SYSTEMS AND METHODS FOR MULTI-ANALYSIS

CROSS-REFERENCE

This application is a continuation-in-part application of PCT Application No. PCT/US2011/53188, filed Sep. 25, 2011, which is incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

The majority of clinical decisions are based on laboratory and health test data, yet the methods and infrastructure for collecting such data severely limit the quality and utility of the data itself. Almost all errors in laboratory testing are associated with human or pre-analytic processing errors, and the testing process can take days to weeks to complete. Often times by the time a practicing physician gets the data to effectively treat a patient or determine the most appropriate intervention, he or she has generally already been forced to treat a patient empirically or prophylactically as the data was not available at the time of the visit or patient triage. Earlier access to higher quality testing information at the time of patient triage enables earlier interventions and better management of disease progression to improve outcomes and lower the cost of care.

Existing systems and methods for clinical testing suffer major drawbacks from the perspectives of patients, medical care professionals, taxpayers, and insurance companies. Today, consumers can undergo certain specialized tests at clinics or other specialized locations. If a test is to be conducted and the result of which is to be eventually relied on by a doctor, physical samples are transported to a location which performs the test on the samples. For example, these samples may comprise blood from a venous draw and are typically collected from a subject at the specialized locations. Accessibility of these locations and the venipuncture process in and of itself is a major barrier in compliance and frequency of testing. Availability for visiting a blood collection site, the fear of needles—especially in children and elderly persons who, for example, often have rolling veins, and the difficulty associated with drawing large amounts of blood drives people away from getting tested even when it is needed. Thus, the conventional sampling and testing approach is cumbersome and requires a significant amount of time to provide test results. Such methods are not only hampered by scheduling difficulties and/or limited accessibility to collection sites for subjects to provide physical samples but also by the batch processing of samples in centralized laboratories and the associated turn around time in running laboraotory tests. As a result, the overall turn around time involved in getting to the collection site, acquiring the sample, transporting the sample, testing the sample and reporting and delivering results becomes prohibitive and severely limits the timely provision of the most informed care from a medical professional. This often results in treatment of symptoms as opposed to underly disease conditions or mechanisms of disease progression.

In addition, traditional techniques are problematic for certain diagnoses. Some tests may be critically time sensitive, but take days or weeks to complete. Over such a time, a disease can progress past the point of treatment. In some instances, follow-up tests are required after initial results, which take additional time as the patient has to return to the specialized locations. This impairs a medical professional's ability to provide effective care. Furthermore, conducting tests at only limited locations and/or infrequently reduces the likelihood that a patient's status can be regularly monitored or

that the patient will be able to provide the samples quickly or as frequently as needed. For certain diagnoses or conditions, these deficiencies inevitably cause inadequate medical responses to a changing and deteriorating physiological conditions. Traditional systems and methods also affect the integrity and quality of a clinical test due to degradation of a sample that often occurs while transporting such sample from the site of collection to the place where analysis of the sample is performed. For example, analytes decay at a certain rate, and the time delay for analysis can result in loss of sample integrity. Different laboratories also work with different quality standards which can result in varying degrees of error. Additionally, preparation and analysis of samples by hand permits upfront human error to occur at various sample collection sites and laboratories. These and other drawbacks inherent in the conventional setup make it difficult to perform longitudinal analyses, especially for chronic disease management, with high quality and reliability

Furthermore, such conventional analytical techniques are often not cost effective. Excessive time lags in obtaining test results lead to delays in diagnoses and treatments that can have a deleterious effect on a patient's health; as a disease progresses further, the patient then needs additional treatment and too often ends up unexpectedly seeing some form of hospitalization. Payers, such as health insurance companies and taxpayers contributing to governmental health programs, end up paying more to treat problems that could have been averted with more accessible and faster clinical test results.

SUMMARY OF THE INVENTION

Being able to detect a disease or the onset of a disease in time to manage and treat it is a capability deeply sought after by patients and providers alike but one that has yet to be realized in the current healthcare system where detection too often coincides with fatal prognoses.

A need exists for improved systems and methods for sample collection, sample preparation, assay, and/or detection. A further need exists for systems and devices that perform one or more of the sample collection, preparation, assay, or detection steps. Systems and methods are needed at the time and place in which care is provided for rapid, frequent and/or more accurate diagnoses, ongoing monitoring, and facilitatation and guidance of treatment. Systems and methods disclosed herein meet this and related needs.

In accordance with an aspect of the invention, a system may comprise: a plurality of modules mounted on a support structure, wherein an individual module of said plurality of modules comprises a sample preparation station, assay station, and/or detection station, wherein the system is configured to perform (a) at least one sample preparation procedure selected from the group consisting of sample processing, centrifugation, separation, and chemical processing, and (b) multiple types of assays selected from the group consisting of immunoassay, nucleic acid assay, receptor-based assay, cytometric assay, colorimetric assay, enzymatic assay, electrophoretic assay, electrochemical assay, spectroscopic assay, chromatographic assay, microscopic assay, topographic assay, calorimetric assay, turbidmetric assay, agglutination assay, radioisotope assay, viscometric assay, coagulation assay, clotting time assay, protein synthesis assay, histological assay, culture assay, osmolarity assay, and combinations thereof; and wherein the multiple types of assays are performed with the aid of isolated (including but not limited to fluidically) assay units contained within the system. In some embodiments, separation includes magnatic separation.