POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF

CROSS-REFERENCE

This application is a continuation application of U.S. application Ser. No. 11/389,409, filed on Mar. 24, 2006, now U.S. Pat. No. 7,635,594 which claims the benefit of U.S. Provisional Application No. 60/678,801, filed May 9, 2005 and U.S. Provisional Application No. 60/705,489, filed Aug. 5, 2005 and U.S. Provisional Application No. 60/717,192, filed Sep. 16, 2005, and U.S. Provisional Application No. 60/721,097, filed Sep. 28, 2005, all of which are incorporated herein by reference in their entirety.

TECHNICAL FIELD

This invention is in the field of medical devices. Specifically, the present invention provides portable medical devices that allow real-time detection of analytes from a biological fluid. The methods and devices are particularly useful for providing point-of-care testing for a variety of medical applications.

BACKGROUND OF THE INVENTION

The discovery of a vast number of disease biomarkers and the establishment of miniaturized microfluidic systems have opened up new avenues to devise methods and systems for the prediction, diagnosis and treatment of diseases in a point-of-care setting. Point-of-care testing is particularly desirable because it rapidly delivers results to medical practitioners and enables faster consultation. Early diagnosis allows a practitioner to begin treatment sooner and thus avoiding unattended deterioration of a patient's condition. Examples of point-of-care analyses include tests for glucose, drugs of abuse, serum cholesterol, pregnancy, and ovulation. However, these and other currently available point-of-care methods and systems do not provide an integrated solution for sample acquisition, testing, analysis and communication of results to medical practitioners or health providers when needed. Thus, there remains a considerable need for a portable, multi-parameter measurement instrument that provides convenient and rapid data collection, transmission, analysis, as well as on-line medical consultation or decision making.

New and improved point-of-care testing is also needed for research and development of therapeutic agents as well as for monitoring possible adverse drug reactions (ADRs), after a drug is brought to the market place.

The safety and efficacy of a drug is determined by the pharmacokinetic (what the body does to the drug) and pharmacodynamic parameters (what the drug does to the body) of the drug. Currently, the pharmacokinetic (PK) and pharmacodymanic (PD) parameters of a drug are generally determined by first drawing blood samples from a patient followed by laboratory analyses. Such approach has numerous shortcomings. First, the patient is generally required to visit a clinic to provide clinical samples such as blood or urine samples at multiple time points. Second, most of the analytical techniques for determining target analyte and biomarker concentrations that reflect either the pharmacokinetic (PK) and pharmacodymanic (PD) parameters require that the blood samples be pre-processed before the parameters can be determined. This results in delay of data response, variability in physiological drug distribution and metabolism (warranting poor dosing), sparse sampling, and the lack of dosing history. Notably, numerous clinical trials often suffer from

insufficient numbers of blood tests because of poor patient compliance; the patients often fail to return to a phlebotomist to provide the blood samples required by the trial.

Similarly, the current techniques and systems for monitoring ADRs are also inadequate. ADRs are one of the leading causes of morbidity and mortality in health care. The Institute of Medicine reported in January 2000 that 44,000 to 98,000 deaths occurred due to medical errors, of which 7,000 deaths were due to ADRs. Other studies conducted on hospitalized patient populations have indicated an ever higher overall incidence of several ADRs. Several reasons contribute to the prevalence of ADRs. First, there are more combination therapies available to patients. Second, there is an increasing trend towards chronic use of drugs (statins such as Lipitor and Cox-2 inhibitors such as Vioxx). Chronic use of drugs also increases the chance that changes in the patient's lifestyle, health status and use of other medications will occur. In women, the chronic use of drugs can result in unanticipated consequences if the woman becomes pregnant. Such risks are of particular concern to the fetus, which is especially susceptible to ADRs including teratogenicity.

A further important factor in managing the risks and benefits of drug therapy is patient compliance. Patients often fail to take scheduled dose of drug, take more than the prescribed dose, or fail to complete a course of drug therapy (especially common in treatment for infectious disease). These behaviors (deliberate or inadvertent) result in improper levels of drugs in the body which can cause serious adverse effects. The patient is typically oblivious to such consequences and the prescribing physician is also unlikely to realize the problem before several consequences occur.

Thus, there remains a pressing need for methods and apparatus that allow real-time data transmission between patient and medical practitioners to enable efficient communication and high throughput point-of-care testing in an ambulatory context. A beneficial system will detect ADRs, and efficacy and/or toxicity of a therapeutic agent in real-time in an ambulatory setting. It may also facilitate medical practitioners assessing patients' physiological conditions in response to therapeutic agents during the course of clinical trials or follow-on treatments. The present invention satisfies these needs and provides related advantages as well.

SUMMARY OF THE INVENTION

One aspect of the present invention is the design of a system capable of providing real-time data transmission between a patient and medical practitioners to facilitate high throughput point-of-care testing in an ambulatory setting. The systems and methods provided herein simplify the laborious and expensive procedures of processing and analyzing the samples collected from a subject (e.g., a patient) without the use of laboratory equipment or facility. The systems and methods are particularly useful for detection of an analyte from a small sample of bodily fluid to effect diagnosis, prognosis, treatment, and development of therapeutics.

Accordingly, in one embodiment, the present invention provides a system for detecting an analyte in a bodily fluid from a subject. The system comprises a) a fluidic device, said fluidic device comprising a sample collection unit and an assay assembly, wherein said sample collection unit allows a sample of bodily fluid of less than 500 ul to react with reactants contained within said assay assembly to yield a detectable signal indicative of the presence of said analyte collected in said sample of bodily fluid; b) a reader assembly comprising a detection assembly for detecting said detectable signal;