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Description

CROSS REFERENCE TO RELATED APPLICATIONS

5 **[0001]** The present application claims priority to U.S. Provisional Application Serial No. 61/594867, entitled "EXTERNAL FILES FOR DISTRIBUTION OF MOLECULAR DIAGNOSTIC TESTS AND DETERMINATION OF COMPATIBILITY BETWEEN TESTS," filed February 3, 2012

BACKGROUND OF THE INVENTION

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Field of the Invention

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[0002] Embodiments disclosed herein relate to methods and systems for performing an automated assay, and particularly to performing a plurality of assays on a plurality of samples on an automated instrument.

Description of the Related Art

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[0003] The medical diagnostics industry is a critical element of today's healthcare infrastructure. In the last decade, the use of nucleic acid based assays for diagnostic testing has become increasingly more common. The automation of processing and testing samples in diagnostic testing is appealing, as it minimizes experimental variability and reduces the need for highly trained technicians. In addition to benefits in the field of diagnostics, automation of processing and testing samples has facilitated high throughput testing.

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[0004] Understanding that processing samples for purposes such as diagnostic testing or high throughput testing may break down into several key steps, it is often desirable to automate one or more steps. For example, in the context of diagnostics, a biological sample, such as those obtained from a patient, can be used in nucleic acid amplification assays in order to amplify a target nucleic acid (e.g., DNA, RNA, or the like) of interest. Once amplified, the presence of a target nucleic acid, or amplification product of a target nucleic acid (e.g., a target amplicon) can be detected, wherein the presence of a target nucleic acid and/or target amplicon is used to identify and/or quantify the presence of a target (e.g., a target microorganism or the like). Often, nucleic acid amplification assays involve multiple steps, which can include

30 nucleic acid extraction, nucleic acid amplification, and detection. It is desirable to automate certain steps of these processes. EP 2 372 367 A1 discloses a computer-implemented method for operating an automated sample workcell, the workcell comprising a sample conveyor connecting at least one centrifuge to a sample input station, the method comprising- receiving samples by the sample input station;- assigning to each sample a centrifugation parameter;- transporting each sample from the sample input station to the at least one centrifuge;- comparing the centrifugation parameters of

35 the samples loaded or to be loaded into the at least one centrifuge and determining the centrifugation parameter of highest centrifugation intensity;- loading the samples into the centrifuge, the loaded samples comprising samples with different centrifugation parameters;- centrifuging the loaded samples in accord with a centrifugation protocol of said highest centrifugation intensity. Other technology is shown in US 2007/243626 A1, US 6 326 147 B1, or US 2006/210435 A1.

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[0005] There is a need for improved methods and devices for carrying out assays on multiple samples in parallel. The embodiments described herein address this need and can advantageously be used in clinical and research settings.

SUMMARY OF THE INVENTION

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[0006] The present technology relates to methods and systems for performing an automated assay, and particularly to performing a plurality of assays on a plurality of samples on an automated instrument. In some embodiments of the present technology, such methods and systems can permit the concurrent performance of discrete assay workflows on an instrument when the assay workflows are compatible, and can prevent the concurrent performance of incompatible assays within the same workstation. Some embodiments relate to performing a plurality of user-defined protocols (UDP) on an automated instrument. Some embodiments relate to performing a plurality of assay definition files (ADF) developed

50 by an assay manufacturer. Some embodiments relate to performing one or more UDPs, optionally in combination with one or more ADFs, concurrently on the same automated instrument.

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[0007] In some embodiments of the technology presented herein, methods of performing an automated assay on a plurality of samples are provided that allow for improved reliability and ease of use when performing an assay on an automated instrument. The method according to the invention is defined in independent claim 1.

[0008] In some embodiments, the first level compatibility can comprise compatibility of performing two assays concurrently at a single workstation, the parameters selected from the group consisting of: incubation time, lysis time, reagent volume, reagent type, incubation temperature, lysis temperature, workstation time demands, regulatory classification,

business considerations, and a combination thereof.

[0009] In some embodiments, the second level compatibility can comprise compatibility of performing two assays concurrently on the automated instrument, the parameters selected from the group consisting of: regulatory classification, workflow incompatibility, business considerations, and a combination thereof.

[0010] In some embodiments, the instrument prevents the concurrent performance of incompatible assays within the same workstation when the first compatibility indexes are different. In some embodiments, the two discrete assay workflows are performed in the same workstation. In some embodiments, the instrument is prevented from concurrently performing assays with different second compatibility index values. In some embodiments, two assays have the same first level compatibility index value and have different second level compatibility index values. In some embodiments, the difference in the second level compatibility index values can comprise a business reason. In some embodiments, the difference in the second level compatibility index values can comprise a regulatory classification.

[0011] In some embodiments, if the assays are compatible, the method can further comprise one or more of the following (d) initiating an assay-specific sample preparation script on the instrument; (e) comparing identifying indicia on a consumable package to a set of assay-specific identifying data stored on the instrument; (f) initiating an assay-specific load cartridge script on the instrument; (g) comparing levels of detectable signals fluorescence ratios in a loaded cartridge to a set of assay-specific detectable signal data stored on the instrument to determine whether the cartridge was successfully loaded; (h) initiating an assay-specific reaction script on the instrument; (i) initiating an assay-specific data analysis algorithm on the instrument; or (j) deriving a final call for the assay, based on one or more assay-specific result algorithms or scripts.

[0012] In some embodiments, the assay protocol can comprise a reaction selected from the group selected from: Polymerase Chain Reaction (PCR), Transcription Mediated Amplification (TMA), Oligonucleotide Ligation Assay (OLA), Ligase Chain Reaction (LCR), Rolling Circle Amplification (RCA), Strand Displacement Amplification (SDA), and a hybridization reaction.

[0013] Also presented herein is a system for performing an automated assay as defined in independent claim 8.

[0014] In some embodiments of the above system, the first level compatibility can comprise compatibility of performing two assays concurrently at a single workstation, the parameters selected from the group consisting of: incubation time, lysis time, reagent volume, reagent type, incubation temperature, lysis temperature, workstation time demands, regulatory classification, business considerations, and a combination thereof.

[0015] In some embodiments of the above system, the second level compatibility can comprise compatibility of performing two assays concurrently on the automated instrument, the parameters selected from the group consisting of: regulatory classification, workflow incompatibility, business considerations, and a combination thereof.

[0016] In some embodiments of the above system, the instrument prevents the concurrent performance of incompatible assays within the same workstation when the first compatibility indexes are different. In some embodiments, the two discrete assay workflows are performed in the same workstation. In some embodiments, the instrument is prevented from concurrently performing assays with different second compatibility index values. In some embodiments, two assays have the same first level compatibility index value and have different second level compatibility index values. In some embodiments, the difference in the second level compatibility index values can comprise a business reason. In some embodiments, the difference in the second level compatibility index values can comprise a regulatory classification.

[0017] In some embodiments of the above system, if the assays are compatible, the system can further comprise instructions for one or more of the following (d) initiating an assay-specific sample preparation script on the instrument; (e) comparing identifying indicia on a consumable package to a set of assay-specific identifying data stored on the instrument; (f) initiating an assay-specific load cartridge script on the instrument; (g) comparing levels of detectable signals in a loaded cartridge to a set of assay-specific detectable signal data stored on the instrument to determine whether the cartridge was successfully loaded; (h) initiating an assay-specific reaction script on the instrument; (i) initiating an assay-specific data analysis algorithm on the instrument; or (j) deriving a final call for the assay, based on one or more assay-specific result algorithms or scripts.

[0018] In some embodiments of the above system, the assay protocol can comprise a reaction selected from the group selected from: Polymerase Chain Reaction (PCR), Transcription Mediated Amplification (TMA), Oligonucleotide Ligation Assay (OLA), Ligase Chain Reaction (LCR), Rolling Circle Amplification (RCA), Strand Displacement Amplification (SDA), and a hybridization reaction.

[0019] In some embodiments of the above system, the system further can comprise a bar code reader. In some embodiments of the above system, the identifying indicia can comprise a bar code.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020]

Figure 1 is a schematic drawing demonstrating a method of assigning first- and second-level compatibility index

values to a particular assay workflow or user defined protocol (UDP).

Figure 2 is a schematic drawing demonstrating a method of identifying first-level and second level compatibility between two assay protocols according to one embodiment.

Figure 3 is a schematic drawing demonstrating a method of selecting and performing concurrent assay protocols according to one embodiment.

