

change can provide a semi-quantitative understanding of analyte concentration. However, such RDTs are limited by the subjective nature of result interpretation by visual inspection and a narrow read time window, both of which require rigorous staff training and quality assurance for result accuracy. Although RDTs that do not require read-out instrumentation can present cost and simplicity advantages, they also present disadvantages, including lack of a link to electronic medical records or laboratory information management system, no automated quality control, no untrained user lockout and no expired lot rejection.

[0011] RDTs have had an enormous impact on infectious disease screening programs worldwide over the last decade, and are the backbone of HIV screening efforts. Some in the global health field argue against any type of instrumented test in a point-of-care setting. Arguments against instrumentation hinge primarily on instrument procurement costs and servicing requirements that are not a factor in visually read tests. However, while RDTs provide the advantages of low cost, simple operation, and no required instrumentation, RDTs also have significant limitations. For example, most RDTs require extensive personnel training and lack the capability to be linked to electronic medical records. The nuance of switching between different RDT protocols is also a challenge for care providers.

[0012] While more sophisticated analyte detection systems are available, they can be bulky, costly, and require extensive training to calibrate, operate and maintain. For example, POC analyte testing machines that use microfluidics have been disclosed, but many such machines have large numbers of moving parts and complicated structures, including micropumps or pressure sources, require expensive and difficult sample preparation and calibration, or have low throughput. In addition, such systems can require multiple sensors, lasers, or highly skilled technical operators, all of which greatly increase the operation cost of the analyte detection system.

BRIEF DESCRIPTION OF THE FIGURES

[0013] FIG. 1 is a view of a reader instrument with an insertable cartridge, in accordance with an embodiment.

[0014] FIG. 2 is a view of a reader instrument with an inserted cartridge, in accordance with an embodiment.

[0015] FIGS. 3-11 are various views of a cartridge, in accordance with an embodiment.

[0016] FIG. 12 is a view of an embodiment of a reader instrument of FIG. 1 with the housing partially removed to reveal positioning of components.

[0017] FIG. 13 is a view of an embodiment of a reader instrument with more of the housing removed to reveal positioning of an imaging system therein.

[0018] FIG. 14 is a side cross sectional view of an embodiment of a reader instrument to indicate relative positioning of components.

[0019] FIG. 15 is perspective view of a cartridge holder assembly, shown in isolation.

[0020] FIG. 16 is a side cross sectional view of the cartridge holder assembly of FIG. 15, with no cartridge inserted.

[0021] FIG. 17 is a side cross sectional view of the cartridge holder assembly of FIG. 15, with a cartridge inserted therein.

[0022] FIG. 18 shows a schematic diagram of a target imaging system, in accordance with an embodiment. The output of a laser diode is collimated, passed through a rotating holographic diffuser, then coupled into a planar waveguide.

[0023] FIG. 19 is a perspective view of a reader instrument including a peripheral device, in accordance with an embodiment.

[0024] FIG. 20 is a view showing an imaging system field of view suitable for reading both markings and analyte markers within the same field of view, in accordance with an embodiment.

[0025] FIG. 21 is schematic top down view of the field of view of an imaging system, including various markings and analyte markers, in accordance with an embodiment.

[0026] FIGS. 22 and 23 respectively illustrate rectangular grid and staggered patterns for reaction site layout, in accordance with an embodiment.

[0027] FIGS. 24 and 25 respectively illustrate reaction sites with different sizes, in accordance with an embodiment.

[0028] FIG. 26 illustrates a diagrammatic illustration of an assay system including the device having a waveguide with an integrated lens, illumination, and imaging system, in accordance with an embodiment.

[0029] FIG. 27 is a schematic representation of the multiplexed fluorescence assay and assay cartridge, in accordance with an embodiment.

[0030] FIGS. 28-30 show the array layout, representative images, array layout, and result summary for an exemplary multiplex HIV/Syphilis/HCV assay.

[0031] FIG. 31 is a flow chart illustrating an exemplary process for operating the reader instrument, in accordance with an embodiment.

[0032] FIG. 32 is a flow chart illustrating further details of an image analysis step in the exemplary process as illustrated in FIG. 31, in accordance with an embodiment.

[0033] FIG. 33 shows the antibody reactivity for clinical samples with known HIV-1 and *T. pallidum* serostatus, as analyzed with an exemplary system, in accordance with an embodiment.

[0034] FIG. 34 shows the antibody reactivity for 181 clinical samples with known HCV antibody serostatus (60 positive and 121 negative), as analyzed with an exemplary system, in accordance with an embodiment.

[0035] FIGS. 35-37 show representative images and a comparison of whole blood and plasma performance on an exemplary system, in accordance with an embodiment.

[0036] FIG. 38 shows a series of diagrams illustrating the steps of an indirect fluorescence assay.

[0037] FIG. 39 shows a series of diagrams illustrating a labeled antigen assay, in accordance with an embodiment.

[0038] FIG. 40 shows a flow chart illustrating the labeled antigen assay process, in accordance with an embodiment.

[0039] FIG. 41 shows an exemplary analysis summary obtained using the assay system, in accordance with an embodiment.

[0040] FIG. 42 is a graph showing the results of a real time signal acquisition for a kinetic analysis of an analyte, using the labeled antigen assay with the assay system, in accordance with an embodiment.

[0041] FIGS. 43-44 show an exemplary analysis summary obtained using the assay system and labeled antigen assay process with whole blood or plasma as the biological sample, in accordance with an embodiment.

[0042] FIGS. 45-46 show a cartridge with integrated tilt mechanisms, in accordance with an embodiment.

[0043] FIG. 47 shows a rack for enabling batch processing and cartridge tilt for assay cartridges, in accordance with an embodiment.