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Galen et al.

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(54) **DIAGNOSTICS SYSTEMS AND METHODS**

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(73) Assignee: **HEMEX HEALTH, INC.**, Portland, OR (US)

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(22) Filed: **Sep. 8, 2017**

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A61B 5/157 (2006.01)
A01H 5/10 (2018.01)
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(52) **U.S. Cl.**
CPC ***A01H 5/10*** (2013.01); ***A01H 1/02*** (2013.01); ***A61B 5/15003*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC G01N 33/49; G01N 21/84; G01N 2035/00891; B01L 3/502;
(Continued)

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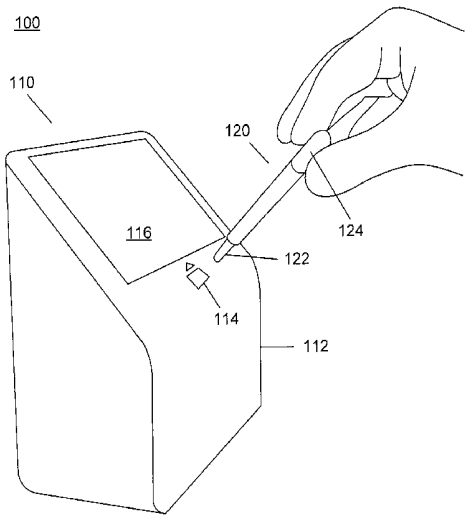
Primary Examiner — Samuel P Siefke
(74) *Attorney, Agent, or Firm* — Lane Powell PC

(57) **ABSTRACT**

A point-of-care diagnostic system that includes a cartridge and a reader. The cartridge can contain a patient sample, such as a blood sample. The cartridge is inserted into the reader and the patient sample is analyzed. The reader contains various analysis systems, such as an electrophoresis detection system that uses electrophoresis testing to identify and quantify various components of the blood sample. The reader can process data from the various patient sample analysis to provide interpretative results indicative of a disorder, condition, disease and/or infection of the patient.

30 Claims, 10 Drawing Sheets



Related U.S. Application Data

(60) Provisional application No. 62/385,146, filed on Sep. 8, 2016.

(51) **Int. Cl.**

G01N 1/31	(2006.01)
B01L 3/00	(2006.01)
G01N 27/447	(2006.01)
A61B 5/151	(2006.01)
A61B 5/15	(2006.01)
A61B 5/00	(2006.01)
G01N 33/49	(2006.01)
A01H 1/02	(2006.01)
C12N 15/82	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 5/157*** (2013.01); ***A61B 5/1519*** (2013.01); ***A61B 5/15087*** (2013.01); ***A61B 5/15192*** (2013.01); ***A61B 5/150755*** (2013.01); ***A61B 5/7282*** (2013.01); ***A61B 5/742*** (2013.01); ***A61B 5/7405*** (2013.01); ***A61B 5/7475*** (2013.01); ***B01L 3/502*** (2013.01); ***B01L 3/50273*** (2013.01); ***C12N 15/8243*** (2013.01); ***C12N 15/8245*** (2013.01); ***C12N 15/8247*** (2013.01); ***C12N 15/8251*** (2013.01); ***C12N 15/8274*** (2013.01); ***C12N 15/8279*** (2013.01); ***C12N 15/8286*** (2013.01); ***C12N 15/8289*** (2013.01); ***G01N 1/312*** (2013.01); ***G01N 27/44717*** (2013.01); ***G01N 27/44756*** (2013.01); ***G01N 33/49*** (2013.01); *A61B 2560/0214* (2013.01); *B01L 2300/021* (2013.01); *B01L 2300/023* (2013.01); *B01L 2300/025* (2013.01); *B01L 2300/0645* (2013.01); *B01L 2300/0672* (2013.01); *B01L 2300/087* (2013.01); *B01L 2300/0816* (2013.01); *B01L 2300/0825* (2013.01); *B01L 2300/18* (2013.01); *B01L 2400/0406* (2013.01); *B01L 2400/0421* (2013.01); *B01L 2400/0481* (2013.01); *G01N 27/44704* (2013.01); *G01N 27/44743* (2013.01); *G01N 2333/805* (2013.01)

(58) **Field of Classification Search**

CPC B01L 2300/0672; B01L 2400/043; B01L 2300/0654; A61B 5/157

See application file for complete search history.

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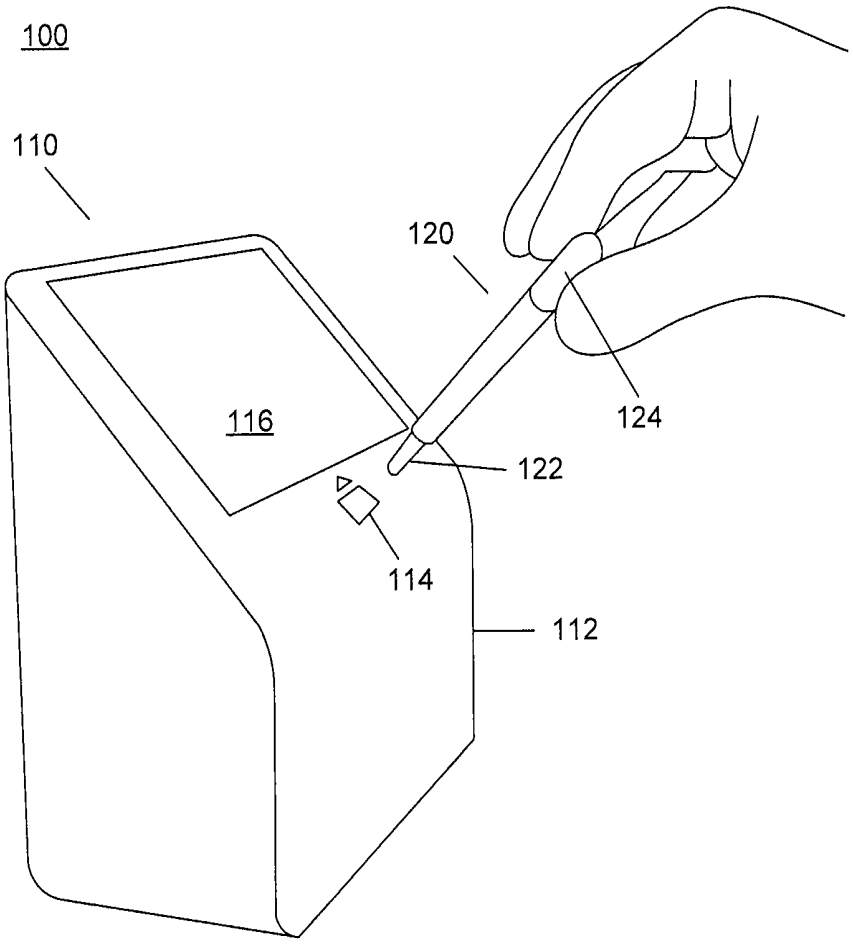

FIG. 1

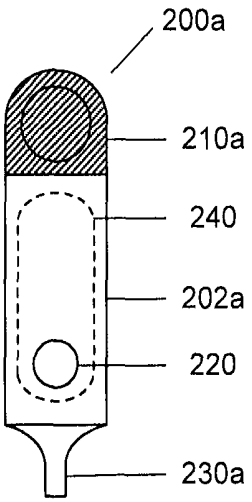

FIG. 2A

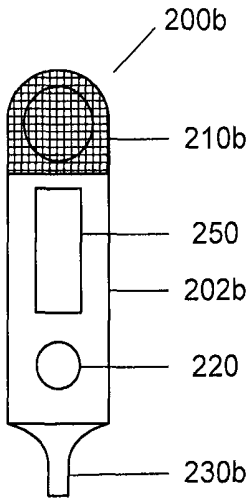

FIG. 2B

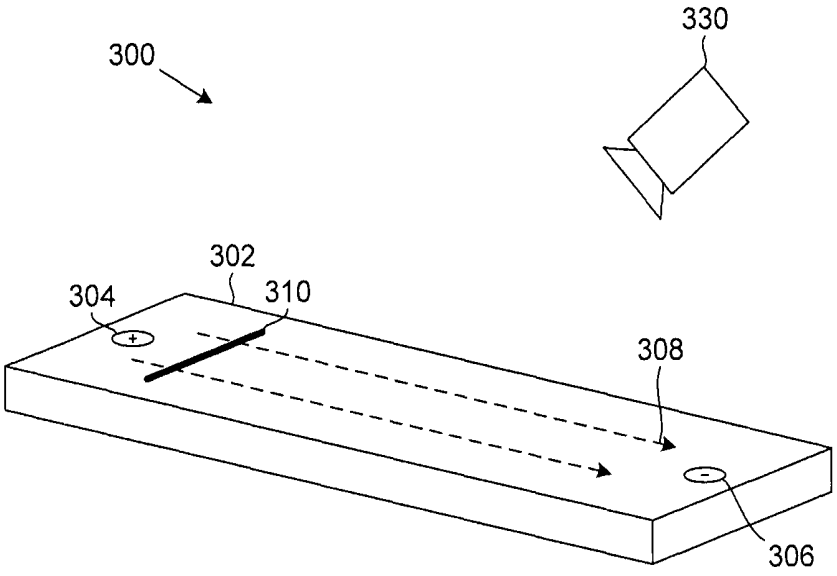
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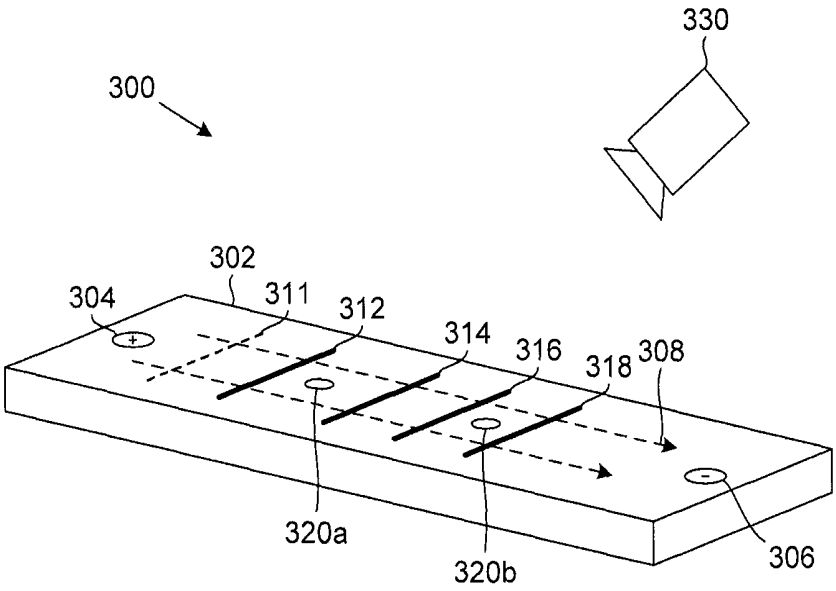
FIG. 3A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320b
306