Figure 4 is a schematic drawing that illustrates an automated instrument with independent workstations and a shared service according to one embodiment.

Figure 5 is a look up table to show rack and run compatibility according to one embodiment.

DETAILED DESCRIPTION

[0021] Automated diagnostic instruments are now able to carry out processing and testing of multiple samples in parallel. These devices can advantageously be used in high throughput to facilitate the sample preparation and testing. By way of example, automated diagnostic instruments can prepare samples for nucleic acid amplification assays, and perform the amplification and detection. Depending on the type of samples and the type of assay, however, many times, assay protocols are not compatible with each other on the same instrument, either because of physical constraints on the instrument, or for business reasons. For example, any two assay protocols may have different incubation times, lysis times, reagent volumes, reagent types, incubation temperatures, lysis temperatures, workstation time demands, or other parameters that render it impossible for the instrument to perform different assays in samples in a single workstation, or even on the same instrument. In addition to physical constraints, regulatory classifications and business considerations are each factors which may prevent the instrument from processing samples concurrently. In order to address this issue, users had to manually compare assay protocols on a chart or table to determine whether they can be performed concurrently on the same rack, or even on different racks of the same instrument. Such manual approaches can be error prone, as well as inefficient and labor intensive. Thus, there exists a great need for improved methods to identify compatible assay protocols and prevent incompatible assay protocols from being performed concurrently.

[0022] In accordance with the above, provided herein are methods and systems for performing an assay protocol on an automated instrument. In some embodiments of the present technology, such methods and systems can permit the concurrent performance of discrete assay workflows on an instrument when the assay workflows are compatible, and can prevent the concurrent performance of incompatible assay protocols within the same instrument. The methods provided herein allow for improved reliability and ease of use when performing an assay on an automated instrument.

[0023] Accordingly, provided herein is a method of providing an automated instrument comprising a first workstation and a second workstation and a common service that is shared by both workstations, each of the first and second workstations configured to receive and processes a plurality of samples according to a plurality of different automated assay workflows, wherein each different automated assay workflow has an associated unique assay definition or user-defined protocol file; determining whether two discrete assay workflows are compatible or incompatible with each other for concurrent processing on the automated instrument; and performing the discrete assay workflows concurrently on the instrument when the assay protocols are compatible.

[0024] As used herein, the terms "workstation," "rack" and like terms refer to an assembly that can hold a plurality of samples within an instrument designed to process those samples together. Thus, two workflows which can be performed concurrently on the same rack are designated herein as "rack-compatible."

[0025] Two workflows which can be performed concurrently on the same instrument are designated herein as "run-compatible." In certain embodiments, two run-compatible workflows are not compatible on the same rack, but can be performed on separate racks in the instrument. In certain embodiments, two run-compatible workflows are compatible on the same rack. In certain other embodiments, two run-incompatible workflows are compatible on the same rack, but cannot, for any one of a variety of reasons, be performed concurrently on the same instrument.

[0026] As used herein, the terms "workflow," "assay workflow," "assay," "assay protocol," "test," and like terms refer to a procedure for processing a sample. In typical embodiments, a workflow can include sample preparation steps, such as cell lysis, nucleic acid extraction, nucleic acid purification, nucleic acid digestion, nucleic acid modification, protein extraction, protein purification, and the like. Several methods of nucleic acid extraction useful in the embodiments disclosed herein are known in the art. Exemplary discussions of nucleic acid extraction can be found, for example, in U.S. Patent Application No. 12/172,214, filed July 11, 2008, U.S. Patent Application No. 12/172,208, filed July 11, 2008, and U.S. Patent Application No. 11/281,247, filed Nov. 16, 2005. Likewise, exemplary discussions of protein extraction can be found, for example, in U.S. Patent Nos. 8,053,239 and 6,864,100.

[0027] In some typical embodiments, a workflow can also include nucleic acid amplification reactions. In some typical embodiments, a workflow can further include data analysis procedures.

[0028] Accordingly, in certain embodiments, workflows are not directly compatible with each other due to physical differences, such as incubation time, lysis time, reagent volume, reagent type, incubation temperature, lysis temperature, workstation time demands, and the like. Each of these parameters place unique physical restraints on the motion and

capacity of either the workstation itself or on a shared service resource within an automated instrument. For example, an RNA extraction protocol, a DNA extraction protocol, and a protein extraction protocol may each require different motions for a pipetting head on an instrument, and therefore cannot be processed at the same time on the same workstation. By way of another example, a PCR assay and an assay based solely upon hybridization of detectable probes to a target may require different temperature cycling and timing requirements, and therefore cannot be processed at the same time. It will be appreciated that any physical, temporal or other limitation can present a reason for which two workflows are not directly compatible with each other.

[0029] In certain embodiments, incompatibility is driven by physical restraints on motion and capacity of a shared service resource within an automated instrument that is shared by two or more workstations. As illustrated in Figure 4, two or more independent workstations can utilize a shared resource. The shared resource can be, for example, a pipettor, a robotic arm, a single detector unit, or any other resource that is shared by two or more workstations.

[0030] The physical, temporal or other parameters need not be identical between assays in order to indicate compatibility. Rather, parameters can fall within a range which confers compatibility of, for example, a shared resource. Table 2 in Example 1 below provides an example for assays with parameters that vary within a range, yet still maintain compatibility, whereas assays with parameters outside any one range are no longer compatible.

[0031] In addition, workflows that are otherwise physically compatible on an instrument can nonetheless be incompatible for other reasons. In certain embodiments, two workflows cannot be performed concurrently in order to comply with regulatory restraints. For example, if one assay protocol has been approved by a regulatory agency such as the United States Food and Drug Administration (FDA), that agency may stipulate that the assay protocol cannot be performed concurrently with an unapproved assay protocol. Likewise, in certain embodiments, a manufacturer or user of instruments, consumable materials, or reagents may be under contractual restrictions or other business limitations, under which two workflows cannot be performed concurrently on the same instrument. It will be appreciated that incompatibility can be determined for any reason for which a manufacturer or user determines that two workflows should be incompatible. The methods and systems provided herein make it possible to identify compatible workflows and perform a plurality of compatible workflows on the same instrument at the same time.

[0032] As illustrated in Figure 3, rack and run compatibility can be determined by any of a number of workflow parameters. For example, parameters which may determine rack or run compatibility include, but are not limited to, reagent strip design, number and type of consumable reagents and the specific processes performed during the workflow, such as nucleic acid extraction or full analysis of a nucleic acid sample after extraction.

Assay Definition Files

[0033] In embodiments of the methods and systems provided herein, each different automated assay workflow has an associated unique assay definition or user-defined protocol file. As used herein, the term assay definition file (ADF) refers to a file that provides at least some, and typically all of the assay specific parameters for that workflow. In addition, an ADF can provide compatibility index values for a particular workflow. In typical embodiments, the ADF can contain all of the information needed to run the assay on an automated instrument. One function of the ADF is to provide a layer of independence between the instrument and the assay. This independence provides the mechanism by which an instrument manufacturer or assay reagent manufacturer can release new assay protocols for an instrument without producing major revisions to the instrument software.

[0034] An ADF can comprise one or more of the components set forth in Table 1 below. In particular, the ADF can include the two-level index values for rack and run compatibility.

Table 1. ADF parameters and settings

Level-1 compatibility index value
Level-2 compatibility index value
Sample prep parameters
Scripts used for sample prep, load cartridge, and PCR.
Required consumable barcodes
Fill check thresholds
PCR Protocol
Script used to generate results
Thresholds used to generate results

(continued)

Parameters used to drive the data analysis engine within the instrument

5 **[0035]** Thus, in some embodiments of the methods and systems provided herein, if the assay protocols are compatible, the ADF can include instructions for performing one or more of the following: initiating an assay-specific sample preparation script on the instrument; comparing identifying indicia on a consumable package to a set of assay-specific identifying data stored on the instrument; initiating an assay-specific load cartridge script on the instrument; comparing levels of
10 detectable signals in a loaded cartridge to a set of assay-specific detectable signal data stored on the instrument to determine whether the cartridge was successfully loaded; initiating an assay-specific reaction script on the instrument; initiating an assay-specific data analysis algorithm on the instrument; or deriving a final call for the assay, based on one or more assay-specific result algorithms or scripts. The detectable signals that are compared during a load cartridge script can be any suitable detectable signal that indicates proper loading. In typical embodiments, the detectable signal is fluorescence, and the ratio of fluorescence at various wavelengths in a sample or reagent can be compared to set of
15 pre-determined fluorescence data in order to determine whether the cartridge was properly loaded.

