

tion reagent or molecule (fluorescent dye, nanoparticle, FRET pair, etc.). The capture molecules are adsorbed or covalently attached to the test cartridge 104 surface in discrete areas, such as wells, pillars, or channels. The method of attachment is accomplished by use of silyl, amino, sulfhydryl, or carboxyl groups depending on the specific molecule used in the process.

[0062] The test cartridge 104 uses microfluidic (or nanofluidic) pump(s) that are micro-machined mechanical pumps that move liquid based on capillary action or wicking forces and have inlet and exit valves that control where and when reagents and samples are delivered. There can be valves for mixing of reagents on the test cartridge 104. Depending on the assay, a detection reagent may be added to the test cartridge 104. The detection reagent would be stored on the test cartridge 104 in a compartment or reservoir.

[0063] The top and/or bottom side of the test cartridge 104 can contain sealed microscale or nanoscale compartments with reagents necessary to run the test. These compartments open as needed during the cycle of the POC device 102 using valves and the reagents delivered to the test cartridge 104 through patterned channels. There can be an empty compartment on the test cartridge 104 to which used reagents can be transferred.

[0064] The sample is then incubated on the test cartridge 104 after delivery to and separation into the discrete functionalized locations on the test cartridge 104. Incubation may occur either at room temperature, with heating, with cooling, or with some combination of temperatures. Different parts of the test cartridge 104 may be held at different temperatures. The POC device 102 can have the ability to heat to temperatures in excess of 100° C. and to cool to below 0° C. The incubation steps require seconds, minutes, or hours, depending on the assay. The POC device 102 has a signal amplification step to increase the sensitivity of the assay and reduce the incubation time.

[0065] The POC device 102 has a light source that is external to the test cartridge 104 with a sufficiently small emission area to be used with the size of the discrete locations of the molecules on the test cartridge 104. The light source is an edge emitting or surface emitting laser diodes or other compact light source. The POC device 102 utilizes integrated chromatic filters on the light source to tune the optical source to specific wavelengths. The POC device 102 measures the electrical impedance and/or the optical properties (transmission, fluorescence, light scattering, refractive index, resonance, etc.) to perform the assay.

[0066] The POC optical detection technique employs a photomultiplier element that provides optical gain to the emission signal prior to imaging the emission signal on the semiconductor detector/array. The detection technique has enhanced optical discrimination function through the implementation of a phased locked detection loop that triggers the detection elements in conjunction with the emission signal on a reoccurring frequency. The semiconductor detector element is sensitivity avalanche photodiode/array. The detector is not part of the test cartridge 104 but illuminates the test cartridge 104 in discrete areas in which the biological molecules are contained.

[0067] When detection has occurred, the screen and a sound can indicate when a test is complete. The user can be prompted to remove the disposable test cartridge 104 from the POC device 102. A warning message can appear on the screen if the test did not work properly. The POC device 102 can

transmit the test results data via secure connection to the Pandora Genomics servers for processing via integrated 3G/4G connectivity or wireless Internet access. Bioinformatics analyses, including, database processing and interpretation of the test results using Pandora Genomics' databases and algorithms, can occur offsite. A report (PgxReport) can be generated. The report provides information on the nature of the test that was ordered; discusses the medication under consideration and the relationship to genotype; provides guidance on dosing (if appropriate); and presents a list of drugs that may negatively interact with the medicine under consideration. The POC device 102 can indicate the status of the data transmission and processing on the screen. Next, the POC device 102 can receive the processed data from the Pandora Genomics servers. The data can be presented in the PgxReport format, and the POC device 102 can indicate when the data analysis is complete and that the report has been received. The software can present the option to the user to print the report, to deliver the results via email, and/or to view a summary of the results directly on the screen. An example of a report is illustrated in FIG. 7. The analysis results can be delivered to remote sites as appropriate: to pharmaceutical companies, to clinicians, to the point-of-care device, etc. The results can be delivered via e-mail or can be accessed remotely via the secure online server. The touch screen interface on the POC device 102 can be used to view the report and the raw data.

[0068] The POC generally does not store the information on the hand set unless the can be protected against unauthorized access and copying in accordance with HIPAA and Pandora Genomics standards. The data and test results are generally stored on a secure, HIPAA-compliant remote server. The data can be accessible and down loaded to the point-of-care device and via online access. The downloaded data is stored on the HIPAA-compliant secure system/computer for review and consultation purposes by the physician. The test results and associated data are stored as electronic health records via standard (e.g., XML) protocols.

[0069] In some embodiments, the POC device 102 is man-portable and includes a wheeled cart or a backpack. As used herein, the term "man-portable" means a system with components that can be positioned by one man regardless of whether the system is designed to be easily moved or not. In some embodiments the system is designed to be reasonably easy to move.

[0070] It will be understood by those of skill in the art that information and signals may be represented using any of a variety of different technologies and techniques (e.g., data, instructions, commands, information, signals, bits, symbols, and chips may be represented by voltages, currents, electromagnetic waves, magnetic fields or particles, optical fields or particles, or any combination thereof). Likewise, the various illustrative logical blocks, modules, circuits, and algorithm steps described herein may be implemented as electronic hardware, computer software, or combinations of both, depending on the application and functionality. Moreover, the various logical blocks, modules, and circuits described herein may be implemented or performed with a general purpose processor (e.g., microprocessor, conventional processor, controller, microcontroller, state machine or combination of computing devices), a digital signal processor ("DSP"), an application specific integrated circuit ("ASIC"), a field programmable gate array ("FPGA") or other programmable logic device, discrete gate or transistor logic, discrete hard-