FIG. 3B

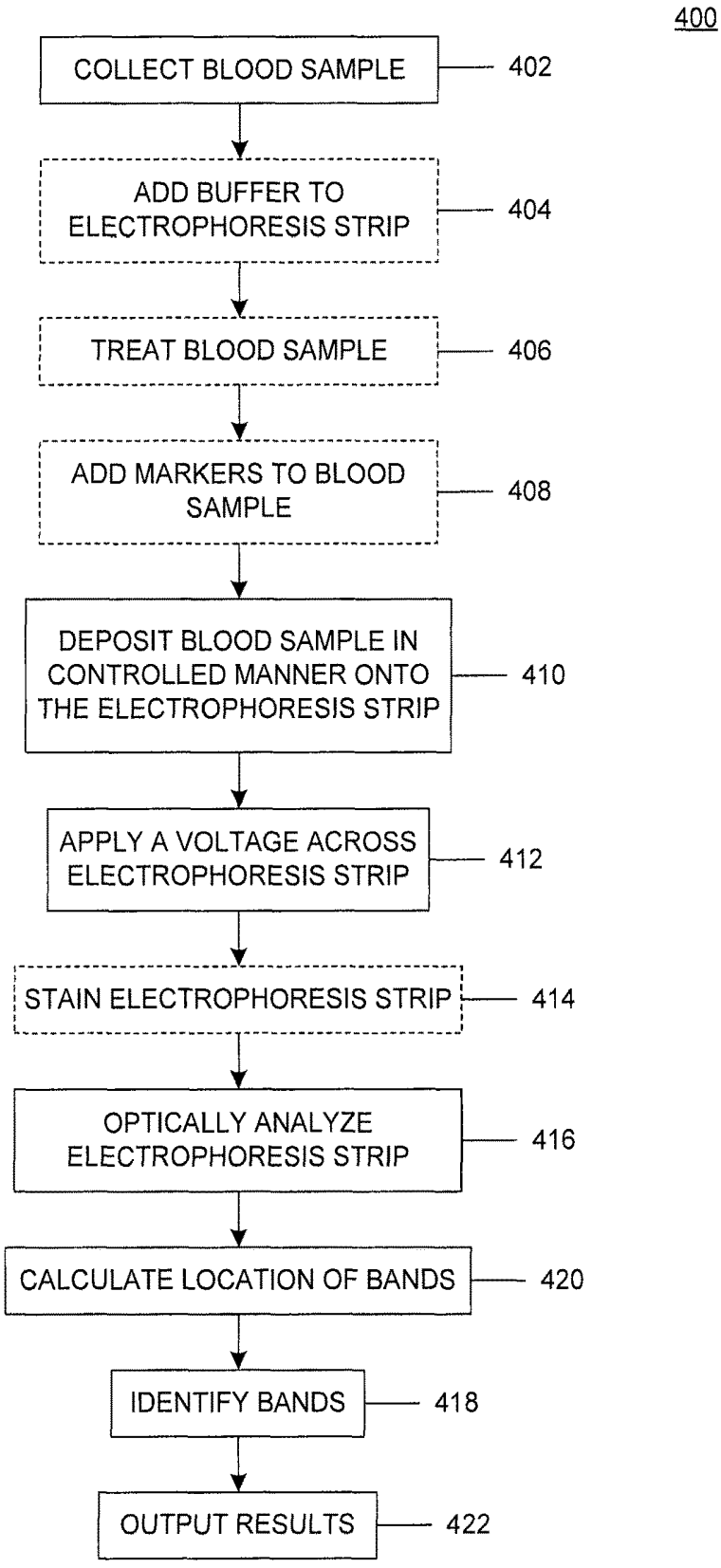

400
COLLECT BLOOD SAMPLE
402
ADD BUFFER TO ELECTROPHORESIS STRIP
404
TREAT BLOOD SAMPLE
406
ADD MARKERS TO BLOOD SAMPLE
408
DEPOSIT BLOOD SAMPLE IN CONTROLLED MANNER ONTO THE ELECTROPHORESIS STRIP
410
APPLY A VOLTAGE ACROSS ELECTROPHORESIS STRIP
412
STAIN ELECTROPHORESIS STRIP
414
OPTICALLY ANALYZE ELECTROPHORESIS STRIP
416
CALCULATE LOCATION OF BANDS
420
IDENTIFY BANDS
418
OUTPUT RESULTS
422

FIG. 4

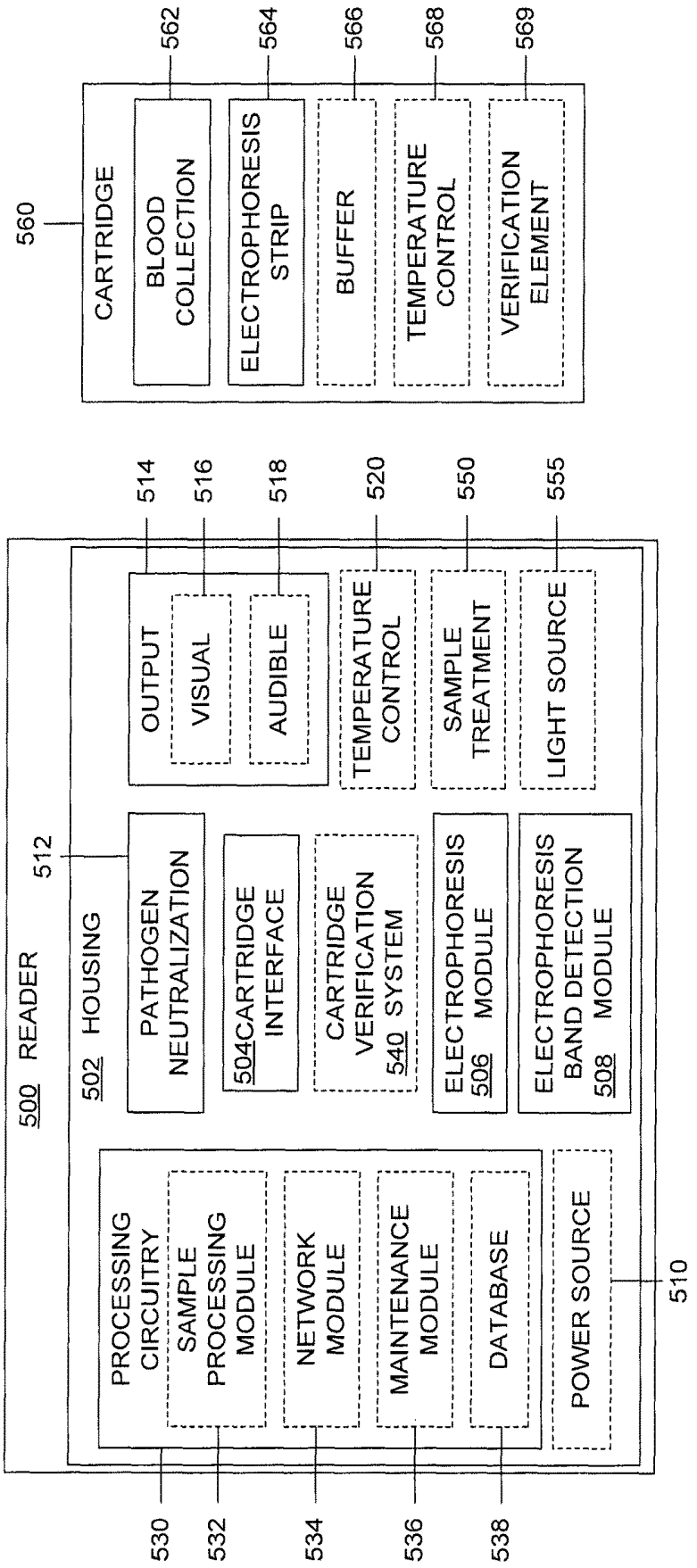
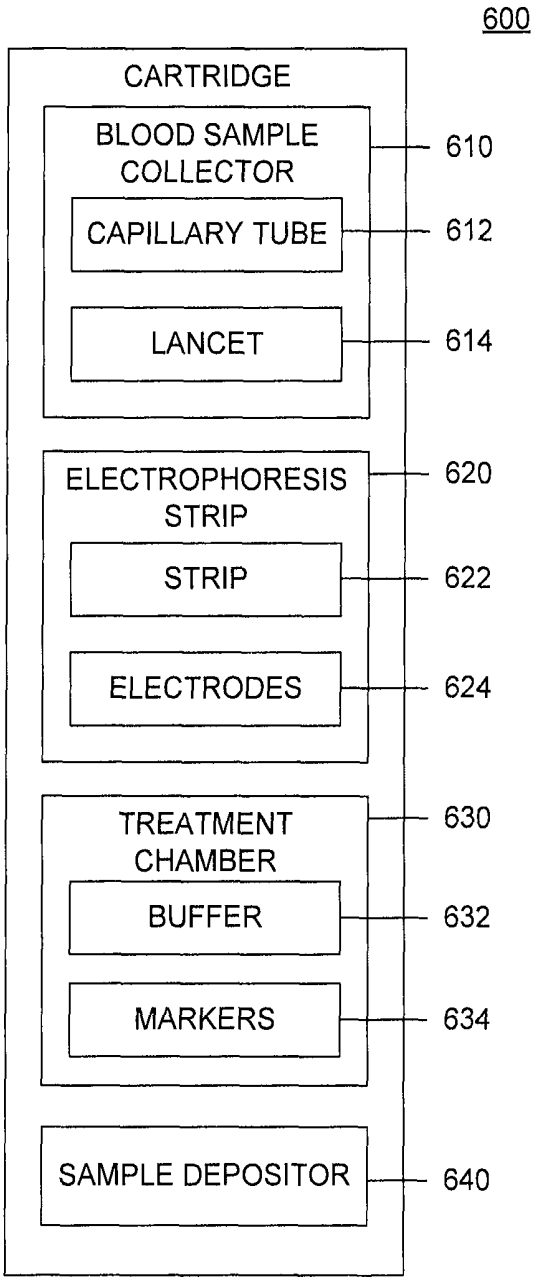

560
CARTRIDGE
BLOOD COLLECTION
562
ELECTROPHORESIS STRIP
564
BUFFER
566
TEMPERATURE CONTROL
568
VERIFICATION ELEMENT
569
500 READER
512
502 HOUSING
OUTPUT
514
VISUAL
516
AUDIBLE
518
TEMPERATURE CONTROL
520
SAMPLE TREATMENT
550
LIGHT SOURCE
555
PATHOGEN NEUTRALIZATION
504CARTRIDGE INTERFACE
CARTRIDGE VERIFICATION 540 SYSTEM
ELECTROPHORESIS 506 MODULE
ELECTROPHORESIS BAND DETECTION 508 MODULE
PROCESSING CIRCUITRY
SAMPLE PROCESSING MODULE
NETWORK MODULE
MAINTENANCE MODULE
DATABASE
POWER SOURCE
510
530
532
534
536
538

FIG. 5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CARTRIDGE
BLOOD SAMPLE COLLECTOR
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CAPILLARY TUBE
612
LANCET
614
ELECTROPHORESIS STRIP
620
STRIP
622
ELECTRODES
624
TREATMENT CHAMBER
630
BUFFER
632
MARKERS
634
SAMPLE DEPOSITOR
640