[0036] In some embodiments, the ADF can also comprise a reaction including, but not limited to: Polymerase Chain Reaction (PCR), Transcription Mediated Amplification (TMA), Oligonucleotide Ligation Assay (OLA), Ligase Chain Reaction (LCR), Rolling Circle Amplification (RCA), Strand Displacement Amplification (SDA), and a hybridization reaction.

[0037] Example 5 below describes an exemplary use of an ADF file to run assay protocols on an instrument.

20 **[0038]** Typically, when a new assay is made available to a customer, the corresponding ADF is installed on the instrument. Once an ADF is installed on the instrument, that assay is then available for execution on the instrument. The instrument software can then use the index values to control addition of tests to a run worklist. If assay protocols share the same rack index value, then they are allowed to be in the worklist in contiguous positions in a single rack. If two assay protocols have a different run index, then they can not be in the same run worklist. When a user selects the first assay to be included in a run, the software checks the compatibility index values of all other assay protocols available
25 on the instrument and modifies the list of assay protocols that the user can select according to the rules listed above, thereby ensuring that the customer does not choose incompatible assay protocols.

[0039] An ADF may be provided in any suitable format. For example, the ADF could be provided by a manufacturer on a storage medium such as CD-ROM or USB key, or downloaded from the manufacturer and then transferred to the terminal that controls the instrument. Multiple ADFs, each defining a distinct assay protocol, can thus be installed on the same instrument. Advantageously, the methods and systems provided herein make it possible for the system to identify assay protocols with the same compatibility index values, rather than force a user to consult a chart or table.

35 User Defined Protocols

[0040] In certain embodiments, assay parameters are determined by the user, rather than the manufacturer. These user defined protocols (UDP) can also be assigned first-level and second-level compatibility index values to ensure compatibility with other commercially-developed assay protocols. One of the benefits of the indexes and assay definition files is that it provides a firewall between user defined assay protocols and commercially-developed assay protocols
40 that also covers compatibility. The index values can be used to set up unique controls for user defined protocols which are different from the index values for commercially-developed assay protocols. In the embodiment illustrated in Figure 1, User Defined Protocols are represented by the boxes labeled as UDP and Extraction Only.

[0041] Thus, as illustrated in Figure 1, first-level and second-level compatibility index values for a UDP can be assigned according to similar factors that determine compatibility for ADFs. Such factors include, for example, the extraction kit and PCR type selected by the user, reagent strip design, the number of MM (master mixes), and the specific process (extraction versus full process). The UDP can thus include compatibility index values as part of the full code, since there is no ADF provided by a manufacturer. An illustration of this process is set forth in Example 6 below.

45 **[0042]** It will be appreciated that new extraction kits, PCR assay types, and other reagents can be provided by a manufacturer with a file similar to an ADF. Thus, when such files are installed on an instrument, and a new UDP is created, the index values for one or more UDPs may be updated accordingly.

First Level Compatibility Index Value

55 **[0043]** According to the invention the assay definition or user defined protocol file comprises a first level compatibility index value. Typically, the first level compatibility index value refers to rack compatibility. However, in certain other embodiments, the first level compatibility index value refers to run compatibility and the second level index value refers to rack compatibility. Thus, the method can comprise (a) selecting a first assay protocol from among a first list of available

assay protocols; and (b) evaluating which of a plurality of other available assay protocols have an assay definition file comprising the same first level compatibility index value as the first assay. In typical embodiments, two assay protocols having the same first level compatibility index value is indicative of first-level compatibility. It will be appreciated, however, that any suitable mechanism that can assign and identify compatibility values to individual assays can serve in the methods and systems provided herein. Thus, in some embodiments, two assay protocols that are rack compatible may have different first level index values. However, for convenience in this disclosure, two assay protocols with first level compatibility are considered as having the same first level compatibility index value.

[0044] The list of available assay protocols can change as the user selects one or more assay protocols to perform, and first level compatibility is evaluated. As such, the evaluating step (b) can comprise the steps of (b1) identifying any assay protocols which have first level compatibility index values different from the first compatibility index value of the first assay; and (b2) providing a second list of second assay protocols, wherein the second list excludes any assay having a first level compatibility index value different from the first compatibility index value of the first assay.

[0045] In some embodiments, the first level compatibility can take into consideration any parameter that could prevent performance of two assay protocols concurrently at a single workstation. Such parameters are known to those of skill in the art, and can include, for example, physical parameters such as incubation time, lysis time, reagent volume, reagent type, incubation temperature, lysis temperature, workstation time demands, and the like. Further, other parameters can include considerations such as regulatory classification, business considerations, and the like.

Second Level Compatibility Index Value

[0046] According to the invention, the assay definition or user defined protocol file comprises a second level compatibility index value. Typically, the second level compatibility index value refers to run compatibility. However, in certain other embodiments, the second level compatibility index value refers to rack compatibility and the second level index value refers to run compatibility. Thus, the method can comprise (c) evaluating which of a plurality of other available assay protocols have an assay definition file comprising the same second level compatibility index value as the first assay, wherein the same second level compatibility index value is indicative of second-level compatibility. In typical embodiments, two assay protocols having the same second level compatibility index value is indicative of second level compatibility. It will be appreciated, however, that any suitable mechanism that can assign and identify compatibility values to individual assays can serve in the methods and systems provided herein. Thus, in some embodiments, two assay protocols that are run compatible may have different second level index values. However, for convenience in this disclosure, two assay protocols with second level compatibility are considered as having the same second level compatibility index value.

[0047] The list of available assay protocols can change as the user selects one or more assay protocols to perform, and second level compatibility is evaluated. As such, the evaluating step (c) can comprise the steps of (c1) identifying any assay protocols which have second level compatibility index values different from the second compatibility index value of the first assay; and (c2) providing a second list of second assay protocols, wherein the second list excludes any assay having a second level compatibility index value different from the second compatibility index value of the first assay.

[0048] In some embodiments, the second level compatibility can take into consideration any parameter that could prevent performance of two assay protocols concurrently at a single workstation. Such parameters are known to those of skill in the art, and can include, for example, physical parameters such as incubation time, lysis time, reagent volume, reagent type, incubation temperature, lysis temperature, workstation time demands, and the like. Further, other parameters can include considerations such as regulatory classification, business considerations, and the like.

[0049] In some embodiments, the instrument prevents the concurrent performance of incompatible assay protocols within the same workstation when the first compatibility indexes are different. In some embodiments, the two discrete assay workflows are performed in the same workstation. In some embodiments, the instrument is prevented from concurrently performing assay protocols with different second compatibility index values. In some embodiments, two assay protocols have the same first level compatibility index value and have different second level compatibility index values. In some embodiments, the difference in the second level compatibility index values can comprise a business reason. In some embodiments, the difference in the second level compatibility index values can comprise a regulatory classification.

[0050] It will be appreciated that the two-level index described above is expandable from a two workflow system to larger numbers of workflows that are desired to run concurrently on an instrument, but may have constraints to run concurrently based on physical or business constraints. Thus, as illustrated in Figure 3, additional workflows may be added to a rack or multiple racks as needed, and the methods described herein will ensure that compatibility among all assays is maintained.

Instruments and Systems

5 [0051] Also presented herein is a system for performing an automated assay, the system comprising an automated instrument comprising a first workstation and a second workstation, each of the first and second workstations configured to receive and processes a plurality of samples according to a plurality of different automated assay workflows, and supported by a single service resource. Each different automated assay workflow typically comprises an associated unique assay definition file or user-defined protocol file. The system also comprises a processor; a storage capacity; and a program for performing an automated assay, the program comprising instructions for determining whether two discrete assay workflows are compatible or incompatible with each other for concurrent processing on the automated instrument; and performing the discrete assay workflows concurrently on the instrument when the assays are compatible.

10 [0052] Automated instruments which can perform multiple assay protocols concurrently are known to those of skill in the art. Exemplary discussions of typical automated instruments for use with the methods provided herein can be found, for example, in U.S. Patent Application No. 12/173,023, filed July 14, 2008.

