SYSTEMS AND METHODS FOR COLLECTING AND TRANSMITTING ASSAY RESULTS

BACKGROUND OF THE INVENTION

[0001] Existing systems and methods for clinical testing suffer many drawbacks from the perspectives of patients, health care professionals, and taxpayers or insurance companies. Today, consumers can purchase certain specialized tests from various locations for consumer use. For example, a consumer can purchase a pregnancy test at a pharmacy and review the results. However, such results are to be viewed by the consumer, and are not to be relied on by the consumer's physician in forming a screening, diagnosis or treatment plan.

[0002] Additionally, if a test result is to be conducted and to be relied on by a doctor, physical samples are transported to a laboratory where the tests on the samples are performed. For example, blood from a fingerstick or venous draw is typically collected from a subject at a hospital or physician's office. The blood sample is shipped to a Clinical Laboratory Improvement Amendments (CLIA) certified laboratory which performs the tests and analysis that is provided to the patient's doctor. Such techniques are cumbersome and cause significant delay in providing the result of a test ordered by a physician, especially because the physical specimens must be transported to a different site for analysis. Moreover, the sample collection sites often have limited hours which further causes inconvenience to patients.

[0003] Conventional techniques are also problematic for certain diagnoses. Some tests are time sensitive, and the results of which may take days or weeks to complete. In such a time, a disease can progress past the point of treatment. This impairs a medical professional's ability to provide quality care.

[0004] 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 actual analysis of the sample is performed. For examples, analytes decay at a certain rate, and the time delay for analysis can result in loss of the sample integrity. Different laboratories also work with different qualities which can result in varying degrees of error. Each laboratory can have its own set of references that further introduce a wide range of variability in coefficients of variation. Additionally, preparation of samples by hand permit upfront human error to occur from various sample collection sites. These and other drawbacks inherent in the conventional setup make it difficult to perform longitudinal analysis with high quality.

[0005] Furthermore, the conventional techniques are typically not very cost effective. For example, delays in test results lead to delays in diagnoses and treatments that can have a deleterious effect on a patient's health. For example, a disease may progress further, resulting in the patient needing additional treatment. 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

[0006] A need exists for improved systems and methods that allow higher quality of care, more rapid and accurate screening, diagnosis and/or treatment. Specifically, there is a considerable need for sample collection,

[00140] The device may be configured to receive one or more cartridge configured for the qualitative and/or quantitative evaluation. In some embodiments, the cartridge may have one or more identifier that is readable by the device.

[00141] In accordance with another aspect of the methods, systems, and devices disclosed herein, Applicants disclose a method of evaluating a biological sample collected from a subject, said method comprising:

[00142] (a) receiving at a laboratory location data transmitted from a device having a housing, said device placed in or on the subject or at a designated sample collection site, said data comprising raw data from said biological sample, said biological sample comprising a cell, wherein the device is configured to process the biological sample within said housing by: (i) receiving the biological sample; (ii) preparing the biological sample and yielding raw data within said housing for a subsequent qualitative and/or quantitative evaluation of said biological sample, said raw data comprising (1) numerical values representative of a physical process or chemical reaction performed by the device and (2) electronic data representative of an image of a cell in said biological sample; and (iii) transmitting electronically the raw data from said sample collection site to an authorized analytical facility and/or an affiliate thereof for performance of said subsequent evaluation at said laboratory location;

[00143] (b) analyzing the raw data transmitted from the device at the authorized analytical facility and/or the affiliate thereof, to provide said evaluation of said biological sample, wherein said analysis is performed using a processor alone or in conjunction with an individual affiliated with the authorized analytical facility; and

[00144] (c) providing oversight of integrity of said analysis and operation of said device such that results generated from said analysis can be utilized by a health care professional for screening, diagnosis or treatment of said subject, wherein the oversight is performed at said laboratory location using a processor alone or in conjunction with an individual affiliated with the authorized analytical facility.

[00144a] In embodiments, the evaluation of a biological sample is effected without physically transporting said sample from the site where the sample is collected to the authorized analytical facility or affiliate thereof. The authorized analytical facility and/or affiliate thereof may be a Clinical Laboratory Improvement Amendments (CLIA)-compliant laboratory. In embodiments, a designated sample collection site may be a retailer site, a military site, the subject's home, a health assessment location, or a health treatment location.