FIG. 6

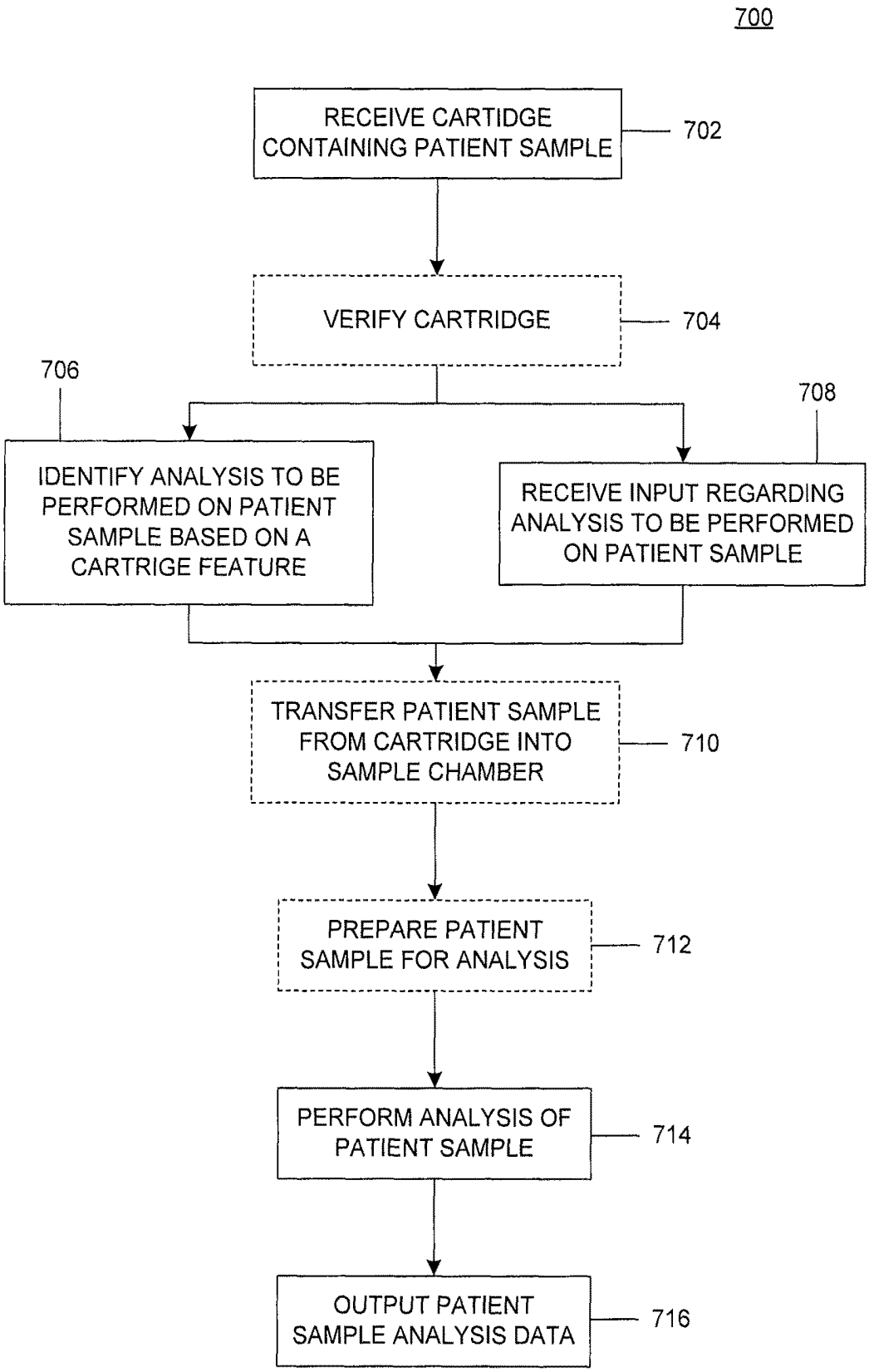
700
RECEIVE CARTIDGE CONTAINING PATIENT SAMPLE
702
VERIFY CARTRIDGE
704
706
IDENTIFY ANALYSIS TO BE PERFORMED ON PATIENT SAMPLE BASED ON A CARTRIGE FEATURE
708
RECEIVE INPUT REGARDING ANALYSIS TO BE PERFORMED ON PATIENT SAMPLE
TRANSFER PATIENT SAMPLE FROM CARTRIDGE INTO SAMPLE CHAMBER
710
PREPARE PATIENT SAMPLE FOR ANALYSIS
712
PERFORM ANALYSIS OF PATIENT SAMPLE
714
OUTPUT PATIENT SAMPLE ANALYSIS DATA
716

FIG. 7

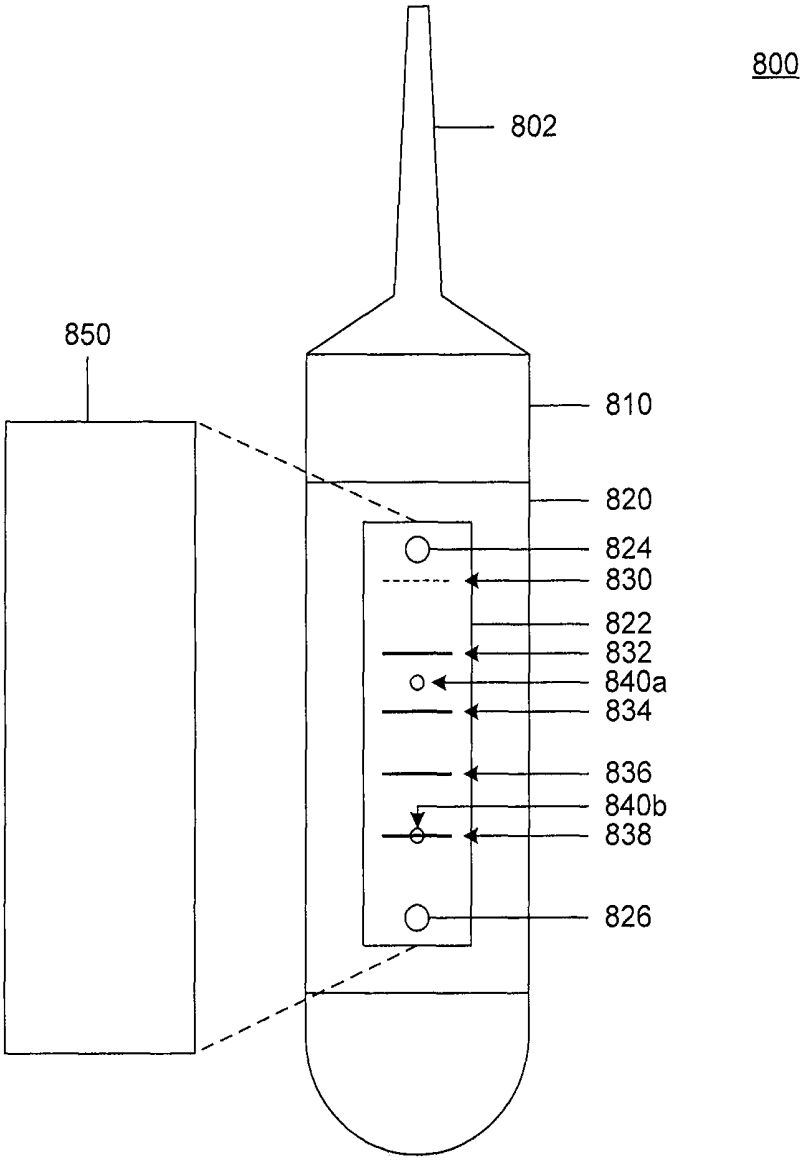

FIG. 8

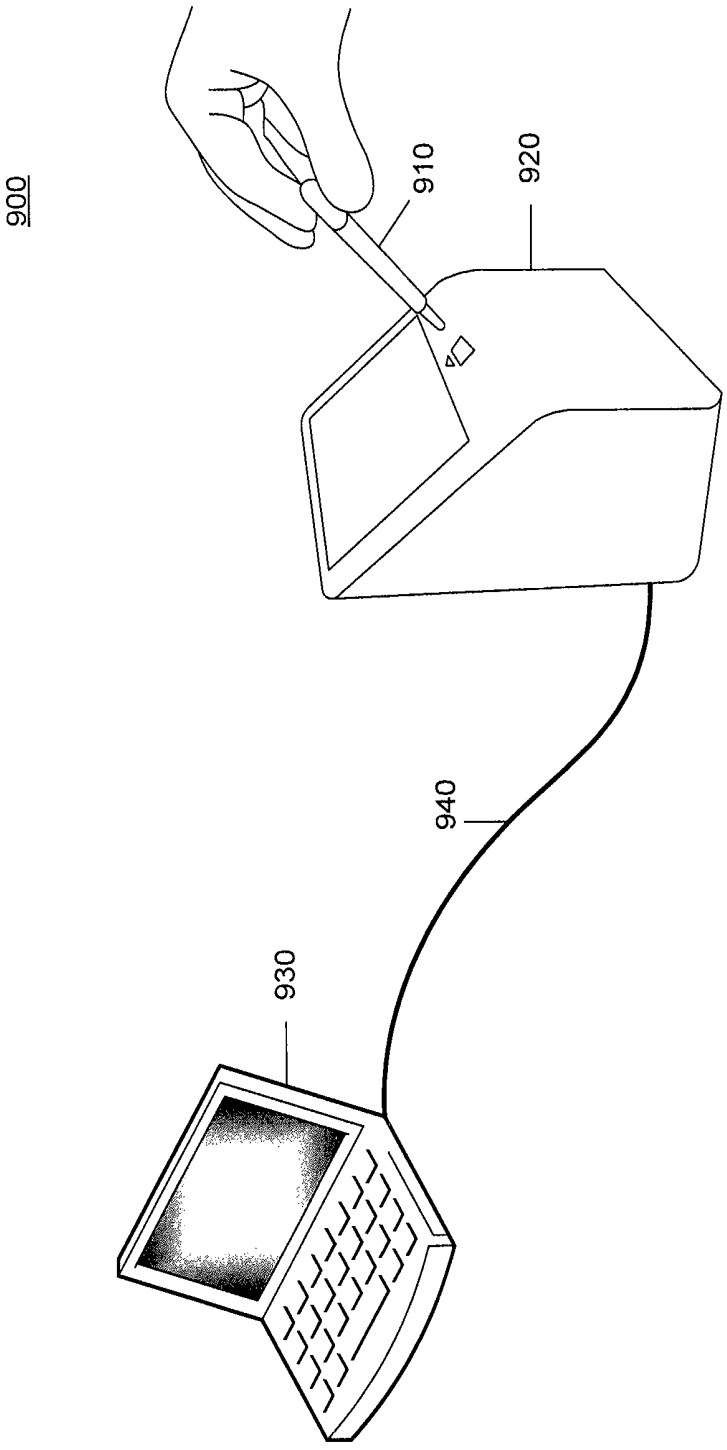

FIG. 9

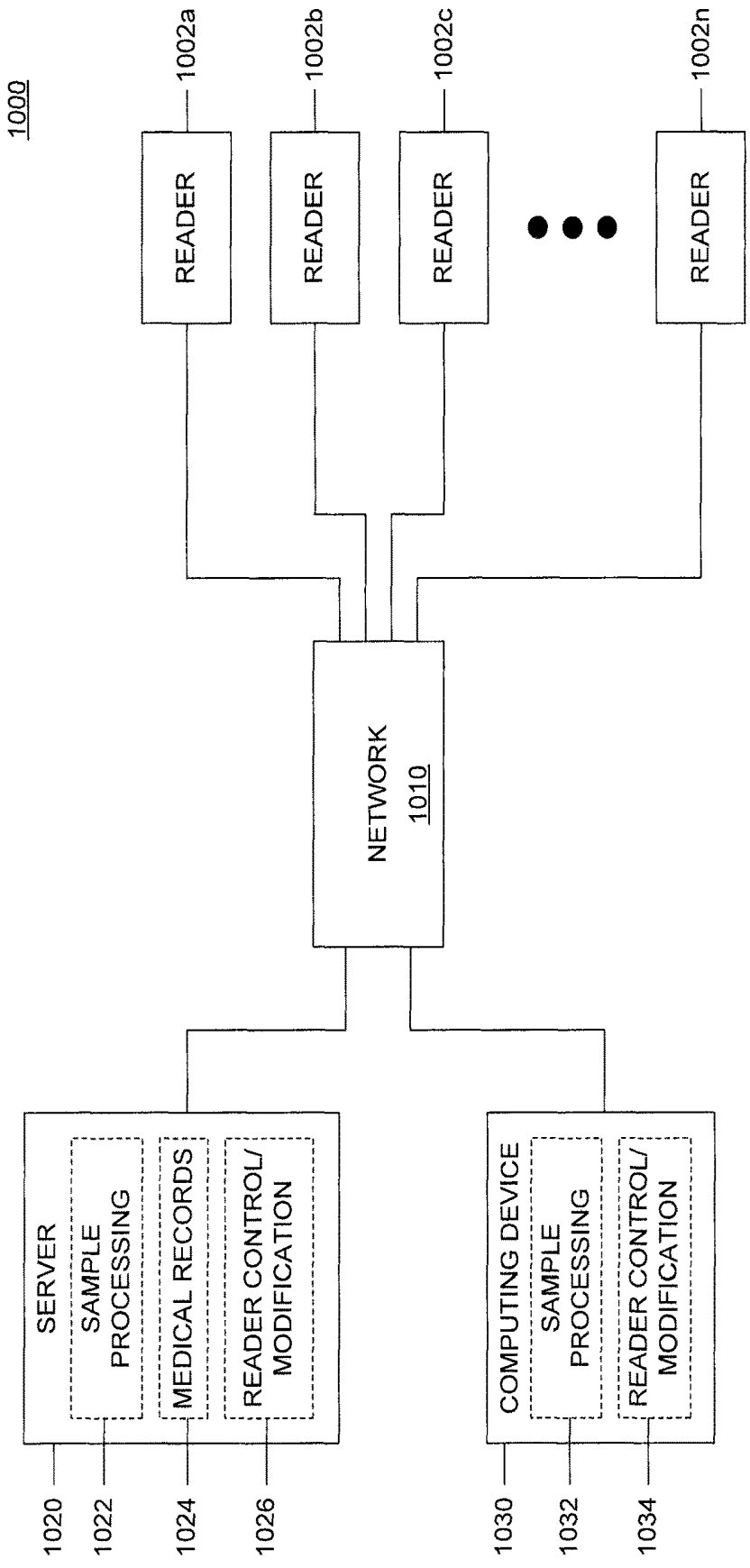
1000
1002a
1002b
1002c
1002n
READER
READER
READER
READER
NETWORK
1010
SERVER
SAMPLE PROCESSING
MEDICAL RECORDS
READER CONTROL/ MODIFICATION
COMPUTING DEVICE
SAMPLE PROCESSING
READER CONTROL/ MODIFICATION
1020
1022
1024
1026
1030
1032
1034

FIG. 10

DIAGNOSTICS SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of pending U.S. patent application Ser. No. 15/599,368, filed May 18, 2017, which claims the benefit of U.S. Provisional Patent Application Ser. No. 62/385,146, filed Sep. 8, 2016, the contents of both of which are herein incorporated by reference in their entirety

This application also claims the benefit of U.S. Provisional Patent Application Ser. No. 62/385,146, filed Sep. 8, 2016, the contents of which are herein incorporated by reference in their entirety.

