

munications device via the one or more communication interfaces in block 506. Other steps can be performed as described herein or as are apparent to one skilled in the art. Moreover, not all of the steps described above have to be performed in any specific order. The foregoing method can be implemented as a computer program embodied on a non-transitory computer readable medium for execution by a computer or processor such that the steps are implemented as one or more code segments.

[0054] Now referring to FIG. 6, a flow chart of a method 600 for evaluating samples or analytes in accordance with yet another embodiment of the present invention is shown. A point-of-care device 102 is provided in block 302. A patient information and/or patient clinical information is received via the user interface 128 or one or more communication interfaces 130 in block 602. A test selection is received from the user interface in block 304. At least a portion of a remotely located database is downloaded or accessed via the one or more communication interfaces in block 604. In block 306, a determination is made whether a test cartridge 104 connected to the test cartridge interface 132 matches the test selection. A test cartridge 104 information is linked to the patient information and/or the patient clinical information in block 606. One or more properties of the sample or the analyte 204 are detected using the one or more detectors or sensors 134 in block 308. A test results data based on the one or more properties is generated in block 310. A report based on an analysis of the test results data, data within the portion of the downloaded or accessed database, and the patient information and/or patient clinical information is generated in block 610 and the report is provided to the user interface in block 314. The report is also transmitted to an output device or a communications device via the one or more communication interfaces in block 506. Other steps can be performed as described herein or as are apparent to one skilled in the art. Moreover, not all of the steps described above have to be performed in any specific order. The foregoing method can be implemented as a computer program embodied on a non-transitory computer readable medium for execution by a computer or processor such that the steps are implemented as one or more code segments.

[0055] An example of using a POC device in accordance with one embodiment of the present invention will now be described. The POC device 102 is approximately 4 inches by 2.5 inches by 1/2 inch thick or less and is powered by a long-life thin-film lithium ion battery that provides two hours of active performance and 24 hours of battery life in standby mode. The POC device 102 preferably uses an inductively coupled charger so that the POC device can be placed on a mat and actively charged. As the battery reaches a critically low level, a text message can be sent to the user to place the POC device 102 on the inductive charger. In parallel, an email can be sent to the system operator to call the POC device user to inquire on the status of the POC device 102. The user interface 128 is a touch screen display with touch screen buttons that enable test selection and input of identifying information to pair the test with a patient. The screen may be a full 256-bit color display with flashing red lights for error function and flashing green lights for positive response from the secure server. The touch screen display user interface 128 can also display shows a running figure that shows the data are being processed. The user interface display 128 can show a bar level identifying a solid secure connection to the remote server.

[0056] The user can use the touch screen and the software to decide which test cartridge 104 is appropriate. The decision process consists of answering questions in a decision tree. If the operator already knows which test is needed, then the decision tree can be bypassed through the software. The software has fields to input patient identifiers (name and/or number), other relevant clinical information, and customizable fields to be used as needed by the site operator to batch samples either by study or for billing purposes.

[0057] In some embodiments, the top of the POC device 102 can be completely open to allow the test cartridge 104 to be inserted. The test cartridge 104 needs to be removed from its sealed packaging prior to placing it into the POC device 102. The test cartridges 104 are stable at ambient temperatures ranging from 4° C. to 25° C. and have a shelf life of one year from the date of manufacture, which can be marked on the outer packaging. The test cartridge 104 is RFID-tagged and/or bar-coded. The POC device 102 contains an internal RFID or optical reader that checks that the test cartridge 104 chosen in the decision tree step matches with the type inserted into the POC device 102. The POC device 102 records the information about the test cartridge 104 (including lot number) and links this information to the sample/patient data file.

[0058] Once the POC device's lid is closed a start button appears on the touch screen. The POC device 102 starts when the start button is pushed. The POC device 102 prompts the user to choose what type of biological sample can be used for the analysis and to indicate how the sample can be obtained and what type of sample.

[0059] The device's sample port 202 is located on the left, top side of the device 102. A prepared, extracted, or purified sample can be inserted directly using a pipet. There can be an adapter 206 that can be fit in the sample port 202 for use with samples obtained via buccal swabs. There is a separate adapter 206 that fits in the sample port 202 for obtaining a blood sample from a finger prick. These adapters 206 are disposable and are included in the packaging of the test cartridge 104. The sample port 202 connects to the test cartridge 104 in the POC device 102. The sample is loaded onto the test cartridge 104.

[0060] The sample is moved (pumped) utilizing a combination of microfluidic or nanofluidic pumps. The micromachined mechanical pump(s) move liquid based on capillary action or wicking forces from the port onto the test cartridge 104 for analysis. Once the sample is loaded onto the test cartridge 104, it may need to be processed. The determination of processing is a function of the selected test. The processing can occur on the test cartridge 104 on the microscale or the nanoscale, which can be accomplished by patterning of the cartridge with channels, wells, reservoirs, or pillars. The sample is then filtered and focused using channels. As required, the sample is then separated into components by centrifugation or magnetic or other type of separation by the POC device 102. The test cartridge 104 may have a capillary electrophoresis channel(s) built into the test cartridge 104. The sample is then lysed by a piezoelectric vibrator while on the test cartridge 104 in order to prepare the sample for analysis. The sample is then distributed on the test cartridge 104 using pressure gradients. Once the sample has been processed, it may be collected on beads, pillars, or wells, the surfaces of which are functionalized to increase the capture efficiency.

[0061] The test cartridge 104 contains immobilized capture molecules (DNA or protein or other molecule) with a detec-