[00145] In embodiments of such methods, preparing the biological sample and yielding raw data within said housing may comprise transporting a reagent, the biological sample, or a portion of the biological sample, with a pipette within the housing; and may comprise centrifuging the biological sample, or a portion thereof, within the housing. In embodiments of such methods, electronic data representative of an image of a cell may include electronic data derived from an optical assessment of histology of said cell, morphology of said cell, hematology, or cell count. In embodiments of such methods, receiving data comprises may include receiving data from an image of a physical process or chemical reaction performed by the device with some or all of a biological sample. In embodiments of such methods, raw data may be yielded by more than one assay, including at least two assays selected from an immunoassay, a nucleic acid assay, a receptor-based assay, and an enzymatic assay. In embodiments, raw data may be yielded by at least three assays selected from an immunoassay, a nucleic acid assay, a receptor-based assay, and an enzymatic assay.

[00146] A biological sample may be selected from the group consisting of blood, serum, plasma, nasal swab, nasopharyngeal wash, saliva, urine, tears, gastric fluid, spinal fluid, stool, mucus, sweat, earwax, oil,

aspects of the methods disclosed herein, the device may be operated under the oversight or control of a CLIA-compliant laboratory, or a CLIA-certified laboratory, where the device may be a CLIA-compliant device or a CLIA-certified device; or may be a device that has been cleared for use by the U.S. Food and Drug Administration; or may be a device classified as exempt by the U.S. Food and Drug Administration; or may be a device that has not been cleared or approved by any regulatory body.

[00151] In accordance with another aspect of the systems, methods, and devices disclosed herein, Applicants disclose a system of evaluating a biological sample collected from a subject, the system comprising:

[00152] (a) a communication unit placed at a laboratory location configured to receive data from a device placed in or on the subject or at a designated sample collection site, wherein the device comprises a housing and is configured to process a biological sample within said housing, said biological sample comprising a cell, said processing by said device generating raw data for a subsequent qualitative and/or quantitative evaluation of said biological sample, and wherein the device comprises: (i) a sample collection unit within said housing configured to receive the biological sample; (ii) a sample preparation unit within said housing configured to prepare the biological sample and to yield raw data for the evaluation within said housing, wherein said raw data (1) comprises numerical values representative of a physical process or chemical reaction performed by the device and (2) and electronic data representative of an image of a cell in said biological sample; and a (iii) transmission unit configured to transmit the raw data from said sample collection site to an authorized analytical facility and/or an affiliate thereof at said laboratory location;

[00153] (b) a processor at said laboratory location that processes said data alone or in conjunction with an individual affiliated with the authorized analytical facility for (a) the evaluation of said biological sample at the authorized analytical facility and/or the affiliate thereof, and (b) the oversight of said integrity of evaluation and operation of said device, such that results generated from said evaluation can be utilized by a health care professional for screening, diagnosis or treatment of said subject.

[00153a] An authorized analytical facility may be a Clinical Laboratory Improvement Amendments (CLIA)-compliant laboratory. A designated sample collection site may be a retailer site, a military site, the subject's home, a health assessment location, or a health treatment location. Evaluation of a biological sample may be effected without physically transporting said sample from the site where the sample is collected to the authorized analytical facility or an affiliate thereof.

[00154] In embodiments, sample preparation units of such systems may include a fluid handling system comprising a pipette within the housing; and may include a centrifuge within the housing. Electronic data representative of an image of a cell in said biological sample may include electronic data derived from an optical assessment of histology or morphology of said cells, and raw data may include raw data from an image of a physical process or chemical reaction performed by the device with said biological sample or a portion thereof. Raw data may include raw data from at least two assays, or from at least three assays, selected from an immunoassay, a nucleic acid assay, a receptor-based assay, and an enzymatic assay.

[00155] In accordance with aspects of the systems disclosed herein, the device may be a Clinical Laboratory Improvement Amendments (CLIA)-waived device. In accordance with other aspects of the systems disclosed herein, the device may be a CLIA-compliant device, may be operated in compliance with CLIA, may be operated by a CLIA-compliant laboratory, or may be operated in a CLIA-compliant location; or may be a CLIA-certified device, may be operated by a CLIA-certified laboratory, or may be operated in a CLIA-certified location;