This application is related to International Patent Application PCT/US2017/033409, filed May 18, 2017, the contents of which are herein incorporated by reference in their entirety.

BACKGROUND

Patient diagnostic services save lives, reduce the time to treatment for the patient and provide valuable insight for targeted treatment. In many developed countries, modern medical facilities can provide patients with the most advanced diagnostic services allowing patients to be efficiently and effectively treated. In less developed countries or regions, high quality medical facilities and diagnostic services can be lacking, often due to economic and infrastructure considerations. In many less developed countries, the economy cannot afford the latest in medical technology and infrastructure, such as a robust power grid or highly trained clinicians, required to support the high demands of modern medical technology. Sadly, a large portion of the world's population resides in underserved or developed areas where the lack of efficient and effective diagnostic services critically impacts the population morbidity, mortality and overall health. This lack of medical care can lead or contribute to knock-on effects, such as low economic and educational development.

Often, many less developed countries and areas also lack sufficient trained users that are typically required to perform the necessary diagnostic services. This can lead to inconclusive or erroneous results from diagnostic services or to significant delays in diagnosis as the diagnostic services are required to be performed in another location that has the requisite infrastructure and/or knowledge to perform the diagnostic service. For patients, this can mean further delays in treatment, which can decrease their chances of survival, increase the spread of the disease, and/or lead to increased debilitation caused by the disease or condition.

Where large laboratories may be prohibitively expensive and difficult to staff, point-of-care diagnostic devices may provide an effective solution. Such a solution could provide timely, accurate, and cost-effective health care.

One of the treatable common ailments effecting less developed countries are hemoglobin disorders, such as sickle cell disease (SCD), thalassemia and other hemoglobinopathies. These are genetic disorders that are believed to have evolved in response to malaria. With population migration, these conditions have spread to the global population and affect the livelihood and health of a large number of people. With early detection or diagnosis, these conditions can be treated and managed before they have significant adverse impact on the stricken individual. As with malaria, these disorders affect the populations of less developed countries and areas, which have limited to no access to the diagnostic services to rapidly, effectively and efficiently diagnose the conditions.

A further challenge is unreliable power sources in less developed areas. Thus it would be desirable to have diagnostic solutions that are of low enough power consumption to be able to run on batteries.

Yet a further challenge is a point-of-care device is subject to varying conditions of the environment, the patient sample, and disposable elements of the device itself. This may yield wide variation in test results. Thus it is desirable to have a diagnostic device that is either insensitive to such variations or is self-calibrating.

What is needed is a diagnostic device or service for the diagnosis of biologic fluid disease, conditions or ailments that is point-of-care, in vitro, low-cost, rapid, accurate, self-calibrating, and capable of evaluating data and producing a diagnosis without the aid of a skilled clinician. Such a device would greatly benefit many countries and areas, especially those that are less developed.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates an example diagnostic system.

FIGS. **2**A-**2**B illustrate example cartridges.

FIGS. **3**A-**3**B illustrate an example electrophoresis detection system.

FIG. **4** illustrates an example disease and/or condition analysis method using the example electrophoresis detection system shown in FIGS. **3**A-**3**B.

FIG. **5** is a block diagram of an example diagnostic system.

FIG. **6** is a block diagram of another example cartridge.

FIG. **7** illustrates an example patient sample analysis process.

FIG. **8** is yet another example cartridge and electrophoresis detection components.

FIG. **9** illustrates a further example diagnostic system.

FIG. **10** is an example reader network.

DETAILED DESCRIPTION

It shall be noted that, as used in the specification and the appended claims, the singular forms "a," "an" and "the" include plural referents unless otherwise specified. Additionally, the use of the words "and" and "or" may be interpreted to be used interchangeably and to generally also encompass "and/or."

Various example point-of-care, in vitro diagnostic devices and methods for detecting and helping to diagnose blood disorders, and specifically inherited blood disorders and/or other conditions/diseases, are described herein. The disclosed diagnostic devices include a cartridge and a reader that interface to analyze a patient biologic sample, such as a blood sample, to provide a diagnosis, or data regarding one or more disorders, diseases, or conditions of the patient. The cartridge can contain or support the biologic sample for analysis by one or more diagnostic systems of the reader. An electrophoresis system, and/or further in vitro diagnostic and/or patient biologic sample analysis systems, such as a magneto-optical system, can be included in the reader and cartridge to diagnose and/or provide patient biologic sample data regarding a variety of diseases or conditions. The cartridge and reader provide an economic, efficient, and effective point-of-care diagnostic system. The biologic sample could be the patient's blood, saliva, urine, other fluid, a liquid suspension of tissue, a combination of fluids

or other biologic component. Several of the examples discussed herein explain the systems and methods of analyzing a patient blood sample, but it is understood that any biologic sample could be used. Additionally, the electrophoresis systems described herein can also be used to analyze other, non-biologic, liquids and/or compounds using the electrophoresis analysis method.

FIG. **1** illustrates an example reader **110** and cartridge **120** of a point-of-care blood diagnostic system **100**. A point-of-care blood diagnostic system includes devices that are physically located at the site at which patients are tested and sometimes treated to provide quick results and highly effective treatment. Point-of-care devices can provide information and help in diagnosing patient disorders and/or infections while the patient is present with potentially immediate referral and/or treatment. Unlike gold standard laboratory-based blood testing for disorders and/or infections, the disclosed point-of-care devices enable diagnosis close to the patient while maintaining high sensitivity and accuracy aiding efficient and effective early treatment of the disorder and/or infection.

The reader **110** includes a housing **112**, a cartridge receptacle **114** and a display **116**. The cartridge **120**, which contains the patient sample and, optionally dilutants, markers, reagents and/or materials, is inserted into the cartridge receptacle **114** of the reader **110** to transfer the patient sample, treated or untreated, into the reader **110** to perform a diagnostic test or analysis. The cartridge **120** more generally is placed in proximity to the reader in such a manner that the reader can interact with one or more elements of the cartridge to perform analysis of the patient sample. The cartridge **120** can include a pipette-like end **122** and a bulb **124** for siphoning a patient sample into the cartridge **120** in preparation for the diagnostic test. Alternatively, the cartridge **120** can include a capillary tube by which the patient sample can be obtained for analysis and/or testing. In a further embodiment, collection of the patient blood sample can be performed using blotting paper that is included in the cartridge **120** to collect a blood spot that can be analyzed by the point-of-care blood diagnostic system **100**.

The housing **112** of the reader **110** can be constructed of materials such as plastic or metal and is preferably sealed with a smooth surface, which allows the reader **110** to be easily cleaned and/or disinfected and resist external water and or dust. Further, the housing **112** is sufficiently strong to allow the safe transport and use of the reader **110** without substantial damage to the reader **110** and the diagnostic systems within. Additionally, the housing **112** can have properties, that shield or minimize the exposure of the interior of the reader **110** to temperature and/or humidity variations and/or light intrusion. The robustness of the reader **110** allows it to be used in a variety of locations and environments without adversely affecting the results of the diagnostic system.

The housing **112** of the reader **110** can also include vibration isolation to prevent vibration of the reader **110** during the measurement process to assist with preventing analysis error of the patient sample. Vibration isolation can include suspending and/or isolating the components and/or systems of the reader **110** within the housing **112** or containing the components and/or systems within an internal housing that is suspended and/or isolated from the external housing **112**. Alternative vibration isolation can include anti-vibration feet or mounts on which the reader **110** can sit on a surface. Additional vibration isolation can include placing the reader **110** on a cushioned and/or anti-vibration mat to reduce or limit the vibration and/or disturbance of the reader **110** by its external environment.

The cartridge receptacle **114** can be conformably shaped to receive the cartridge **120**. The cartridge **120** can be received partially or completely into the cartridge receptacle **114** or the reader **110**. Alternatively, the cartridge **120** can be otherwise connected, such as by an external receptacle or conduit, to the reader **110** to transfer the patient sample, or portion thereof, into the reader **110**. Such an external receptacle or conduit can be electrically coupled to the electronics housed in the reader **110** by a wireless or hard-wire connection of any suitable configuration.

FIGS. **2**A-**2**B illustrate example cartridges **200***a* and **200***b*. Each of the example cartridges **200***a*, **200***b* include a housing **202***a*, **202***b* an upper portion **210***a*, **210***b* and a lower portion **230***a*, **230***b*. The cartridges **200***a*, **200***b* can include a sample chamber, such as **240** of FIG. **2**A, that is internal to the cartridge **200***a*, **200***b* and can store a patient sample, such as a blood sample, within the cartridge **200***a*, **200***b*. The cartridges **200***a*, **200***b* transport or store a patient sample for analysis, or reading, by a reader. Further, the cartridges **200***a*, **200***b* can interface with the reader to assist with or facilitate the reading or analysis of the patient sample stored within the cartridge **200***a*, **200***b*. That is, the cartridge **200***a*, **200***b* can include features, such as an optical window **220** and an electrophoresis element **250** of cartridge **200***b* of FIG. **2**B to assist with the analysis of the patient sample within the cartridge **200***a*, **200***b*. The cartridge **200***a*, **200***b* can also transfer all or a portion of the patient sample to the reader for analysis of the patient sample. The patient sample, or portion thereof, from the cartridge **200***a*, **200***b* can be transferred to a blood sample chamber of the reader or to another location of the reader, or external from the reader, for analysis of the patient blood sample.

The cartridges **200***a*, **200***b* can be condition, disease and/or ailment specific or multiple condition, disease and/or ailment specific. The cartridges **200***a*, **200***b* can include various features, external and/or internal, that customize a particular cartridge for the analysis of a specific, singular or multiple, condition, disease and/or ailment. The cartridge specificity can include the patient sample size volume of the cartridge, various dilutants, markers and/or reagents in the cartridge, the interface of the cartridge with the reader and other design and/or construction specification of the cartridge in relation to one or more particular conditions, diseases and/or ailments.

The housing **202***a*, **202***b* of the cartridge **200***a*, **200***b* can include structural, material and/or geometric features that assist or facilitate the analysis and/or acquisition of the patient sample. Such features can include internal chambers, such as the sample chamber **240** of FIG. **2**A, to store the patient sample or other fluids or compounds, that are sized to ensure adequate sample size for the analysis of the collected patient blood sample, interfaces that interact with, engage, or facilitate the systems of the reader during analysis of the patient sample. Other features can include environmental controls that maintain the collected patient sample in a suitable condition for analysis, and other features and/or considerations. For example, an internal chamber of the reader could manually or automatically interface with the inserted cartridge via a port to cause dilutants, markers and/or other chemical treatments to mix with the patient sample in the cartridge. Such a port would be a passage, like a tube, that connects the sample chamber of the cartridge with the port so fluids can be added to the cartridge. The addition of such external fluids can be triggered manually when a user actuates a switch or other actuator, which the

user may do in response to a user prompt to do so. The cartridge housing **202***a*, **202***b* can be formed of a suitable material such as a plastic, composite and/or metal to create a robust, disposable cartridge **200***a*, **200***b*. Additionally, the housing **202***a*, **202***b* material can be selected for the ability to be sterilized, such as sterilizing the cartridge **200***a*, **200***b* prior to use, for reuse or for killing pathogens prior to disposal.