15 [0053] It will be appreciated that the methods and systems described herein can apply to instruments that comprise 2, 3, 4 or more workstations wherein at least 2 of the workstations are supported by a common service resource. For example, an instrument with 4 workstations and a single pipette head could still be compatibility controlled by the 2 index concept described herein.

20 [0054] As used herein, the terms storage capacity, storage device, storage and the like can refer to any medium, device or means of storage of information. Storage can include, but is not limited to, a disk drive device such as a hard drive, floppy disk, optical or magnetooptical disk, memory such as RAM or ROM chips, and any other medium used to record or store data. In some embodiments, a storage capacity is connected to a processor which sends information to be recorded on the storage capacity after it is acquired. In specific embodiments, data is acquired by a system and is recorded on a storage capacity. In other embodiments, data is acquired by a system and information is first processed and the processed information is recorded on a storage capacity.

25 [0055] The files and programs provided herein can be in any suitable programming language. In certain embodiments, the ADF utilizes XML as a mechanism for formatting files. Further, in certain embodiments, ADF utilizes Python as a scripting language to provide a mechanism for executing result logic using common technologies available on the instrument. It will be appreciated that any suitable file format and programming language can be utilized in the methods and systems provided herein. In certain embodiments, files can be encrypted to protect against the use of counterfeit reagents and to control specific parameter details on assay runs.

30 [0056] As used herein, an "input" can be, for example, data received from a keyboard, rollerball, mouse, voice recognition system or other device capable of transmitting information from a user to a computer. The input device can also be a touch screen associated with the display, in which case the user responds to prompts on the display by touching the screen. The user may enter textual information through the input device such as the keyboard or the touch-screen.

35 [0057] The invention is operational with numerous other general purpose or special purpose computing system environments or configurations. Examples of well-known computing systems, environments, and/or configurations that may be suitable for use with the invention include, but are not limited to, microcontrollers, personal computers, server computers, handheld or laptop devices, multiprocessor systems, microprocessor-based systems, programmable consumer electronics, network PCs, minicomputers, mainframe computers, distributed computing environments that include any of the above systems or devices.

40 [0058] As used herein, "instructions" refer to computer-implemented steps for processing information in the system. Instructions can be implemented in software, firmware or hardware and include any type of programmed step undertaken by components of the system.

45 [0059] A "microprocessor" or "processor" may be any conventional general purpose single- or multi-core microprocessor such as a Pentium® processor, Intel® Core™, a 8051 processor, a MIPS® processor, or an ALPHA® processor. In addition, the microprocessor may be any conventional special purpose microprocessor such as a digital signal processor or a graphics processor. A "processor" may also refer to, but is not limited to, microcontrollers, field programmable gate arrays (FPGAs), application-specific integrated circuits (ASICs), complex programmable logic devices (CPLDs), programmable logic arrays (PLAs), microprocessors, or other similar processing devices.

50 [0060] The system is comprised of various modules as discussed in detail herein. As can be appreciated by one of ordinary skill in the art, each of the modules comprises various sub-routines, procedures, definitional statements and macros. Each of the modules are typically separately compiled and linked into a single executable program. Therefore, the following description of each of the modules is used for convenience to describe the functionality of the preferred system. Thus, the processes that are undergone by each of the modules may be arbitrarily redistributed to one of the other modules, combined together in a single module, or made available in, for example, a shareable dynamic link library.

55 [0061] Certain embodiments of the system may be used in connection with various operating systems such as SNOW LEOPARD®, iOS®, LINUX, UNIX or MICROSOFT WINDOWS®.

[0062] Certain embodiments of the system may be written in any conventional programming language such as as-

sembly, C, C++, C#, BASIC, Pascal, or Java, and run under a conventional operating system.

[0063] In addition, the modules or instructions may be stored onto one or more programmable storage devices, such as FLASH drives, CD-ROMs, hard disks, and DVDs. One embodiment includes a programmable storage device having instructions stored thereon.

[0064] In some embodiments of the above system, the system further can comprise a device for reading identifying indicia on reagent packaging. It will be appreciated that any suitable device for reading identifying indicia can be used in the systems provided herein. Likewise, any suitable identifying indicia may be used that is compatible with the device on the instrument. Examples include bar codes, QR codes, RFID tags, color codes and the like. In typical embodiments, the device can be a bar code reader, and the identifying indicia can comprise a bar code. Example 4 below describes use of barcode labels to properly identify consumable reagents.

Advantages and Improvements

[0065] The methods and systems presented herein provide numerous advantages over existing approaches. For example, the use of an ADF by a manufacturer for the distribution of an assay protocols provides a mechanism for release of new or modified assay protocols on the instrument platform without requiring a coordinated instrument software update. By eliminating the need for instrument software revisions, this approach provides a more direct path towards release for the assay. Additionally, as needed, the manufacturer can modify compatibility between assay protocols to meet business or other needs without having to revise the instrument software.

[0066] Compatibility has traditionally been controlled using a table or other means that is maintained within the system and requires an update to expand menu. Using a two-level index does not require updating a table or any other means in the software to expand menu. Further, users do not need to have any specific knowledge about assay compatibility since the instrument software controls which assay protocols are available to mix in a single run.

[0067] An additional advantage of using an ADF is that barcode information in the ADF can be used to confirm that reagents are appropriately loaded onto the instrument, thereby preventing user error and the resulting loss of time and resources.

[0068] Having generally described this invention, a further understanding can be obtained by reference to certain specific examples which are provided herein for purposes of illustration only, and are not intended to be limiting.

EXAMPLE 1

Assigning First-Level and Second-Level Compatibility Index Values for User Defined Protocols and Commercially-Supplied Assay Protocols

[0069] This example demonstrates the process of assigning first- and second-level compatibility index values to a particular assay workflow or user defined protocol (UDP). An automated sample processor and analysis instrument has the ability to run two discrete sample processing workflows, or racks, concurrently (run compatible). However, there are certain actions within a sample processing workflow that modified and still maintain compatibility (rack-compatible) as well as certain actions that render workflows incompatible on the instrument in the same run (incompatible). In addition to physical limitations, there may be business requirements to keep assay protocols from running together on an instrument.

[0070] To manage this range of performance demands, a two-level index was generated that identifies rack-compatible and run-compatible assay protocols. The index is assigned and maintained by the instrument manufacturer. The first level index implicates rack-compatibility, that is, assay protocols with the same index value can run in the same rack. The second level index implicates run-compatibility, that is, assay protocols which can be practiced in the second rack on an instrument relative to the assay in the first rack; by definition, rack-compatible assay protocols are also run-compatible. If assay protocols do not share a rack or run compatible index level, then the instrument is prevented from performing assay protocols on the instrument concurrently.

[0071] Figure 1 illustrates an exemplary embodiment of this process. In the process shown in Figure 1, run compatibility (second level compatibility) is indicated by protocols on the same vertical level. Rack compatibility (first level compatibility) is indicated by protocols on the same horizontal level. Thus, for example, two samples must be in the same box in the diagram to be in the same rack in a worklist. Boxes on the same horizontal level share the same Level 2 compatibility index, that is, assay protocols from different boxes can be on separate racks inside the same run, but not in the same rack.

[0072] As shown in Figure 1, factors that determine compatibility are reagent strip design, the number of MM (master mixes), the use of a UDP or ADF (user defined protocol versus assay definition file), and the specific process (extraction versus full process).

[0073] Table 2 below illustrates several parameters that can influence compatibility. For example, in Table 2, cells with italic text highlight the parameters in Assays 4 and 5 that break compatibility with Guardrail Family A. Specifically,

for Assay 4, aspiration height, lysis temperature, number of washes and magnet speed are outside of the limits for each parameter defined for Assays 1-3. Similarly, for Assay 5, aspiration height and lysis time are outside the limits for those parameters.

Table 2

Guardrail Family A						
Assay Step	Limits	Compatible Assays			Incompatible Assays	
		Assay 1	Assay 2	Assay 3	Assay 4	Assay 5
Aspiration Height	1200 - 1600	1600	1550	1200	1150	1700
Lysis Time	0 to 30 min	10 min	5 min	0 min	10 min	35 min
Lysis Temperature	30 to 50 °C	42 °C	36 °C	50 °C	27 °C	42 °C
Number of washes	1	1	1	1	2	1
Magnet Speed	Slow	Slow	Slow	Slow	Fast	Slow

[0074] Table 2 thus illustrates that physical, temporal or other parameters need not be identical between assays in order to indicate compatibility. Rather, parameters can fall within a range which confers compatibility of, for example, a shared resource.

