MODULAR POINT-OF-CARE DEVICES AND USES THEREOF

CROSS-REFERENCE

[0001] This application claims the benefit of U.S. Provisional Application No. 60/997,460, filed October 2, 2007, which application is incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

[0002] The discovery of a vast number of disease biomarkers and the establishment of miniaturized medical systems have opened up new avenues for the prediction, diagnosis and monitoring of treatment of diseases in a point-of-care setting. Point-of-care systems can rapidly deliver test results to medical personnel, other medical professionals and patients. Early diagnosis of a disease or disease progression can allow medical personnel to begin or modify therapy in a timely manner.

[0003] Multiplexed biomarker measurement can provide additional knowledge of the condition of a patient. For example, when monitoring the effects of a drug, three or more biomarkers can be measured in parallel. Typically, microtiter plates and other similar apparatuses have been used to perform multiplexed separation-based assays. A microtiter plate (for example, a 384 well microtiter plate) can perform a large number of assays in parallel.

[0004] In a Point-of-Care (POC) device, the number of assays that can be performed in parallel is often limited by the size of the device and the volume of the sample to be analyzed. In many POC devices, the number assays performed is about 2 to 10. A POC device capable of performing multiplexed assays on a small sample would be desirable.

[0005] A shortcoming of many multiplexed POC assay devices is the high cost of manufacturing the components of the device. If the device is disposable, the high cost of the components can make the manufacturing of a POC device impractical. Further, for multiplexed POC devices that incorporate all of the necessary reagents onboard of the device, if any one of those reagents exhibit instability, an entire manufactured lot of devices may have to be discarded even if all the other reagents are still usable.

[0006] When a customer is interested in a customizing a POC device to a particular set of analytes, manufacturers of multiplexed POC assay systems are often confronted with a need to mix-and-match the assays and reagents of the device. A multiplexed POC assay suitable to each customer can be very expensive, difficult to calibrate, and difficult to maintain quality control.

[0007] POC methods have proven to be very valuable in monitoring disease and therapy (for example, blood glucose systems in diabetes therapy, Prothrombin Time measurement in anticoagulant therapy using Warfarin). By measuring multiple markers, it is believed that complex diseases (such as cancer) and therapies such as multi-drug therapy for cancer can be better monitored and controlled.

SUMMARY OF THE INVENTION

[0007a] In one aspect, provided herein is a method for detecting an analyte in a bodily fluid sample using a point-of-care system including a cartridge, an assay assembly, a fluid transfer device, and a detection assembly, the method comprising: positioning, via the fluid transfer device, the assay assembly at a first location that places a sample unit of the cartridge into fluid communication with the assay assembly, the assay assembly comprising a tip and an interior reaction site having thereon an immobilized binding reagent configured to bind with the analyte; transferring the bodily fluid sample from the sample unit to the assay assembly via the tip of the assay assembly; positioning, via the fluid transfer device, the assay assembly at a second location that places an addressable reagent unit of the cartridge into fluid communication with the assay assembly, the addressable reagent unit comprising a cartridge

reagent; transferring the cartridge reagent from the addressable reagent unit to the assay assembly via the tip of the assay assembly such that a reaction occurs within the assay assembly to produce a signal indicative of the presence of the analyte in the bodily fluid sample; and detecting, by the detection assembly, the signal indicative of the presence of the analyte.

[0008] Thus, there remains an unmet need for alternative designs of POC devices. A desirable design provides modular capture surfaces and assay incubation elements. Furthermore, modular capture surfaces and assay incubation elements need to be integrated into POC disposables suited for just-in-time (JIT) manufacturing methods. It would be desirable to provide a customizable POC device at a practical cost to user and the manufacturer. The present invention addresses these needs and provides related advantages as well.

[0009] In an aspect, a cartridge is disclosed for automated detection of an analyte in a bodily fluid sample comprising: an array of addressable assay units configured to run a chemical reaction that yields a detectable signal indicative of the presence or absence of the analyte; and an array of addressable reagent units, wherein an individual