Environmental considerations can also be used in the determination of a suitable material(s) for the cartridge housing **202***a*, **202***b*. Such environmental considerations can include the biodegradability of the housing material, the recyclability of the housing material, the incineration by-products of the housing material and other environmental considerations. These environmental considerations can reduce the environmental impact of the disposal, recycling and/or reuse of the cartridges **200***a*, **200***b* after use.

The housing **202***a*, **202***b* of the cartridge **200***a*, **200***b* can include a patient identification marker or an area to apply or mark patient identification onto the cartridge **200***a*, **200***b*. This marker could be in machine readable or human readable form or both. The patient identification allows the correlation of the analysis of the collected patient sample with a particular patient. Additionally, the reader can detect the patient identification marker to correlate the analysis with a patient, including automatically appending the analysis results to a patient's medical records. In an example embodiment, the patient identification can be obfuscated to remove patient personal information, such as a name, from the cartridge **200***a*, **200***b*, instead the patient can be assigned a random number, or sequence of characters, that is correlated to the particular patient in the reader, a computer or other system.

Patient diagnostic and demographic information can also be used for analysis to determine trends or emergence of conditions, disorders, diseases and/or ailments. This analysis can be used to prevent or minimize the spread of the condition/disorder and/or targeted diagnosis and/or treatment of the condition/disorder. For various conditions once properly diagnosed, such as a sickle cell and other hemoglobin conditions, geographical correlation of the prevalence of the condition can be used to perform measures to mitigate and minimize the effects of the condition on the target population.

The upper portion **210***a*, **210***b* of the cartridge **200***a*, **200***b* can include identification marker(s), such as a color, pattern, name, or other distinguishing features. The identification marker can be used to indicate the use of the cartridge **200***a*, **200***b* for the analysis of a specific condition(s), disease(s), and/or ailment(s). This can provide a clear, visual indication to a user that the cartridge **200***a*, **200***b* is to be used with specific analysis or analyses.

Additionally, the upper portion **210***a*, **210***b* can be a portion of a sample collection element, such as a suction bulb, actuation element, or capillary tube to assist or facilitate the collection of the patient sample into the cartridge **200***a*, **200***b*. As a suction bulb, the upper portion can be formed of a resilient or flexible material capable of deforming in volume to assist in the uptake of a patient sample within the cartridge **200***a*, **200***b*. As an actuation element, the application of pressure or other input by a user, other or device to the upper portion **210***a*, **210***b* of the cartridge **200***a*, **200***b* can actuate the passive or active acquisition of a patient sample into the cartridge **200***a*, **200***b* in preparation for analysis, such as extending and/or retracting a needle or capillary tube. A capillary tube is one means of passively collecting the sample with no user or machine pressure required.

Further, the upper portion **210***a*, **210***b* can contain a dilutant, marker, reagent or other fluid or substance that is stored internally in a chamber and that can be released into and/or mixed with the patient sample within the cartridge **200***a*, **200***b*. Application of pressure to the upper portion **210***a*, **210***b* of the cartridge **200***a*, **200***b* can introduce the contained substance or fluid into the patient sample within the cartridge **200***a*, **200***b* which mixes the patient sample with the contained substance(s) or fluid(s). Example dilutant ratios can include from 1:0.5 to 1:100. The contained substance or fluid can assist with the analysis of the patient sample, preparation of the patient sample for analysis, preservation of the sample for analysis or other desirable or necessary patient sample modification for efficient and effective analysis of the patient sample.

Additionally, the upper portion **210***a*, **210***b* of the cartridge **200***a*, **200***b* can be contoured and/or shaped to provide a comfortable, ergonomic, and/or easy grip for a user to handle the cartridge **200***a*, **200***b* during insertion and/or extraction into/from the reader or diagnostic device. Alternatively, the surface texture of the upper portion **210***a*, **210***b* can be such that it improves the ability of a user to grip the cartridge **200***a*, **200***b*.

The optical window **220** can be included on the cartridge **200***a*, **200***b*, which allows light to pass into and/or through a portion of the cartridge **200***a*, **200***b* such as a sample chamber containing the patient sample, such as **240** of FIG. **2**A. The ability to pass light into and/or through the sample volume within the cartridge **200***a*, **200***b* can be a necessary step during analysis of the patient sample within the cartridge **200***a*, **200***b*. The optical window **220** can be a material and/or construction that necessarily or desirably alters light entering the optical window **220** as a part of the analysis of the patient sample within, such as collimating, filtering, and/or polarizing the light that passes through the optical window **220**. Alternatively, the optical window **220** can be transparent or translucent, or can be an opening within the housing **202***a*, **202***b* of the cartridge **200***a*, **200***b*. The cartridge **200***a*, **200***b* can include a reflector opposite the optical window **220**, **220***b* that reflects the incoming light back through the optical window **220***a*, **220***b* or through another optical window, or can include a further optical window opposite the light entry window to allow light to pass through the cartridge **200***a*, **200***b*.

An electrophoresis element, such as **250** of cartridge **200***b* of FIG. **2**B, can assist with performing an electrophoresis analysis of a patient sample within the cartridge **250**. The electrophoresis element **250** can include electrodes to establish an electrical gradient across the element to perform the electrophoresis analysis. A cover can be included to protect the electrophoresis element, while still allowing the results to be viewed either through the cover or by removal of the cover. The cover can be optically transparent to allow optical viewing of the results and/or the electrophoresis process being performed. Light can be reflected off of and/or transmitted through the electrophoresis element **250** to assist with viewing the results displayed thereon. The cartridge **200***b* can include one or more structural features to facilitate the transmission of light through the electrophoresis element **250**.

The lower portion **230***a*, **230***b* can house or be a portion of the sample collection system. In the examples shown in FIGS. **2**A and **2**B, the lower portion **230***a*, **230***b* can include a channel or tube through which the patient sample can be

transferred into the interior of the cartridge **200***a*, **200***b*. The lower portion **230***a*, **230***b* can also house a portion of the sample collection system, such as an extendable needle like a lancet or a capillary tube through which the patient sample can be transferred to the interior of the cartridge **200***a*, **200***b*.

The lower portion **230***a*, **230***b* can also include elements and/or systems to assist with the analyzing and/or storage of the patient sample. This can include an interface and/or mechanism to release at least a portion of the patient sample from within the cartridge **200***a*, **200***b* into the reader and/or a barrier or seal that restrains and/or preserves the patient sample within the cartridge **200***a*, **200***b*.

The lower portion **230***a*, **230***b* can further include an indicator that is visible once the cartridge **200***a*, **200***b* has been previously used. This can prevent cross-contamination of patient specimens and/or prevent the reuse of a single-use cartridge **200***a*, **200***b* which could alter or otherwise compromise the results of the patient sample analysis. The indication can be structural in nature, with an alteration, such as a removal or break in a portion of the cartridge **200***a*, **200***b* housing **202***a*, **202***b* of the lower portion **230***a*, **230***b* that is a visible once the cartridge **200***a*, **200***b* has been used or has acquired a patient sample. Additionally, the lower portion **230***a*, **230***b* can deform after acquisition of a patient sample within the cartridge **200***a*, **200***b*, which prevents further collection of a patient sample(s) using the cartridge **200***a*, **200***b*. The indication could be electrical.

FIGS. **3**A-**3**B illustrate an example electrophoresis detection system **300**. The electrophoresis detection system **300** includes an electrophoresis strip **302**, electrodes **304**, **306**, patient sample **310** and an optical imaging device **330**. The electrophoresis analysis of a patient sample **310** can be used to evaluate aspects of the patient sample **310** that are effected due to an applied electric potential or voltage. Aspects of the patient sample **310** that can be affected by an electric potential can include hemoglobin, due to its charge. Various hemoglobin disorders can be diagnosed, evaluated and/or monitored using the electrophoresis testing, including determining the relative proportions of the hemoglobin types of the patient sample **310**. Results of the electrophoresis analysis can be optically captured by imaging. A light source, not shown, can be used to assist the capture of the results, with the light source emitting light that is then reflected and/or transmitted through the electrophoresis strip **302** to assist with imaging and/or visualizing the electrophoresis results thereon.

FIG. **3**A illustrates the initial set-up of the electrophoresis process. The electrophoresis strip **302** can have a buffer solution deposited thereon to assist with establishing the electrical conductivity between the two electrodes **304** and **306**. A patient sample **310**, such as a blood sample, is placed on the electrophoresis strip **302** in a controlled manner. In the example shown in FIG. **3**A, the patient sample **310** is shown deposited as a line, the more precise and/or controlled the sample is deposited onto the electrophoresis strip **302** the more clearly the banding can be visualized. Additionally, the patient sample **310** can include added compounds/components, such as one or more markers. The added compounds/components can assist with the electrophoresis process and/or assist with interpreting the electrophoresis results.

For example, the one or more markers can have known migrations rates and/or distances for a given applied voltage and/or voltage application time. Alternatively, these markers can normalize the results of the electrophoresis process by having migration rates relative to the sample, thereby reducing the effects of sample-to-sample variability. These markers can assist with evaluating the resultant banding of the patient sample **310**. With the patient sample **310** in place, a voltage is applied using the electrodes **304** and **306**, causing various components of the patient sample **310** to migrate across the electrophoresis strip in the direction indicated by arrow **308** over a defined time. The various components of the patient sample **310** will separate into bands due to the applied voltage and the physical and electrical properties of the various components. One or all of the applied voltage, current and the application time can be predetermined or preset based on the various parameters of the electrophoresis testing being performed. Alternatively, one or more of the voltage, current and application times can be variable and based on the banding of the patient sample or an added compound/component therein. For example, the movement of a marker added to the patient sample **310** can be monitored as the marker moves across the electrophoresis strip **310**. That is, imaging/monitoring of the electrophoresis testing, and/or the markers thereon, can be performed in a continuous or timed interval manner during the testing process. For example, images of the electrophoresis process can be continuously captured, such as by a video imaging process, or the images can be captured at regular intervals based on time and/or the distance one or more bands have traveled. Once the marker has reached a predetermined location across the electrophoresis strip **302**, the test can be terminated with the removal of the applied voltage.

FIG. **3**B illustrates the completed electrophoresis process. After applying a voltage, via electrodes **304** and **306**, for an amount of time, the patient sample **310** has separated into the various bands, **312**, **314**, **316** and **318**, which have moved from an initial patient sample location **311**. Additionally, added markers **320***a* and **320***b* have separated from the initial patient sample **310** and have moved along the length of the electrophoresis strip **302**. The intensity, location and/or other band detection characteristics of the various bands **312**, **314**, **316** and **318** can be used to identify the components, and their relative proportions, of the initial patient sample **310**. The optical imaging device **330** can image the electrophoresis strip **302**, during and/or after the electrophoresis process, for processing to identify the compounds represented by the various bands **312**, **314**, **316** and **318** and their relative proportions.

The electrophoresis detection system **300** can be used to identify and monitor hemoglobin disorders, such as sickle cell disease (SCD) and thalassemia. For SCD, monitoring the various hemoglobin types and their proportions is an important part of patient treatment. SCD patients produce sickle hemoglobin (HbS), resulting in malformed red blood cells that have reduced oxygen carrying capacity and present other patient issues due to their malformed shape and properties. The treatment for SCD patients is often blood transfusions, which increases the proportion of normal adult hemoglobin (HbA) for the patient and hydroxyurea which stimulates the formation of fetal hemoglobin (HbF). A patient's hemoglobin levels can be monitored to determine the efficacy of the treatment regime and to properly time the administration of various therapies. Using the disclosed electrophoresis systems and methods disclosed herein, levels of the various hemoglobin types of a patient can be monitored to more accurately and effectively treat hemoglobin disorders.

