

## DETECTION AND QUANTIFICATION OF ANALYTES IN BODILY FLUIDS

### CROSS REFERENCE

This application is a continuation application of U.S. Ser. No. 11/939,509, filed on Nov. 13, 2007, now abandoned which claims the benefit of U.S. Provisional Application No. 60/865,805 filed Nov. 14, 2006, which is incorporated herein by reference in its entirety.

### BACKGROUND OF THE INVENTION

Many medical procedures require tests to be performed with a sample of a patient's fluid. The ability to rapidly and accurately detect a wide range of analytes present in a bodily fluid is often critical for diagnosis, prognosis, and treatment of diseases.

Traditionally, detecting a range of analytes present in a bodily fluid such as blood has been performed in laboratories by trained technicians. Performing such assays is usually time-consuming and costly. The desire for rapid turnaround time creates a need to facilitate testing that can be delivered at the point-of-care. Point-of-care testing is particularly desirable because it rapidly delivers results to medical practitioners, enables faster consultation, and avoids unattended deterioration of a patient's condition.

Although several point of care testing devices are available, the majority of which is adapted to detect a single analyte, or one type of analytes for a single indication. Examples of such point of care devices are tests for glucose, drugs of abuse, serum cholesterol, pregnancy, or ovulation.

Thus, there remains a need for alternative designs of point of care systems that are capable of detecting a range of analytes from bodily fluid. A desirable system would allow quantitative and qualitative measurements of analytes in a more cost effective and timely fashion. The present invention addresses this need and provides related advantages as well.

### SUMMARY OF THE INVENTION

One aspect of the present invention is the design of a system to effect detection of different analytes in a bodily fluid. In one embodiment, the present invention provides a system that typically comprises a) a fluidic device comprising a cartridge, said cartridge comprising a sample collection unit and an assay assembly, wherein said sample collection unit allows a sample of bodily fluid to react with reactants contained within said assay assembly to yield a colored product having an absorbance spectrum corresponding to at least one wavelength from a light source; b) a light source transmitting the at least one wavelength to the assay assembly; and c) a detector that detects absorption of light of the at least one wavelength, wherein said absorption is indicative of the presence of the analyte in said bodily fluid. In general, the amount of absorption is related to the concentration of the analyte in the bodily fluid. Preferably, the amount of absorption is stoichiometrically related to the concentration of the analyte in the bodily fluid. The subject system is preferably configured to be a point-of-care system.

In a related but separate embodiment, the present invention provides a fluidic device capable of detecting the presence or absence of an analyte in a bodily fluid from a subject. The fluidic device can be part of the system described above. The subject fluidic device typically comprises (a) a cartridge, said cartridge comprising a sample collection unit, an assay assembly, and (b) a light source, wherein said sample collec-

tion unit is configured to collect a sample of bodily fluid from said subject and wherein said assay assembly comprises at least one reaction site containing a reactant that reacts with said analyte to yield a colored product having an absorbance spectrum corresponding to at least one wavelength from said light source. Where desired, the fluidic device can be employed to detect a plurality of analytes.

The assay assembly employed in the subject fluidic device or system is generally configured to run an enzymatic assay yielding a colored product. The assay assembly can be configured to run assays capable of detecting a wide variety of analytes. Non-limiting exemplary analytes include drug, drug metabolite, biomarker indicative of a disease, tissue specific marker, and tissue specific enzyme. Preferred analytes for detection include without limitation HDL cholesterol, LDL cholesterol, total cholesterol, lipids, and glucose. Where desired, the assay assembly is configured to run an immunoassay.

The light source employed in the subject fluidic device or system typically produces at least one wavelength corresponding to the absorbance spectrum of the colored product generated by an assay. A suitable light source can comprise a light emitting diode and/or luminescent paint. Where luminescent paint is used as the light source, it is typically coated on the assay assembly.

The present invention also provides a method of detecting an analyte in a bodily fluid from a subject. The method typically involves the steps of a) introducing a sample of bodily fluid into a fluidic device comprising a sample collection unit and an assay assembly, said assay assembly comprising reactants that are capable of reacting with said analytes; b) allowing said sample of bodily fluid to react with said reactants contained within said assay assembly to yield a colored product having an absorbance spectrum corresponding to at least one wavelength from a light source; c) transmitting the at least one wavelength to the fluidic device from said light source; and d) detecting absorption of light of the at least one wavelength transmitted to the fluidic device, wherein said absorption is indicative of the presence of the analyte in said bodily fluid. The method can be employed to detect analytes in a sample of bodily fluid that is less than about 500 ul, less than about 50 ul, or less than about 20 ul, or even less than about 10 ul. Where desired, the methods can be applied to detect analytes in a predetermined amount of bodily fluid that can be undiluted, unprocessed or diluted or processed by, e.g., filtration, centrifugation and other like processes.

### INCORPORATION BY REFERENCE

All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

### BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. 1 depicts an exemplary point-of-care system of the present invention.