[0075] Table 3 below is an example of a table that assigns rack and run compatibility values for a set of assay protocols.

Table 3.

Assay Protocol	Workflow Type	Level 1 Index	Level 2 Index
1	Extract DNA	1	1
2	UDP DNA	2	2
3	Family A	3	2
4	Family A	3	2
5	Family A	4	3
6	Extract RNA	5	1
7	Extract RNA	5	1
8	UDP RNA	6	2
9	Family B	7	2
10	Family C	8	4

[0076] In Table 3, Families A, B, and C represent workflows that are not directly compatible with each other due to physical differences, such as incubation time, lysis time, reagent volume, reagent type, incubation temperature, lysis temperature or workstation time demands. In the diagram and the table, families A and B are run compatible, meaning that a first workstation could practice tests in Family A (not B), and that a second workstation could practice test in Family B (not A, if a B is selected for that workstation first). As shown in Figure 1, Family C is neither rack- nor run-compatible with the other workflows.

[0077] In Table 3, three different Family A tests have a different compatibility index. While the workflows would indicate that they should be physically compatible, there could be other reasons that the manufacture chooses not to practice them on in the instrument at the same time. For example, when the manufacturer partners with a third party company, it may be desirable to prevent the user to run both manufacturer-supplied and third party-supplied tests on the instrument at the same time, even if the workflow of the test would allow it.

EXAMPLE 2

Identification of Assay Compatibility

[0078] This example demonstrates identification of first-level and second-level compatibility between two assay pro-

5 protocols according to one embodiment. In the exemplary methods shown in Figure 2, the compatibility between a first and second assay is determined by comparing two levels of compatibility index values. In order to avoid running incompatible assays concurrently, users had to manually compare assay protocols on a chart or table to determine whether they can be performed concurrently on the same rack, or even on different racks of the same instrument. An example of such a look up table is shown in Figure 5. Such manual approaches can be error prone, as well as inefficient and labor intensive. This example provides an example of an automated method to identify compatible assay protocols and prevent incompatible assay protocols from being performed concurrently.

10 **[0079]** Assay protocols on the same rack. As described in the schematic shown in Figure 2, a first assay is selected by the user from a list of all available assay protocols. Based on user input, the first-level (rack) compatibility index value for the selected first assay is obtained from the assay definition file (ADF) for the first assay, or from the UDP if the selected assay is user-defined. That compatibility index value is then compared to the first-level compatibility index value (obtained from the ADF or UDP for each respective assay) of each of the other available assay protocols. All assay protocols are identified which share a first-level compatibility index value with the selected assay, and any non-compatible assay protocols are excluded from further consideration.

15 **[0080]** Next, the system obtains the second-level (run) compatibility index value for the selected first assay and compares the value to the second-level compatibility index value of all other remaining assay protocols. All assay protocols are identified which share a second-level compatibility index value with the selected assay, and any non-compatible assay protocols are excluded from further consideration. A list is then displayed which contains only first- and second-level compatible assay protocols. The user selects a second assay from that list, and when selection is complete, the system begins to perform the two assay protocols concurrently on the same rack, or on separate racks if desired.

20 **[0081]** Assay protocols on separate racks. Alternatively, the system can identify and run assay protocols on separate racks when they are not compatible to run together on the same rack. As described in the schematic shown in Figure 2, a first assay is selected by the user from a list of all available assay protocols. Based on user input, the first-level (rack) compatibility index value for the selected first assay is obtained from the assay definition file (ADF) for the first assay, or from the UDP if the selected assay is user-defined. That compatibility index value is then compared to the first-level compatibility index value (obtained from the ADF or UDP for each respective assay) of each of the other available assay protocols. If no assay protocols are identified which share a first-level compatibility index value with the selected assay, the system then obtains the second-level (run) compatibility index value for the selected first assay and compares the value to the second-level compatibility index value of all other available assay protocols. All assay protocols are identified which share a second-level compatibility index value with the selected assay, and any non-compatible assay protocols are excluded from further consideration. A list is then displayed which contains only assay protocols which are compatible to run concurrently on separate racks. The user selects a second assay from that list, and when selection is complete, the system begins to perform the two assay protocols concurrently on separate racks.

25 **[0082]** No other compatible assay protocols. In the event that the system does not identify other assay protocols which are either rack-compatible or run-compatible, the user can choose to perform a single assay protocol, using one or multiple samples, on the same or separate racks.

EXAMPLE 3

40 Addition of Tests to a Run Worklist

[0083] This example demonstrates the process of preparing a run worklist, including identification of assay protocols which can run concurrently in the same worklist, either on the same or on separate racks.

45 **[0084]** A user has a predetermined number of samples, each of which must be assigned an assay protocol. As shown in Figure 3, a blank worklist is provided, setting forth a complete list of available assay protocols. The user selects a first test from the test list. Upon entry of the user selection, the system auto-excludes all protocols with a different first-level compatibility index value, and displays a list of only those assay protocols that are not excluded. From the list of remaining protocols, the user selects another protocol from the list. This process repeats until all samples have been assigned an assay protocol, or until the first rack is full.

50 **[0085]** If the first rack is full, the system allows the user to begin selecting assay protocols for the second rack. The system displays all protocols with the same level 2 (run compatible) index values as those in the first rack. The user then selects a protocol from that list of run compatible protocols. Once a first selection has been made for the second rack, the system auto-excludes all protocols with a different first-level compatibility index value, and displays a list of only those assay protocols that are not excluded. From the list of remaining protocols, the user selects another protocol from the list. This process repeats until all samples have been assigned an assay protocol, or until the second rack is full.

EXAMPLE 4

Use of barcodes

5 **[0086]** This example demonstrates the use of barcodes as identifying indicia for consumable packaging.
[0087] Consumable reagents provided by a supplier include a barcode label that the instrument can read. When an assay is created, the expected barcodes are identified in the ADF. When an instrument run commences, the instrument executes a catalog process, which confirms that the user loaded the proper consumables on the instrument deck. The barcode data stored in the ADF is used to provide this verification. If the barcode is not read, the instrument alerts the user and waits for assistance in acquiring the barcode. If the barcode is read, but does not match that expected for the assay test that was requested by the user, then the instrument alerts the user and waits for assistance in correcting the difference by, for example, swapping reagents. The use of barcodes on the reagents and barcode information in the ADF provides process assurance that the user has run the assay appropriately.

15 EXAMPLE 5

Use of ADF to run Assay Protocol on Instrument

[0088] This example demonstrates the use of an ADF to accurately run assay protocols on an instrument.
20 **[0089]** The instrument first checks the ADF to determine the sample prep script needed to complete the run. The script data is then combined with the sample prep parameters defined in the ADF and the sample preparation process is initiated.
[0090] Upon completion of sample prep, the instrument again checks the ADF and executes the loadcartridge script identified in the ADF.
25 **[0091]** When loadcartridge completes, the instrument looks in the ADF to find out the fluorescence ratios needed to determine if the cartridge successfully loaded and compares those ratios with readings taken. If the instrument determines that the cartridge was successfully loaded, it then looks in the ADF to determine the PCR scripts to be used and PCR protocol necessary. Once these values are retrieved, the instrument begins the PCR process.
[0092] Upon completion of PCR, the instrument retrieves the parameters needed to run the data analysis algorithms from the ADF and executes the data analysis.
30 **[0093]** When data analysis completes the instrument combines the values returned from the data analysis engine with the result logic and result script identified in the ADF to derive a final call for that particular test.

EXAMPLE 6

35 Generation of UDP and Assignment of First-Level and Second-Level Compatibility Index Values

[0094] This example demonstrates the creation of a UDP and assignment of compatibility index values to the UDP to accurately run assay protocols on an instrument.
[0095] A user generates a new UDP by responding to prompts on a touch-screen display, selecting the assay type, assay parameters and reagents for the protocol. Factors that are selected include, for example, type of extraction kit and PCR parameters. Specifically, selecting from several available options, the user selects a particular reagent strip design, a particular of MM, and the specific process (extraction versus full process). The user elects to program a full process, and as such, the user can further define cycle times, temperatures and other parameters for PCR.
40 **[0096]** Following a process set forth in Figure 1, the system assigns first-level and second-level compatibility index values for the UDP according to similar factors that determine compatibility for ADFs. Based upon parameters including aspiration height, lysis temperature, lysis time, number of washes and magnet speed, the new UDP is assigned a first-level index value of '2' and a second-level index value of '2.'
[0097] Thus, going forward, when the user adds protocols to a run worklist, the user will be able to perform the new UDP concurrently with other ADFs or UDPs that have first and second level index values of 2 and 2, respectively.
50 **[0098]** It is to be understood that this invention is not limited to particular embodiments described, as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting.
[0099] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the embodiments belong. Although any methods and materials similar or equivalent to those described herein may also be used in the practice or testing of the embodiments, the preferred methods and materials are now described.
55 **[0100]** The term "comprising" as used herein is synonymous with "including," "containing," or "characterized by," and is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.