FIG. **4** is an example analysis method **400** The analysis of a patient sample, which is patient blood in this example, is performed to determine a blood characteristic, which can include the presence of a disease or condition, quantification of a disease or condition, likelihood of the presence of a disease or condition, a characteristic that can be indicative of

a disease or condition, a quantification of a characteristic that can be indicative of a disease or condition, and/or other blood characteristic that can be effected by the presence of a disease or condition of the patient. The example method of FIG. **4** can be performed using a reader and cartridge system, such as the example shown in FIG. **1**. The reader can include one or more systems and/or elements to analyze, quantify, identify and/or otherwise determine characteristics of a patient sample that can be indicative of the presence of a disease and/or condition of the patient.

An initial step **402** of the method **400** can include the collection of a patient sample for analysis, in this example, a blood sample. Alternative and/or further patient samples, such as saliva, tissue and/or other bodily fluids and also non-biological samples can be collected for analysis by one or more systems of the reader.

At **404**, a buffer can be added to the electrophoresis strip in preparation for the electrophoresis testing of the collected blood sample. The buffer can be a liquid that wets the electrophoresis strip and can contain salts or other compounds to assist with the application of a current across the electrophoresis strip. The buffer can be stored within the cartridge or the reader and applied by the cartridge or reader in response to starting an electrophoresis testing process, such as by a user, the reader and/or the cartridge. Alternatively, the electrophoresis strip can have the buffer pre-applied during a manufacturing or other process. In a further embodiment, the electrophoresis strip can include one or more components of the buffer that are applied to the electrophoresis strip in a dry state, such as during a manufacturing process, and a fluid, such as deionized water, can be applied to the electrophoresis strip prior to use to hydrate the dry state components and wet the electrophoresis strip with the buffer solution.

The collected blood sample **402** can then be treated, if necessary or desired, for analysis. The treatment of the blood sample can include diluting the blood sample, which can be done by mixing the collected blood sample with a dilutant, such as deionized water or other fluid that dilutes the blood sample. The dilutant can alter the viscosity of the blood sample, the opacity or translucence of the blood sample, or otherwise prepare the blood sample for analysis using the reader. Preferably, the dilutant does not impact the resulting analysis of the blood sample and/or assists with preparing the blood sample for analysis. This can include lysing the cells of the blood sample to release the various cellular components for electrophoresis analysis by the reader. Lysing agents can include fluids, such as water or various chemicals, and powders. Additionally, mechanical lysing can be used, such as by sonication, maceration and/or filtering, to achieve adequate lysing of the cells of the blood sample in preparation for analysis of the sample.

At **408**, one or more markers can be added to the blood sample. The added markers can assist with visualizing the completed electrophoresis results. For example, a marker that moves at the same relative rate as a hemoglobin type due at a predetermined applied voltage can be added. The marker will move with the hemoglobin type containing portion of the blood sample across the electrophoresis strip in response to the applied voltage. The marker can have a color, or other optical properties that makes visualizing the marker easier. Since the marker moves with the relative to a specific hemoglobin type, the easier to visualize marker can make it easier to determine the distance the hemoglobin type has moved across the electrophoresis strip in response to the applied voltage.

At **410** the blood sample can be deposited onto the electrophoresis strip in a controlled manner, preferably applied in a "line" perpendicular to the length of the electrophoresis strip. The controlled manner of deposition can include controlling the amount of blood sample deposited, the area across which the blood sample is deposited, the shape of the area across which the blood sample is deposited and/or other deposition characteristics. One or more systems and/or components of the reader and/or cartridge can be used to deposit the blood sample in the controlled manner onto the electrophoresis strip.

Alternatively, the process **402** of collecting the blood sample can be combined with the deposition of the blood sample **410** into a single step. The patient blood sample can be directly deposited, such as from a fingerstick, onto a region of the electrophoresis strip for analysis.

With the blood sample deposited onto the electrophoresis strip, a voltage can be applied across the electrophoresis strip at **412** to cause the separation of the blood sample into various bands of components. The voltage or current can be applied at a predetermined level or series of levels and for an amount of time. As discussed previously, the application time of the voltage can be predetermined or based on the movement of one or more bands of the patient sample, measurement of an electrical parameter such as resistance or an added compound/component. A higher applied voltage can cause the bands to move across the electrophoresis strip at a greater speed, however, the band shape can be distorted making the interpretation of the banding difficult. A lower applied voltage can increase band fidelity but can take a longer time to perform the requisite testing. The applied voltage can be selected to optimize testing efficiency while maintaining a desired or minimum fidelity level. Further, the applied voltage can be varied during testing, such as applying a higher voltage initially and then applying a lower voltage. The varied application of the voltage can cause the initial band separation and movement and the later applied lower voltage can assist with increasing the fidelity of the resultant banding pattern. Additionally, varying voltages and/or currents can be applied during the electrophoresis process in response to a measurement of the bands formed by the blood and/or the band or bands formed by the markers in a predetermined ratio, to maintain a constant rate of travel of the marker band or a portion thereof.

Additionally, environmental conditions within the reader and/or cartridge can be controlled during the electrophoresis process. Control of the environmental conditions can be done to maintain a stable environment in which the electrophoresis process is performed in order to minimize potential error and variance that can be caused due to environmental fluctuations. For example, a heat sink can be thermally connected to the electrophoresis strip, the cartridge and/or the reader, or portions thereof, to limit the temperature of the electrophoresis strip during testing to improve or maintain the quality of the results.

After completion of the electrophoresis process, the electrophoresis strip can be optionally stained at **414**. Staining the electrophoresis strip and the bands thereon can assist with the analysis and/or evaluation of the banding. For example, a stain for hemoglobin can be used to stain the bands to assist with determining a position of the bands across the electrophoresis strip. The cartridge and/or reader can include the stain and the required systems/components for applying the stain to the electrophoresis strip. Alternatively, a user can stain the electrophoresis strip before band analysis. Alternatively or in addition, a short high voltage can be applied at the end of the test essentially burning the

hemoglobin bands and making them visually persistent. The high voltage may also reduce the risk of viable pathogens.

At **416**, the electrophoresis strip can be optically analyzed, including imaging the electrophoresis strip and the bands thereon. The electrophoresis strip can be imaged using one or more light sources emitting one or more spectrums of light. Multiple images of the electrophoresis strip can be captured in various lighting conditions in order to assist with analyzing/evaluating the bands. The image capture can be accomplished using one or more imaging sensors, such as a digital imaging sensor and can be performed throughout the testing process or at the conclusion of the test. The captured image(s) can be processed to evaluate and/or analyze the electrophoresis test results.

At **418**, the final location of the bands can be calculated. The calculation can determine the distance each of the bands traveled, due to the applied voltage during testing, from the initial blood sample placement on the electrophoresis strip. Along with the distance of travel, a speed of travel of each band can be calculated based on the elapsed voltage application time and the distance traveled. Using the identity and location of each of the bands, the various components/compounds of the initial blood sample, and their proportions, can be determined. For a hemoglobin disorder test, this can include identifying the various hemoglobin types (HbS, HbA, HbF) present in the blood sample and the proportions of each.

As part of the analysis of the electrophoresis tests, the bands formed during the testing can be identified at **420**. Identification of the bands can include associating one or more compounds/components of the initial blood sample with each of the bands of the electrophoresis. For example, identifying the bands can include associating each of the bands with a hemoglobin type. The identification of the bands can be assisted by markers that were previously added to the blood sample prior to the electrophoresis testing. The markers can be selected so that their final position along the electrophoresis test aligns with one or more of the compounds/components of interest in the blood sample. Alternatively, the marker can be selected to be interspersed between two bands so assist with differentiating the bands for identification.

Once the analysis of the blood sample is complete, the results can be output **422**. The output of the results can include the identified blood characteristic(s), which can include a disorder, condition, disease and/or ailment, the identification of the compounds/components of the blood sample and relative proportions of each of the identified compounds/components. For example, the results can include the identification of the various hemoglobin types present in the initial blood sample and the proportions of each hemoglobin type. The output can be displayed or relayed to the user in a visual output, such as on a display, auditory such as by a speaker, or other manner. This can include transmitting the output results to an external device, such as a computer, through a wired or wireless connection or communication protocol, such as by a Bluetooth® connection.

FIG. **5** illustrates an example reader **500** and a cartridge **560**. The reader **500** can include all or a portion of the required systems and/or elements required to perform analysis of a patient sample. The cartridge **560** can include none or a portion of the systems and/or elements required to perform analysis of the patient sample. The reader **500** and cartridge **560** interface to perform the analysis, such as the method **400** of FIG. **4**, of a patient sample.

The reader **500** includes a housing **502** that surrounds and encloses some portion or all of the reader components. FIG. **5** shows that the housing encloses all components of the reader **500**, however, one of skill in the art will appreciate that any one or more components can be external to the housing, as needed or desired. As previously discussed, the housing **502** of the reader **500** is constructed of suitable materials which may involve a suitably robust construction such that the reader **500** is rugged and portable. Alternatively, the reader **500** can be designed and/or constructed for use in a permanent or semi-permanent location, such as in a clinic or laboratory. Example materials that can be included in the housing **502** include plastics, metals, and composites. The housing **502** can be constructed of multiple or a singular material and can include geometry and/or structural features that enhance the usability of the reader **500**. Such features can include a smooth outer surface that is easily cleaned, grips or handles for carrying the reader **500**, shock protection and/or increased structural strength in locations to prevent damage to the internal components of the reader **500**, insulation and/or heat dissipation structure(s) assist with maintaining a desired and/or a stable temperature, or range, within the housing **502**, a membrane or construction to prevent the intrusion of moisture and/or dust into the interior of the reader **502**, connections, ports and/or interfaces for connecting the reader **500** to an external element and/or device using a physical or wireless connection, instructions regarding the use of the reader **500**, identification markings such as a serial number and/or additional necessary or desirable features that can facilitate the safe, effective, efficient and/or proper use of the reader **500**. The housing **502** can feature access points, such as removable or openable panels, to allow access to the interior of the reader **500** for maintenance and/or repair of the internal components, elements and/or systems of the reader **500**. Additionally, the housing **502** of the reader **500** can be removable or separable from the other components, elements and/or systems of the reader **500**, allowing the replacement of the housing **502**, easing the cleaning of the housing **502**, providing access to the components, elements and/or systems of the reader **500** and/or other abilities that require and/or made easier by the removal of the housing **502** of the reader **500**.

The portability of the reader **500** can be an important consideration in the design and packaging of the reader **500**, including the housing **502**. The reader **500** may need to be rugged and easily transported so that it can be moved to and used in a variety of embodiments. Considerations, such as operating environment and access to infrastructure, can be considered when designing and/or constructing the reader **500** such that the reader can be used safely, effectively, and efficiently in a variety of environments and/or locations reliably. Depending on the environment of and infrastructure available in a particular location in which the system is to be used, the housing can be customized to best operate in that location by the addition and/or modification of existing reader features. Alternatively, the reader **500** can be designed and/or packaged to be more permanently located, such as in a laboratory, clinic, or other setting.

The housing **502** of the reader **500** includes a cartridge interface **504** that interacts with and/or engages the cartridge **560** for analysis of a patient sample. The cartridge interface **504** can be a slot that is shaped to receive the cartridge **560**. Alternative designs and/or structures of cartridge interfaces **504** can be used with the reader **500**. Additionally, the cartridge interface **504** can include additional structures, such as a door, that can effect insertion of the cartridge **560** within the reader **500**. The user inserts the cartridge **560** into

the slot in preparation for analysis of the patient sample. The slot can include internal geometry that aligns and/or orients the inserted cartridge **560** in a proper alignment and/or orientation for the components, elements and/or systems of the reader **500** to perform the requisite or desired analysis of the patient sample contained within the cartridge **500**. For example, the cartridge interface **504** can accept a variety of cartridges **560** having different cross-sections, such as square, rectangular, and circular cross-sections. The unique shape of each cartridge **560**, the unique cross-section, can interact with the geometry of the cartridge interface **504** to properly align the cartridge **560** within the reader **500** for analysis. For example, the circular cross-section cartridge can insert into the cartridge interface **504** to a first position at a first orientation, the square cross-section cartridge can insert into the cartridge interface **504** to a second position at a second orientation. The various orientations and positions a specific cartridge **560** can be inserted into the cartridge interface **504** can be the same or different for multiple condition/disease-specific cartridges **560**.

