[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 and transporting and processing the sample using pipettes having nozzles, and pipette tips engaged with said pipette nozzles; (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 imaging of pipette tips for one or more of: confirming proper engagement of pipette tips with pipette nozzles; imaging of liquid volumes within pipette tips; the presence or absence of conditions which may interfere with proper processing or analysis; and (iii) transmitting electronically the pipette-tip image information and 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, said oversight including use of said pipette-tip image information, 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, a fluid handling system comprising a pipette nozzle within said 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 camera configured to image pipette tips for one or more of: engagement with pipette nozzles; liquid volumes within pipette tips; the presence or absence of conditions which may interfere with proper processing or analysis; and a (iii) transmission unit configured to transmit pipette-tip image information and 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, said oversight including use of said pipette-tip image information, 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;

CLAIMS

WHAT IS CLAIMED IS:

1. A method of evaluating a biological sample collected from a subject, said method comprising:

(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 and transporting and processing the sample using pipettes having nozzles, and pipette tips engaged with said pipette nozzles;

(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 imaging of pipette tips for one or more of: confirming proper engagement of pipette tips with pipette nozzles; imaging of liquid volumes within pipette tips; the presence or absence of conditions which may interfere with proper processing or analysis; and

(iii) transmitting electronically the pipette-tip image information and 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;

(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

(c) providing oversight of integrity of said analysis and operation of said device, said oversight including use of said pipette-tip image information, 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.

2. The method of claim 1, wherein preparing the biological sample and yielding raw data within said housing comprises transporting a reagent ~~or a biological sample~~ with a pipette within said housing.

3. The method of claim 1, wherein preparing the biological sample and yielding raw data within said housing comprises centrifuging a biological sample within said housing.

4. The method of claim 1, wherein the device is a Clinical Laboratory Improvement Amendments (CLIA)-waived device.

5. The method of claim 1, wherein the device is a Clinical Laboratory Improvement Amendments (CLIA)-compliant device, is operated in compliance with CLIA, is operated by a CLIA-compliant laboratory, or is operated in a CLIA-compliant location.

6. The method of claim 1, wherein the device is a Clinical Laboratory Improvement Amendments (CLIA)-certified device, is operated by a CLIA-certified laboratory, or is operated in a CLIA-certified location.

7. The method of claim 1, wherein the device is a device that has been cleared for use by the U.S. Food and Drug Administration.

sweat, earwax, oil, glandular secretion, cerebral spinal fluid, tissue, semen, and vaginal fluid, throat swab, breath, hair, finger nails, skin, biopsy, placental fluid, amniotic fluid, cord blood, lymphatic fluids, cavity fluids, sputum, mucus, pus, microbiota, meconium, breast milk and other excretions.

23. The method of claim 1, wherein the biological sample is a fluid sample having a volume of 250 μL or less.

24. The method of claim 1, wherein said oversight includes the selection of analysis methodology and procedures.

25. The method of claim 1, further comprising the step of verifying insurance eligibility of said subject prior to, concurrent with or subsequent to said analysis.

26. The method of claim 1, further comprising generating a report for said subject based on said evaluation.

27. The method of claim 1, comprising evaluating a plurality of types of biological samples collected from a subject, wherein said data transmitted from said device comprises raw data from said plurality of types of biological samples, wherein at least one of said biological samples comprises a cell.

28. The method of claim 27, wherein preparing the biological sample and yielding raw data within said housing comprises yielding raw data within said housing from at least two types of biological samples and at least two assays selected from an immunoassay, a nucleic acid assay, a receptor-based assay, and an enzymatic assay.

29. The method of claim 27, wherein the evaluation of said plurality of types of biological samples is effected without physically transporting any of said samples from the site where the sample is collected to the authorized analytical facility and/or an affiliate thereof.

30. The method of claim 27, wherein fluid samples of the plurality of types of biological samples each have a volume of 250 μL or less.

31. The method of claim 27, wherein said oversight includes the selection of analysis methodology and procedures for each of said plurality of types of biological samples.

