releasably supporting the cartridge within the carrier. FIG. **14**B shows system **400**, which includes a hexagonal array of modules **401** and a similarly shaped loading track **410**. Loading track **410** includes cartridge carriers **411**, similar to those described in system **300**, that transport cartridges to the loader for loading into the hexagonal array. FIG. **14**C shows system **500**, which includes a circular array of modules **501** and a pair of linear loading tracks **510** that transport cartridges directly to a pair of loaders on each side of the array. Such linear tracks can include any features of the loading tracks described herein or any suitable transport mechanism as would be known to one of skill in the art. FIG. **14**D shows system **600**, which includes two circular arrays of modules and a dumbbell shaped loading track **610** that transports cartridges to either of the module arrays. As can be seen, loading track **610** can transport a cartridge to any of the loaders associated with either of the module arrays. Such an approach allows the cartridges to be distributed between multiple arrays regardless of whether the cartridge is placed on the loading track **610**. Alternatively, the cartridges could be allocated to a particular array, as desired. In this embodiment, loading track **610** utilizes carriers **611** such that those described above in system **300**. It is appreciated that loading track could include any loading track feature described herein or could use any suitable alternate transport mechanism. While certain shapes of the module arrays and loading tracks have been described, it is appreciated that various other shapes and arrangements could be utilized in accordance with the principles described herein.
[0074] In the foregoing specification, the invention is described with reference to specific embodiments thereof, but those skilled in the art will recognize that the invention is not limited thereto. Various features, embodiments and aspects of the above-described invention can be used individually or jointly. Further, the invention can be utilized in any number of environments and applications beyond those described herein without departing from the broader spirit and scope of the specification. The specification and drawings are, accordingly, to be regarded as illustrative rather than restrictive. It is recognized that the terms "comprising," "including," and "having," as used herein, are specifically intended to be read as open-ended terms of art.

## Claims

**1-70**. (canceled)
**71**. 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 in an array, each diagnostic assay module configured for receiving a diagnostic assay cartridge of the plurality and performing a diagnostic assay on the biological sample within the respective diagnostic assay cartridge; one or more module sensors associated with each module within the array; and a controller having an input and an output, the controller being configured to determine a preferred diagnostic assay module from the plurality of diagnostic assay modules into which one diagnostic assay cartridge of the plurality of diagnostic assay cartridges is to be inserted.
**72**. The system of claim 71, wherein the controller determination is based on any of: proximity, a temperature measurement, a load balance, a heat balance, a distribution among the array, a time length of assay, or any combination thereof.
**73**. The system of claim 71, wherein the controller determination is based on a cartridge identification, an assay type, or a combination thereof.

**74**. The system of claim 71, wherein each diagnostic assay module includes a door to allow access to a loading bay of the respective module.
**75**. The system of claim 71, further comprising an array support assembly adapted to support the plurality of diagnostic assay modules in the array, wherein the array has at least two dimensions and comprises a plurality of rows, each row including a plurality of carriers for supporting the plurality of diagnostic assay modules, the plurality of carriers being securely attached to a frame that is rotatable about a central rotating hub, wherein the plurality of diagnostic assay modules in each row are coupled to power and communication while supported within the array support assembly.
**76**. The system of claim 75, wherein the array support assembly comprises a plurality of stacked circular frames defining an open central column and is configured so as to define a cylindrical array; and wherein the system further comprises, one or more temperature sensors disposed at one or more locations within the array; a cooling system comprising, one or more fans, one or more diverters configured to divert air from the open central column to one or more rows of the array, and an external air cooler, wherein one or more of the one or more fans are disposed to intake air from the external air cooler and direct the air upward from a bottom of the open central column toward a top of the open central column; and a temperature controller communicatively coupled to the cooling system and to one or more of the one or more temperature sensors, wherein the temperature controller is configured to maintain the environment of the array assembly within range of temperatures suitable for processing of the biological samples within the modules of the array.
**77**. The system of claim 76, wherein the range of suitable temperatures is between 10 and 40 degrees Celsius to facilitate a PCR analysis.
**78**. The system of claim 71, wherein each of the diagnostic assay modules is adapted to perform a diagnostic assay independent from each other.
**79**. The system of claim 71, further comprising a loader adapted to load the plurality of diagnostic assay cartridges within the plurality of diagnostic assay modules while supported within an array support assembly, the loader being translatable between rows of the array support assembly and including a grasper for grasping each of the plurality of diagnostic assay cartridges for loading and/or unloading the respective cartridge from any of the plurality of diagnostic assay modules, 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 the loader;
**80**. The system of claim 79, 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.
**81**. The system of claim 79, wherein the controller is further 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 module sensors that the diagnostic assay module is available for loading.
**82**. The system of claim 81, wherein the controller is further configured 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.
**83**. The system of claim 81, wherein the one or more module sensors are further configured to obtain a unique ID of each a diagnostic assay module and an associated cartridge loaded therein.
**84**. The system of claim 71, wherein each diagnostic assay module includes a communication unit adapted to communicate with the controller.
**85**. The system of claim 84, wherein the 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.

**86**. The system of claim 71, wherein the controller is further configured to track which diagnostic assay module of the plurality is associated with each diagnostic assay cartridge of the plurality.
**87**. The system of claim 71, further comprising an array support assembly adapted to support the plurality of diagnostic assay modules in the array.
**88**. The system of claim 87, wherein the array has at least two dimensions and the array support assembly includes at least two rows.
**89**. The system of claim 71, wherein the range of suitable temperatures is within a pre-defined delta from a target temperature.
**90**. The system of claim 71, further comprising a temperature controller communicatively coupled to a cooling system including one or more fans, the temperature controller being configured to adjust air flow through the system by adjusting fan speed of one or more of the one or more fans.