The reader **500** can also include a cartridge verification system **540**. The cartridge verification system **540** can be integrated with or separate from the cartridge interface **504** and/or included internal to or external from the reader **500**. The cartridge verification system **540** can verify the legitimacy of a cartridge to assist with efficient and effective analysis of a patient sample. An example verification system **540** can include a verification element **569** of the cartridge **560** that interacts with the cartridge verification system **540** to verify the cartridge prior to further processing of the patient sample. Additionally, verification of the cartridge **560** can include determining that the cartridge has not been previously used. The reuse of cartridges can be allowed or not and the verification system **540** can be used to enforce the desired or required limitation on reuse of the cartridge **560**. Once the cartridge is verified, further analysis of a patient sample contained within the cartridge can be allowed to proceed. The verification of the cartridge can be the threshold analysis of the in vitro diagnostics process of the patient sample, in some examples. This verification can include limiting the analysis to a specific single or multiple analyses based on the cartridge verification.

A positive engagement or lock in the reader **500** can engage the cartridge **560** when properly and fully inserted. This engagement can also provide a tactile, audible, and/or visual cue to the user to signify proper insertion or interfacing of the cartridge **560** and reader **500**. An example positive engagement or lock can include a notch and protrusion arrangement, the notch is sized to receive and releasably restrain the protrusion when engaged such that the notch of one element, the reader **500** or cartridge **560**, engages the protrusion on the opposite element, reader **500** or cartridge **560**, to releasably connect, interface with and/or engage the two elements, the reader **500** and cartridge **560**, together. When prompted, such as when the analysis is completed or an error situation, the user can remove the cartridge **560** from the reader **500**.

The cartridge interface **504** can also include an actuator or other element of the reader **500** that assists with the proper insertion and/or interfacing of the cartridge **560** and reader **500**. The actuator can engage the cartridge **560** before the cartridge is fully inserted, the actuator can then position the cartridge **560** in a proper alignment and/or orientation with the reader **500** for the reader **500** to analyze the patient sample within the cartridge **560**. When prompted, such as automatically by the reader **500** or manually by the user, the actuator can "eject" or disengage the cartridge **560** from the reader **500**. The disengagement can fully or partially remove the cartridge **560** from the reader **500**. Alternatively, the actuator can assist with the engagement or interfacing of the cartridge **560** with the reader **500** and not with the disengagement of the cartridge **560** and reader **500**. In this example, the user can be required to remove the cartridge **560** from the reader **500** when prompted.

The cartridge interface **504** can be shaped to engage one or more specific cartridges **560**, which prevents the insertion of an incorrect or improper cartridge **560** within the reader **500**. The cartridge interface **504** can also be reconfigurable, either manually by a user or automatically by the reader **500** to accommodate a specific cartridge design to perform one or more specific analyses of a patient sample. For example, a user can input a desired or required analysis to be performed on a patient sample, the reader **500** can then reconfigure or prompt the reconfiguration of the cartridge interface **504** to accept a specific cartridge **560** that corresponds to the requested analysis.

For example, the cartridge interface **504** can include multiple configurable elements, such as panels, that can be configured and/or arranged automatically in response to a received analysis to be performed, such as a user-selected disorder, condition, infection or disease for which to analyze the patient sample. The now configured and/or arranged configurable elements of the cartridge interface **504** are in a specific geometry into which only a compatible cartridge can be inserted. The analysis to be performed can be an input by a user into the reader **500** or from a remote administrator or system. In a further example, a specific cartridge interface **504** can include removable and/or replaceable cartridge interfaces **504** that can be removed from and/or inserted in the reader **500**. Each cartridge interface can include geometry to accept a specific cartridge design(s). Additionally, the inserted cartridge interface **504** can be detected or otherwise communicated to the reader **500** and the reader **500** can limit available options, such as the analyses that can be performed, based on the inserted cartridge interface **504**. Each cartridge interface **504**, or cartridge interface **504** design or geometry, can correspond to a specific analysis or analyses. Further, the reader **500** can be limited to the specific analysis or analyses corresponding to the particular cartridge interface **504** and/or cartridge interface **504** geometry.

In a further example, the cartridge interface **504** can initially accept any inserted cartridge. Once a cartridge is inserted, the cartridge interface **504**, a sensor or other reader **500** system or element can detect the cartridge type and the corresponding analysis or analyses that can be performed based on the cartridge type. The cartridge interface **504** can manipulate the cartridge position and/or orientation, the reader **500** can properly position and/or orient analysis systems or elements relative to the cartridge, and/or the cartridge interface **504** and/or reader **500** systems or elements can be configured to perform the analysis or analyses corresponding to the cartridge type.

Also, a sample processing module **532** of the processing circuitry **530** of the reader **500**, or an external sample processing system and/or element, can alter the processing of the sample analysis data to correct, compensate or otherwise modify the collected sample analysis data based on the type of cartridge inserted within the reader **500**. Instead of or in addition to positioning and/or aligning the cartridge and/or reader **500** analysis systems relative to the reader, the processing of the collected sample analysis data can be manipulated and/or modified to compensate based on the type of cartridge inserted. Additional modifiers can include compensating for position/alignment errors caused by

improper alignment/positioning of the cartridge relative to the analysis systems and/or elements.

Further, the cartridge interface **504** can include multiple orientation and/or alignment features that engage specific cartridge **560** features to properly align a specific, inserted cartridge with a specific analysis process. For example, a first cartridge for a first specific analysis is inserted into the cartridge interface **504** which guides, aligns, and/or orients the first cartridge properly in a first position for the first analysis to be performed, a second cartridge for a second specific analysis can be interested in the same cartridge interface **504**, which can properly guide, align, and/or orient the second cartridge in a second position for the second analysis to be performed. In this manner, the cartridge interface **504** ensures the proper positioning of a variety of specific cartridge designs within the reader **500** allowing a corresponding variety of specific analyses to be performed, each analysis corresponding to one or more specific cartridge designs.

The cartridge interface **504** can also include a number for position points corresponding to various steps of analysis. For example, an analysis can require that the cartridge **560** is inserted partially to a first position within the reader **500** to perform a first step of the analysis, the reader **500** can prompt the user to advance or move the cartridge **560** to a second position, such as further insertion of the cartridge **560** within the reader **500**, to perform a further step of the analysis. Each position can include a tactile, audible, or visual indication to a user manually inserting the cartridge **560** within the cartridge interface **504** to assist the user with properly position the cartridge **560** within the cartridge interface **504**. An actuator, such as described previously, can position the cartridge **560** at the various analyses required positions automatically, or can assist the user with the cartridge **560** positioning.

Insertion of the cartridge **560** into cartridge interface **504** of the reader **500** can automatically initiate or prompt a user to initiate analysis of the patient sample contained within the cartridge **560**. An actuator and/or sensor can be connected to the processing circuitry of the reader **500** and triggered by and/or sense the insertion of the cartridge **560** to automatically initiate or to prompt a user to initiate the analysis of the patient sample. Initiating analysis of the patient sample can include powering-up, preparing, and/or running the various analyses systems and/or devices, such as an electrophoresis module **506** and an electrophoresis band detection module **508**. In some examples, the user need only insert the cartridge **560** in the reader **500** to actuate or trigger the entire diagnostics process to an output.

The cartridge interface **504** and additional elements, such as guides or actuators can be integrated into the housing **502** of the reader **500** or can be separate components, elements and/or systems. Each of the additional elements can be further separable from each other allowing for replacement, substitution, repair and/or maintenance of the additional elements as necessary or required.

The reader **500** can include a single cartridge interface **504**, such as the example shown in FIG. **1**, or can include multiple cartridge interfaces **504** in the same reader **500**. The multiple cartridge interfaces **504** can allow the reader **500** to analyze multiple patient samples simultaneously and/or in succession by allowing more than one cartridge **560** to be interfaced with the reader **500**. Additionally, each of the multiple cartridge interfaces **504** can accept the same and/or different cartridges to perform the same and/or different analyses. Further, in conjunction with a multi- or singular cartridge interface **504**, a guide, rack, carousel and/or system can hold multiple cartridges in preparation for analysis. The guide, rack, carousel and/or system can feed or guide, actively or passively, cartridges **560** to the reader **500** by the cartridge interface **504** allowing multiple patient samples and/or cartridges **560** to be analyzed with minimal interruption between the analyses.

The reader **500** shown in FIG. **5** includes an electrophoresis module **506** that can interface with the cartridge **560** to perform the electrophoresis test. The electrophoresis module **506**, alone or in conjunction with the processing circuitry **530**, can control the electrophoresis test, including voltage/current application time and/or level. The electrophoresis module **506** can supply electrical power from a power source **510** of the reader **500** to the cartridge **560**, or electrophoresis strip **564** directly, to establish the necessary voltage across the electrophoresis strip **564** for testing. The voltage can be applied at a higher level to increase the speed of the testing, however, the increased speed can cause decreased band fidelity, which can increase the difficulty and error of the band analysis and evaluation. A lower applied voltage can increase band fidelity but can lengthen the required testing time. Alternatively, the electrophoresis module **506** can vary the applied voltage or current, while maintaining the other stable, to achieve a desired or required level of band fidelity and testing speed. For example, an initial test to identify a patient condition can be carried out at a higher level voltage level to speed the test and a subsequent test to quantify the condition can be carried out a lower voltage level to generate clearer or more accurate results.

The electrophoresis band detection module **508**, alone or in conjunction with **530**, can capture, analyze and/or evaluate the electrophoresis test results and/or any other band detection characteristic(s) related to or otherwise based on the electrophoresis test results. The electrophoresis band detection module **508** can include an imaging device, such as a digital image sensor, to capture an image of the electrophoresis strip and the banding thereon at the conclusion of the electrophoresis test. Using the captured image data, each of the bands can be associated with one or more compounds/components of the patient blood sample and the proportions of each can be determined.

The reader **500** can also include an optional sample treatment **550**. The sample treatment **550** can include a buffer solution for use with the electrophoresis strip, markers to add to the blood sample, dilutants and/or other solutions/compounds for use in the electrophoresis testing. The sample treatment(s) **550** can be contained within removable cartridges to ease replacement and/or change of the sample treatment **550**. Alternatively, the reader **500** can include internal containers for storing the sample treatment **550**. Associated tubing, systems and/or components can be included to facilitate the transfer of the sample treatment **550** to the cartridge and/or other systems/components of the reader **500**.

The positioning and structure of the cartridge **560** within the reader **500** can be such that one or both of the electrophoresis module **506** and the electrophoresis band detection module **508** are properly aligned with the cartridge **560** when inserted into the reader. The electrophoresis module **506** can interface with contacts on the cartridge **560**, or the electrophoresis strip **564** itself, to supply the necessary voltage to the electrophoresis strip **564**. The electrophoresis band detection module **508** can be aligned to monitor and/or capture an image of the electrophoresis strip **564** during and/or after the electrophoresis test.

The reader **500**, the electrophoresis module **506** and/or the electrophoresis band detection module **508** can include an optional light source **555**. The light source **555** can illuminate the electrophoresis strip **564** to assist with capturing the electrophoresis results for analysis. Light emitted by the light source **555** can be reflected from and/or transmitted through the electrophoresis strip **564** to assist with imaging the electrophoresis strip **564**. Additionally, the light emitted by the light source **555** can have constant and/or varying properties, such as a wavelength, intensity and/or a frequency of the emitted light. The light source **555** can include one or more illumination elements to generate light having the required, or desired, properties to assist with imaging and/or analyzing the electrophoresis results.