32. A system of evaluating a biological sample collected from a subject, said system comprising:

(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, a fluid handling system comprising a pipette nozzle within said 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 camera configured to image pipette tips for one or more of: engagement with pipette nozzles; liquid volumes within pipette tips; the presence or absence of conditions which may interfere with proper processing or analysis; and a

(iii) transmission unit configured to transmit pipette-tip image information and the raw data from said sample collection site to an authorized analytical facility and/or an affiliate thereof at said laboratory location;

(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, said oversight including use of said pipette-tip image information, such that results generated from said evaluation can be utilized by a health care professional for screening, diagnosis or treatment of said subject.

~~33. The system of claim 32, wherein said sample preparation unit comprises a fluid handling system comprising a pipette within said housing.~~

3433. The system of claim 32, wherein said sample preparation unit comprises a centrifuge within said housing.

~~34~~35. The system of claim 32, wherein the device is a Clinical Laboratory Improvement Amendments (CLIA)-waived device.

~~35~~36. The system of claim 32, wherein the device is a Clinical Laboratory Improvement Amendments (CLIA)-compliant device, is operated in compliance with CLIA, is operated by a CLIA-compliant laboratory, or is operated in a CLIA-compliant location.

~~36~~37. The system of claim 32, wherein the device is a Clinical Laboratory Improvement Amendments (CLIA)-certified device, is operated by a CLIA-certified laboratory, or is operated in a CLIA-certified location.

~~37~~38. The system of claim 32, wherein the device is a device that has been cleared for use by the U.S. Food and Drug Administration.

~~38~~39. The system of claim 32, wherein the device has been classified as exempt by the U.S. Food and Drug Administration.

~~39~~40. The system of claim 32, wherein the device is a device that has not been cleared or approved by any regulatory body.

~~40~~41. The system of claim 32, wherein the authorized analytical facility and/or affiliate thereof is a Clinical Laboratory Improvement Amendments (CLIA)-compliant laboratory or a CLIA-certified laboratory.

~~41~~42. The system of claim 32, wherein the device is operated under the control or oversight of a Clinical Laboratory Improvement Amendments (CLIA)-compliant or CLIA-certified laboratory.

~~42~~43. The system of claim 32, wherein the device is a Clinical Laboratory Improvement Amendments (CLIA)-waived device operated under the control of a CLIA-compliant or CLIA-certified laboratory.

~~43~~44. The system of claim 32, wherein the device is a Clinical Laboratory Improvement Amendments (CLIA)-waived device operated under the oversight of a CLIA-compliant or CLIA-certified laboratory.

~~44~~45. The system of claim 32, wherein the device is operated under the oversight or control of a CLIA-compliant or CLIA-certified laboratory, and wherein the device is a Clinical Laboratory Improvement Amendments (CLIA)-compliant device; or a CLIA-certified device; or a device that has been cleared for use by the U.S. Food

and Drug Administration; or a device that has been classified exempt by the U.S. Food and Drug Administration; or a device that has not been cleared or approved by any regulatory body.

4645. The system of claim 32, wherein the device is a sample processing device or a sample processing unit.

4746. The system of claim 32, wherein the device has been classified by a regulatory body as a sample processing device or a sample processing unit.

4847. The system of claim 32, wherein said designated sample collection site is a site selected from the group consisting of a retailer site, the subject's home, and a health assessment/treatment location.

4948. The system of claim 32, wherein said electronic data representative of an image of a cell in said biological sample comprises electronic data derived from an optical assessment of histology or morphology of said cells, and said raw data comprises raw data from an image of a physical process or chemical reaction performed by the device with said biological sample.

5049. The system of claim 32, wherein said raw data comprises raw data from at least two assays selected from an immunoassay, a nucleic acid assay, a receptor-based assay, and an enzymatic assay.

5150. The system of claim 32, wherein the evaluation of said biological sample is effected without physically transporting said sample from the site where the sample is collected to the authorized analytical facility or an affiliate thereof.

5251. The system of claim 32, wherein said processor at said laboratory location is configured to generate a report.

5352. The system of claim 32, wherein the processor is configured to communicate with a record database comprising one or more medical records of, or insurance information for, the subject.

5453. The system of claim 32, wherein the processor is configured to communicate with a payer database comprising the insurance information for the subject.