[0101] It must be noted that as used herein and in the appended claims, the singular forms "a," "and," and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a method" includes a plurality of such methods and equivalents thereof known to those skilled in the art, and so forth.

5 **[0102]** The steps of a method or algorithm described in connection with the embodiments disclosed herein may be embodied directly in hardware, in a software module executed by a processor, or in a combination of the two. A software
module may reside in RAM memory, flash memory, ROM memory, EPROM memory, EEPROM memory, registers, hard
10 disk, a removable disk, a CD-ROM, or any other form of storage medium known in the art. An exemplary storage medium
may be coupled to the processor such the processor can read information from, and write information to, the storage
medium. In the alternative, the storage medium may be integral to the processor. The processor and the storage medium
may reside in an ASIC. The ASIC may reside in a user terminal. In the alternative, the processor and the storage medium
may reside as discrete components in a user terminal.

PATENTKRAV

1. Fremgangsmåde til udførelse af en automatiseret assay på adskillige prøver, hvilken fremgangsmåde omfatter:

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tilvejebringelse af et automatiseret instrument omfattende en første arbejdsstation og en anden arbejdsstation, idet hver af den første og anden arbejdsstation er konfigurerede til at modtage og bearbejde adskillige prøver i overensstemmelse med adskillige forskellige automatiserede assay-arbejdsforløb, under anvendelse af i det mindste en delt resource, hvor hvert forskelligt automatiseret assay-arbejdsforløb har en associeret unik assay-definitionsfil eller bruger-defineret protokolfil omfattende en første niveaukompatibilitetsindeksværdi;

10

modtagelse, via en dataindføringsindretning knyttet til det automatiserede instrument, af et valg af et første assay-arbejdsforløb valgt fra en liste;

15

evaluering af hvilke af adskillige andre tilgængelige assay-arbejdsforløb, som har en assay-definitionsfil eller bruger-defineret protokolfil omfattende den samme første niveaukompatibilitetsindeksværdi som det nævnte valgte første assay-arbejdsforløb, hvor den samme første niveaukompatibilitetsindeksværdi er en indikation for en første niveaukompatibilitet, hvor første niveaukompatibilitet omfatter

20

kompatibilitet med udførelse af to assays samtidigt på den samme arbejdsstation i det automatiserede instrument, hvor det nævnte evalueringstrin omfatter

identificering af ethvert assay-arbejdsforløb, som har første niveaukompatibilitetsindeksværdier, som er forskellige fra den første niveaukompatibilitetsindeksværdi for det valgte første assay, og

25

fremvisning, på et display associeret med det automatiserede instrument, af en anden liste af andet arbejdsforløb-assays, hvor den anden liste ekskluderer ethvert assay-arbejdsforløb, som har en første niveaukompatibilitetsindeksværdi, som er forskellig fra det første niveaukompatibilitetsindeks for det nævnte første

30

valgte assay;

modtagelse, via dataindføringsindretningen, af et valg af et andet assay-arbejdsforløb valgt fra den anden liste; og

35

udførelse af det valgte første assay-arbejdsforløb og det valgte andet assay-arbejdsforløb samtidigt på den samme arbejdsstation i det automatiserede instrument;

hvor hver assay-definitionsfil eller bruger-defineret protokolfil yderligere omfatter en anden niveaukompatibilitetsindeksværdi, og hvor fremgangsmåden yderligere omfatter:

5 evaluering af hvilke af adskillige andre tilgængelige assay-arbejdsforløb, som har en assay-definitionsfil eller bruger-defineret protokolfil omfattende den samme anden niveaukompatibilitetsindeksværdi som det valgte første assay-arbejdsforløb, hvor den samme anden niveaukompatibilitetsindeksværdi er en indikation for anden niveaukompatibilitet, hvor anden niveaukompatibilitet omfatter kompatibilitet for
10 udførelse af to assays samtidigt på forskellige arbejdsstationer i det automatiserede instrument, og hvor evalueringstrinnet omfatter

identificering af vilkårlige assay-arbejdsforløb, som har anden niveaukompatibilitetsindeksværdier, som afviger fra den anden niveaukompatibilitetsindeksværdi
15 for det valgte første og andet assay-arbejdsforløb, og

fremvisning, på displayet, af en tredje liste af tredje assay-arbejdsforløb, hvor den nævnte tredje liste ekskluderer ethvert assay-arbejdsforløb, som har en anden niveaukompatibilitetsindeksværdi, som afviger fra de anden niveaukompatibilitetsindeksværdier for de valgte første og andet assay-arbejdsforløb; og
20 modtagelse, via dataindføringsindretningen, af et valg af et tredje assay-arbejdsforløb valgt fra den tredje liste; og
udførelse, samtidigt, af det valgte første assay-arbejdsforløb og det andet assay-arbejdsforløb på den samme arbejdsstation og det valgte tredje assay-arbejdsforløb
25 på en afvigende arbejdsstation i det automatiserede instrument;
hvilken fremgangsmåde yderligere omfatter
anmodning om yderligere assay-arbejdsforløb fra den anden liste af andet assay-arbejdsforløb indtil antallet af assay-arbejdsforløb anmodet fra den anden liste er lig med antallet af de adskillige prøver, som den første arbejdsstation er konfigureret
30 til at modtage og bearbejde;
modtagelse af udvælgelse af yderligere assay-arbejdsforløb fra den anden liste;
anmodning om yderligere assay-arbejdsforløb fra den tredje liste af tredje assay-arbejdsforløb indtil antallet af assay-arbejdsforløb anmodet fra den tredje liste er lig med antallet af de adskillige prøver, som den anden arbejdsstation er konfigureret
35 til at modtage og bearbejde; og
modtagelse af udvælgelser af yderligere assay-arbejdsforløb fra den tredje liste;

udførelse af assay-arbejdsforløbene valgt fra den anden liste samtidigt på den første arbejdsstation og assay-arbejdsforløbene valgt fra den tredje liste samtidigt på den anden arbejdsstation, hvor assay-arbejdsforløbene udført på den første og anden arbejdsstation udføres samtidigt.

5

2. Fremgangsmåde ifølge krav 1, hvor den første niveaukompatibilitetsindeksværdi er bestemt baseret på parametre valgt fra gruppen bestående af inkuberingstid, lysistid, reagensvolumen, reagentype, inkuberingstemperatur, lysistemperatur, arbejdsstation tidsbehov, regulatorisk klassifikation, forretningsovervejelser og en kombination deraf, og hvor den anden niveaukompatibilitetsindeksværdi er bestemt baseret på parametre valgt fra gruppen bestående af regulatorisk klassifikation, arbejdsforløbsinkompatibilitet, forretningsovervejelser og en kombination deraf.

10

3. Fremgangsmåde ifølge ethvert af kravene 1 eller 2, hvor det automatiserede instrument forhindrer den samtidige udførelse af inkompatible assay-arbejdsforløb i den samme arbejdsstation, når de første niveaukompatibilitetsindeks er forskellige, og hvor det automatiserede instrument er forhindret i samtidigt at udføre assay-arbejdsforløb med forskellige anden niveaukompatibilitetsindeksværdier.

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4. Fremgangsmåde ifølge ethvert af kravene 1 til og med 3, hvor i det mindste to af de valgte første, andre eller tredje assay-arbejdsforløb har samme første niveaukompatibilitetsindeksværdi og har forskellige anden niveaukompatibilitetsindeksværdier.

20

5. Fremgangsmåde ifølge krav 4, hvor forskellen i de anden niveaukompatibilitetsindeksværdier omfatter en forretningsårsag eller en regulatorisk klassifikation.

