

[0042] The POC device is generally initiated by acquiring a sample. Based on the type of sample collected, different forms of sample acquisition can be required. As an example, blood samples are collected into PAXgene or EDTA tubes. The collection tubes are generally bar coded to match code on molecular test and read by optical scanning and required to be stored for historical records. They may be readable by RFID. In the example of saliva, urine, or vaginal fluid, a simple swatch can suffice to transfer the sample to the POC device **102**. Once delivered to the POC device **102**, analytes are extracted from the sample. Analytes may also be referred to as biomarkers in some cases. With the addition of PCR or microarray in the POC device **102**, whole blood or serum can be analyzed directly without use of the extraction process. The POC device **102** is then able to analyze the genetics, genomics, cytogenetics, epigenetics, epigenomics, proteomics (including but not limited to post-translation analyses such as glycomics and phosphoproteomics), metabolomics, microbiomics, transcriptomics (RNA, including but not limited to mRNA, tRNA, and miRNA; and gene expression), viral genomics, bacterial genomics, cellular analysis (including but not limited to phenotyping and morphology), and tissue analysis (including but not limited to histology and immunohistochemistry).

[0043] The POC device's physical tests are stable at ambient temperatures that may range from 4° C. to 25° C. and have a shelf life of one year from the date of testing. Similar to the processing of a blood sample, the POC device **102** can use a bar code for identification by the point-of-care device that can be read by RFID or optical scanning and required to be kept for historical records.

[0044] The POC device's test formats conform to standard protocols and methodologies (cartridges) include, but are not limited to, microarrays, wells, channels, and pillars. The scale generated on these cartridges range from micro, nano, or pico depending on the results of the sample processing. The test cartridges **104** and the interior surfaces are made a wide variety of materials including: glass, plastic, polymers, natural materials, plant-based materials (including paper), and/or metals or metal compounds. The test construction results in the attachment of a specific molecule (in or to the cartridge) to capture the analyte of interest, which include, but are not limited to, nucleic acid probes, aptamers, antigens, and other types of binding partners. The POC device **102** evaluates the captured analyte molecule is then analyzed by fluorophores, dyes, quantum dots, nanoparticles and/or method. The POC device **102** uses a piezoelectric element similar to the vibrator for a cell phone to evenly distribute the analyte across the testing platform. Other methods of distributing the analyte across the testing platform include, but are not limited to, aliquoting, shaking, low power ultra sonic agitation, rocking, and the use of microfluidic and nanofluidic devices/technologies.

[0045] The POC device **102** may produce a yes/no result for the presence of specific molecules and the relative quantities of specific molecules, plus identification if wild-type/mutant, etc. The types of molecules that the POC device **102** can provide readout to include but are not limited to:

[0046] DNA: detect mutations, indels, CNVs, methylation status.

[0047] RNA: relative copy number, splice variants, presence/absence.

[0048] Protein relative quantity, mutation status, identification/characterization, presence/absence, conforma-

tion status, biological activity, post-translation modification status (including but not limited to phosphorylation, glycosylation, SUMOylation, myristoylation, palmitoylation, methylation, acetylation, ubiquitination, and sulfation), binding, affinity, aggregation, immune response.

[0049] Carbohydrates: identification/characterization, prokaryotic/eukaryotic.

[0050] Metabolites: relative quantity, presence/absence, kinetics, identification/characterization.

[0051] Referring now to FIG. 3, a flow chart of a method **300** for evaluating samples or analytes in accordance with one embodiment of the present invention is shown. A point-of-care device **102** is provided in block **302**. A test selection is received from the user interface in block **304**. In block **306**, a determination is made whether a test cartridge **104** connected to the test cartridge interface **132** matches the test selection. 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 is generated in block **312** and the report is provided to the user interface in block **314**. Other steps can be performed as described herein or as are apparent to one skilled in the art. 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.

[0052] Now referring to FIG. 4, a flow chart of a method **400** for evaluating samples or analytes in accordance with another embodiment of the present invention is shown. FIG. 4 shows the interaction of the hardware, firmware, software, and communication and the intelligent algorithm. The data acquisition (block **402**), extraction (block **404**), automated loading (block **406**) can take as little as ten(s) of seconds in the optimized POC device **102**. The sample is then incubated for a period of a few minutes or less in block **408**. The sample is then detected using the integrated array and microfluidic device, producing the raw data in block **410**. The raw data is analyzed then transmitted to the data center for evaluation by the intelligent algorithm producing comprehensive data analysis with clinically actionable results in block **412**. The results are then transmitted to the POC device **102** in block **414**. The comprehensive report can then be printed out by the physician and shared with patient.

[0053] Referring now to FIG. 5, a flow chart of a method **500** 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 test selection is received from the user interface in block **304**. In block **306**, a determination is made whether a test cartridge **104** connected to the test cartridge interface **132** matches the test selection. 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**. The test results data is transmitted to a remote device via the one or more communication interfaces **130** in block **502**. The remote device generates a report based on an analysis of the test results data. The report is received from the remote device via the one or more communication interfaces **130** in block **504** and the report is provided to the user interface in block **314**. The report is also transmitted to an output device or a com-