25

6. Fremgangsmåde ifølge ethvert af kravene 1 til og med 5, hvilken fremgangsmåde yderligere omfatter ét eller flere af følgende:

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initiering af et assay-specifik prøvepræparationsskript på instrumentet;
sammenligning af identificerende indicier på en konsumerbar emballage med et sæt af assay-specifikke identificerende data lagret på instrumentet;
initiering af et assay-specifikt indsæt patron skript på instrumentet;
sammenligning af fluorescensforhold i en indsat patron med et sæt af assay-specifikke fluorescensforholdsdata lagret på instrumentet for bestemmelse af om den nævnte patron blev indsat med held;

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initiering af et assay-specifikt reaktionsskript på instrumentet;
 initiering af en assay-specifik dataanalyse-algoritme på instrumentet;
 udledning af et endeligt kald for assayet, baseret på én eller flere assay-specifikke
 resultatalgoritmer eller skripts.

5

7. Fremgangsmåde ifølge ethvert af kravene 1 til og med 6, hvor i det mindste ét af de
 valgte assay-arbejdsforløb omfatter en reaktion valgt fra gruppen valgt blandt: poly-
 merasekædereaktion (PCR), transkriptionsmedieret amplifikation (TMA), oligonucleotid
 ligationsassay (OLA), ligasekædereaktion (LCR), rullende cirkelamplifikation (RCA),
 10 strengforskydningsamplifikation (SDA) og en hybridiseringsreaktion.

8. System til udførelse af et automatiseret assay, omfattende:

et automatiseret instrument omfattende en første arbejdsstation og en anden ar-
 15 bejdsstation, hvor hver af den første og anden arbejdsstation er konfigureret til at
 modtage og bearbejde adskillige prøver i overensstemmelse med adskillige for-
 skellige automatiserede assay-arbejdsforløb, under anvendelse af i det mindste én
 delt resource, hvor hvert forskelligt automatiseret assay-arbejdsforløb har en
 associeret unik assay-definitionsfil eller bruger-defineret protokolfil;

20

et display;

en dataindføringsindretning;

en processor;

en lagringskapacitet; og

et program til at udføre et automatiseret assay, hvilket program omfatter instruk-
 25 tioner til at udøve en fremgangsmåde til udførelse af et automatiseret assay på
 adskillige prøver som angivet i ethvert af de foregående krav.

9. System ifølge krav 8, hvor den første niveaukompatibilitetsindeksværdi er bestemt
 baseret på parametre valgt fra gruppen bestående af inkuberingstid, lysistid, reagens-
 30 volumen, reagentstype, inkuberingstemperatur, lysistemperatur, arbejdsstationstidsbe-
 hov, regulatorisk klassifikation, forretningsovervejelser og en kombination deraf, og
 hvor den anden niveaukompatibilitetsindeksværdi er bestemt baseret på parametre
 valgt fra gruppen bestående af: regulatorisk klassifikation, arbejdsforløbsinkompabilitet,
 forretningsovervejelser og en kombination deraf.

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10. System ifølge ethvert af kravene 8 til og med 9, hvor i det mindste to af de valgte første, anden eller tredje assay-arbejdsforløb har den samme første niveaukompatibilitetsindeksværdi og har forskellige anden niveaukompatibilitetsindeksværdier.
- 5 11. System ifølge krav 8 eller 9, hvor instruktionerne yderligere omfatter ét eller flere trin til:
- 10 initiering af et assay-specifikt prøvepræparationsskript på instrumentet;
sammenligning af identificerende indicier på en konsumerbar emballage med et sæt af assay-specifikke identificerende data lagret på instrumentet;
- 15 initiering af et assay-specifikt indført patron skript på instrumentet;
sammenligning af fluorescensforhold i en indført patron med et sæt af assay-specifikke fluorescensforholdsdata lagret på instrumentet for bestemmelse af om patronen blev indsat med held;
- 20 initiering af et assay-specifikt reaktionsskript på instrumentet;
initiering af en assay-specifik dataanalysealgoritme på instrumentet;
udledning af et endeligt kald for assayet, baseret på én eller flere assay-specifikke resultat algoritmer eller skripts.
- 20 12. System ifølge krav 11, hvor systemet yderligere omfatter en stregkode-læser og de identificerende indicier omfatter en stregkode.

DRAWINGS

Drawing

Fig. 1

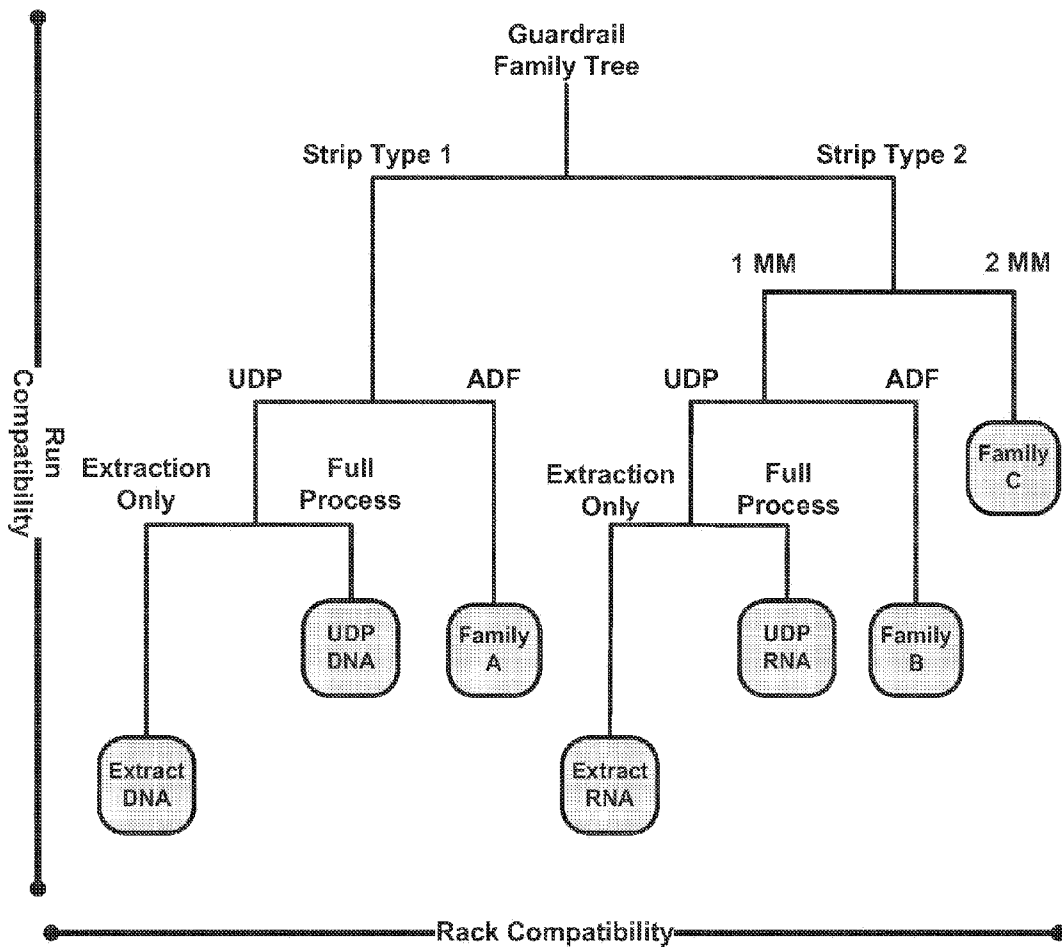


Fig. 2

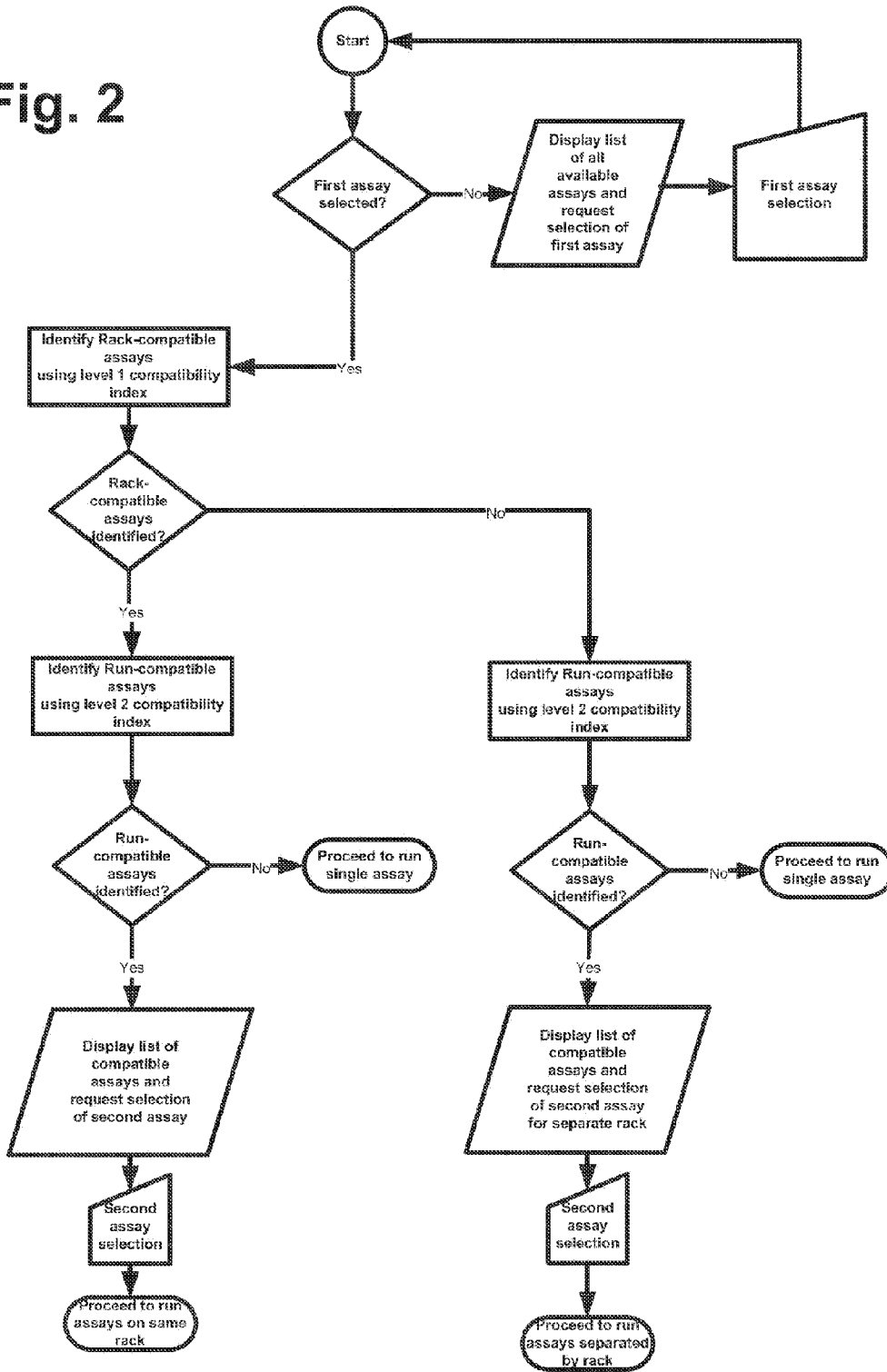


Fig. 3

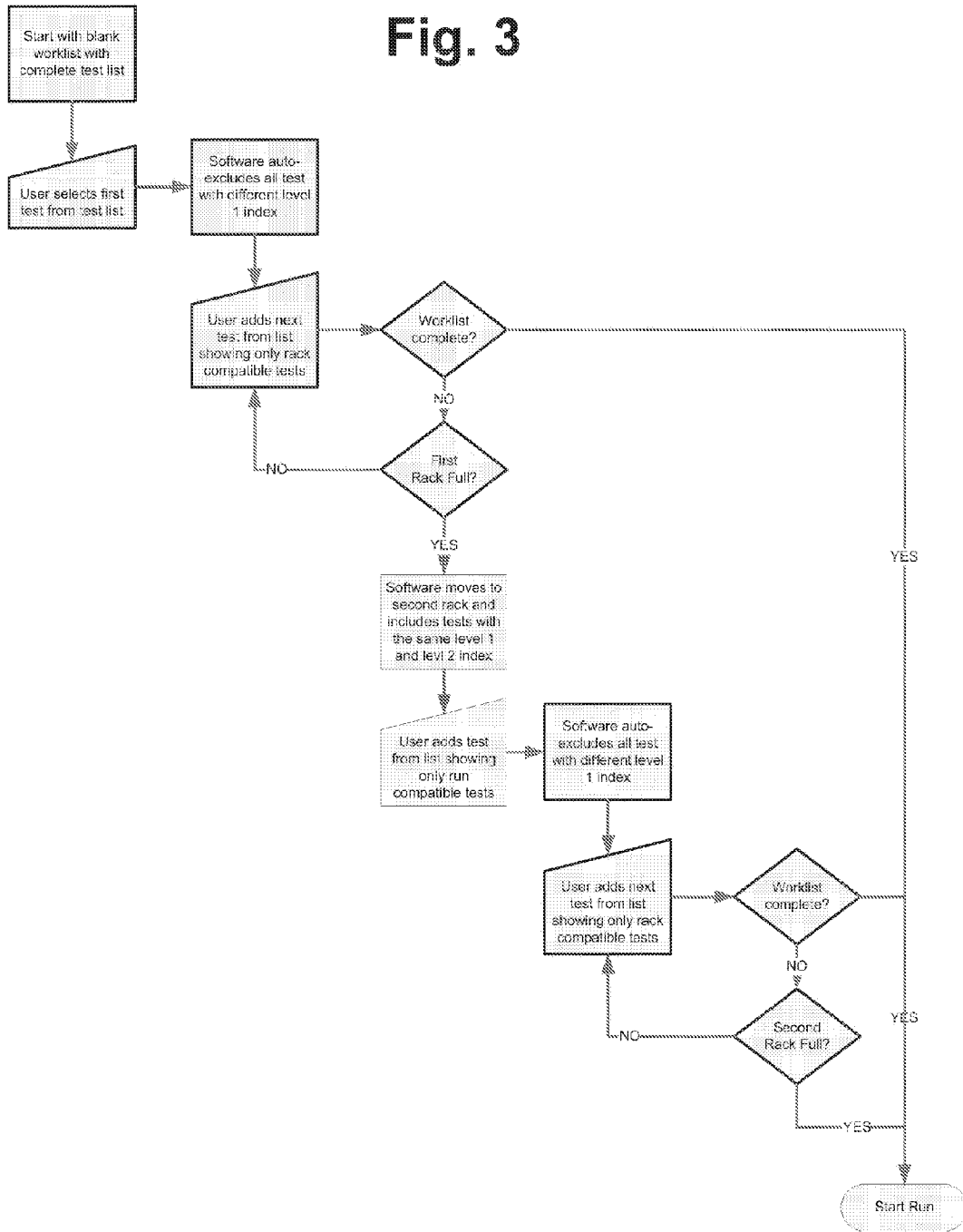


Fig. 4

Automated Instrument with Independent Workstations and a Shared Service

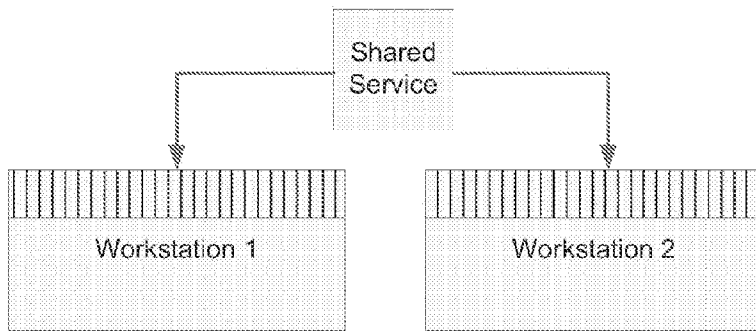


Fig. 5

		Level 2 Index: Run Compatible?									
		1	2	3	4	5	6	7	8	9	10
Level 1 Index: Rack Compatible?	1		N	N	N	N	Y	Y	N	N	N
	2	N		Y	Y	N	N	N	Y	Y	N
	3	N	N		Y	N	N	N	Y	Y	N
	4	N	N	Y		N	N	N	Y	Y	N
	5	N	N	N	N		N	N	N	N	N
	6	N	N	N	N	N		N	N	N	N
	7	N	N	N	N	N	Y		N	N	N
	8	N	N	N	N	N	N	N		Y	N
	9	N	N	N	N	N	N	N	N		N
	10	N	N	N	N	N	N	N	N	N	

Tests with the same Level 1 Index are by definition rack and run compatible