The reader **500** can include an internal power source **510** that supplies the necessary power to run the components, elements and/or systems of the reader **500** to perform analysis of patient samples and/or preserve a minimal, required functionality of the reader. The power source **510** can supply power to the processing circuitry **530**, the electrophoresis module **506**, the electrophoresis band detection module **508** and/or other component, elements and/or systems of the reader **500**. The power source **510** can include one or more batteries or other energy storage devices that provide a required or desired level of power for the reader **500**. Additionally, the power source **510** or a portion thereof can be external to the reader **500** and connected thereto as needed or required. External power sources can include batteries or other energy storage devices and/or a connection to a nearby power source such as a generator, municipal power, or solar array.

The reader **500** can also include pathogen neutralization **512**. The pathogen neutralization **512** can include physical components, such as a device or system, and/or a chemical component. There are many different methods of pathogen neutralization and many different devices/systems capable of performing the methods. The goal of pathogen neutralization is to target specific undesirable biological material, such as diseases and parasites, for destruction/neutralization or to destroy biological material indiscriminately, such as by sterilization. Various systems, such as devices or chemicals that interrupt biological processes and/or cause the breakdown of biological materials can be to neutralize pathogens within a reader **500** and/or a cartridge **560**.

An ultraviolet (UV) light source is an example pathogen neutralization **512** device that could be used within the reader **500** is e. Exposure to UV light has a debilitating effect on biological material and exposure to intense UV light can cause biological destruction. A UV light source can be placed within the reader **500** and activated to bathe the interior of the reader in UV light, which neutralizes at least a portion of the biological material, including pathogens, within the reader **500**. Alternatively, the UV light can be continuously powered on when the reader **500** is in use. The UV light can also be targeted, with one or more UV light sources placed in specific areas of the reader **500** to perform the desired pathogen neutralization. Additionally, the UV light can be positioned to penetrate and/or bathe a cartridge **560** inserted within the reader **500** to neutralize the patient sample within the cartridge **560** after analysis has been performed. A timing device can be connected to the UV light source to ensure that the UV light source is activated for a necessary amount of time to perform the pathogen neutralization. A photo- or light detector can also be included to monitor the output of the UV light source to check the continued efficacy of the UV light source and/or monitor the output of the UV light source to ensure it is activated for a long enough duration to achieve a level of pathogen neutralization. The emitted UV light can affect materials, such as plastic, adversely causing them to become brittle. In some examples, shielding can be included within the housing **502** of the reader **500** to protect areas, components, elements and/or systems which could be damaged by UV light exposure.

A further pathogen neutralization **512** system can include the use of chemicals to neutralize biological material within the reader **500** and/or cartridge **560**. A chemical based pathogen neutralization **512** system can include the application of chemicals within the reader **500** and/or cartridge **560** on a temporary or permanent basis. That is, a chemical application can be applied within the reader **500** during manufacture, the applied chemical application can continuously destroy at least a portion of biological material that contacts a surface upon which the chemical was applied. A temporary chemical based pathogen neutralization **512** system can include a chemical dispersal system that deploys or applies chemicals within the reader **500** and/or cartridge **560** on actuation, the chemicals contact various surfaces, elements, components and/or systems of the reader **500**, destroying at least a portion of biological material thereon.

In an example embodiment, pathogen neutralizing chemicals, such as a bleach-based solution, can be sprayed, fogged, and/or distributed about the interior of the reader **500** and/or cartridge **560** to perform the pathogen neutralization. The pathogen neutralizing chemicals can be added to the reader **500** and/or cartridge **560** by a user, contained within a vessel that is housed, inserted within or fluidically connected to the reader **500**. The pathogen neutralizing chemicals, such as the bleach-based solution, can be prepared as needed or can be prepared and stored for later use. An indicator or timer can be included that can indicate to a user once the pathogen neutralization process is complete. The indicator or timer can also prevent the use of the reader **500** until the pathogen neutralization process is complete. As with the previously described pathogen neutralization systems, the chemical-based pathogen neutralization method can also neutralize at least a portion of biological material on and/or within a cartridge **560** inserted within the reader **500**. Additionally, the chemical-based pathogen neutralization chemicals can be pumped or transported through the various components, elements and/or systems of the reader **500**, to disinfect portions that can contact a patient sample, which helps to prevent cross-contamination of patient samples.

An example pathogen neutralization system to neutralize at least a portion of the pathogens of the cartridge **560** can include a portion that is included in the cartridge **560**. Pathogen neutralization material, such as powders, fluids and/or other components can be included in the reader **500** and/or cartridge **560** assist with neutralization of pathogens within the cartridge **560**. The pathogen neutralization material can be included in a portion of the cartridge **560** and dispersed into the collected sample and/or other portions of the cartridge **560** upon actuation, such as by a user, the reader **500**, the cartridge **560**, or another source. The pathogen neutralization material can also be integrated with a portion of the cartridge. Alternatively, the pathogen neutralization material can be included in the reader **500** and the reader **500** can circulate, or otherwise insert, the pathogen neutralization material into the cartridge **560**. The pathogen neutralization material can be targeted to a specific pathogen or be a general wide spectrum pathogen neutralizer.

The reader **500** can include an output **514** that includes one or more visual **516** and/or audible **518** outputs although in other examples the output is data and does not include

visual and/or audible outputs. The output **514** shown in FIG. **5** communicates information regarding the status of the reader **500**, the results of analysis of a patient sample, instructions regarding use of the reader **500** and/or other information to a user or other computing device. The visual **516** output **514** can include a display, such as a screen, such as a touchscreen, lights, and/or other visual indicators. The touchscreen used to display information, such as analysis results, to the user can also be used by a user to input to the reader **500**. Alternative interfaces can be included on and/or connected to the reader **500**, such as a keyboard and/or mouse. Additionally, user devices, such as a cellphone or tablet, can be connected to the reader **500** to provide an interface portal through which a user can interact with the reader **500**. The audible **518** output **514** can include a speaker, buzzer, or other audible indicators. The output **514**, visual **516** and/or audible **518**, can be output through an external device, such as a computer, speaker, or mobile device connected physically and/or wirelessly to the reader **500**. The output **514** can output data, including the collected analysis data and/or interpretative data indicative of the presence or absence of a disorder, condition, infection and/or disease within the patient and/or the patient sample. An example can include the identification and proportions of the various hemoglobin types within the patient sample. The interpretive data output can be based on the analysis data collected and processed by the processing circuitry **530** of the reader **500**.

The reader **500** can also include temperature control **520**. The temperature control **520** can actively and/or passively control the temperature of at least a portion of the reader **500**. Active temperature control **520** can include heating and/or cooling a portion of the reader **500** and/or cartridge **560**. Temperature control **520** can also include heating one portion of the reader **500** and/or cartridge **560** and cooling another portion of the reader **500** and/or cartridge **560**. The temperature control **520** can include a refrigeration system, resistive heater, infrared heater, thermoelectric elements, radiator, and/or other temperature control devices and/or systems. Passive temperature control can include structures to contain a thermal material in portions of the reader **500** and/or cartridge **560**. This can include holders for ice, hot water, ice packs, and other thermal materials, the holders retain the thermal material in portions of or about components, elements and/or systems of the reader **500** and/or cartridge **560**.

The reader **500** and/or cartridge **560** can also include a filter. The filter can attract, extract, collect and/or otherwise remove unwanted components or particles in a patient sample of the cartridge **560** or concentrate the wanted components or particles. The filtering of the patient sample by the filter can occur as the patient sample is transferred from the cartridge **560** into the reader **500** or the patient sample can be transferred from the cartridge **560**, through the filter and back into the cartridge **560** for analysis or internal to the cartridge **560**. The filter can include structural and chemical features that allow the filter to remove desired or required components from the patient sample. The filter can be affixed in a stationary position to contact the patient sample or moveable through the patient sample to filter the patient sample.

Processing circuitry **530** can be included in the reader **500** to receive input from various components, elements and/or systems, such as the electrophoresis module **506** and/or the electrophoresis band detection module **508**, of the reader **500**. The processing circuitry **530** can process the received inputs to perform analysis of the patient sample and output results and/or data of that analysis. The processing circuitry **530** can include a sample processing module **532**, a network module **534**, a maintenance module **536** and a database **538**. The various elements, **532**, **534**, **536**, **538** and others, of the processing circuitry **530** can be removable and/or replaceable, allowing replacement and addition of various elements to the processing circuitry **530**. In example embodiments, all or a portion of the processing circuitry **530** can be included in the reader **500** and a portion of processing circuitry included in the cartridge **560**. The processing circuitry **530** can also control the various components, elements and/or systems, such as pathogen neutralization **512**, the electrophoresis module **506**, the electrophoresis band detection module **508**, and others, of the reader **500**.

The processing circuitry **530** can initiate and/or control the analysis of a patient sample within a cartridge **560**. The processing circuitry **530** can include preset routines, which may be defaults or selectable by the user, that can be executed by the reader **500** to analyze a patient sample. The preset routines can include prompts for user input and/or the processing circuitry **530** can prompt a user for input before, during and/or after analysis of a patient sample. User prompts can include acknowledgement and/or authorization to proceed through one or more portions of the analysis process. Alternatively, the processing circuity **530** can initiate, perform, and/or direct the analysis of the patient sample automatically without user prompts. The processing circuitry **530** can proceed through the various processes and procedures of an analysis of a patient sample, engaging any one or more of the reader **500** systems and collecting the analysis data. The processing circuitry **530** can further automatically process the collected data and transmit a result to a user or other, including an indication the analysis is complete, information regarding the analysis and/or other indications. The processing circuitry **530** can also transmit the collected data to an external system or device for processing and can transmit a result to the user and/or the result can be transmitted by one or more of an external system and/or device.

The sample processing module **532** can receive inputs from the electrophoresis band detection module **508**. Based on the received band detection data the sample processing module **532** can determine at least a characteristic of the patient sample, such as a disease or condition, an identity of the various compounds/components of the patient sample and quantification of the various compounds/components of the patient sample. The sample processing module **532** can output the identification and proportions of the compounds/components, and/or other various data based on the analysis of the patient sample. For example, the sample processing module **532**, using the band detection data from the electrophoresis band detection module **508**, can identify and quantify the various hemoglobin types of the patient sample. The output from the sample processing module **532** can be transmitted through the output **514** of the reader **500** or transmitted to an external device and/or system, such as a computer, mobile device, and remote server or database.

The sample processing module **532** can analyze the patient sample to determine a hemoglobin characteristic, such as a hemoglobin affecting disease and/or condition, based on the data from various components, elements and/or systems of the reader **500**. The results of the analysis can be output from the sample processing module **532** to the output **514** to convey the information to a user or other.

A network module **534** can be included in the processing circuitry **530**. The network module can allow the reader **500** to communicate with other readers, computing devices,

servers, databases and/or other devices or systems. The network module **534** can communicate with another device through a physical, such as a local area network (LAN), Universal Serial Bus (USB), and/or wireless, such as Bluetooth®, connection. In an example, the reader **500** can communicate to a remote server through the network module **530** allowing the reader to upload patient sample analysis to the patient's medical records stored on the remote server. The network module **534** can transmit and/or receive communication to/from the reader **500** and another device or system. In another example, information on the patient can be downloaded to the reader and added to the display or output or used in the analysis(es). For example, demographic information such as age, sex, etc. Information on prior results or health history could also be used to modify the analysis performed in the Reader **500**.

A maintenance module **536** can be included in the processing circuitry **530**. The maintenance module **536** can perform, initiate and/or prompt maintenance, calibration, and/or other processes of the reader **500**. Maintenance of the reader **500** can include automatically, or by prompting a user, clean a portion of the reader **500**, replenish resources of the reader **500** and other regular or unscheduled maintenance of the reader **500**. Calibration of the reader **500** can include testing components, elements and/or systems of the reader **500** to check if the reader **500** is in an effective operable state and/or to adjust measurement or analysis parameters to take the measured state of the machine into account. Additionally, the calibration of the reader **500** can be performed by the maintenance module **536** and/or prompt a user to perform necessary calibration procedures to allow the reader **500** to perform patient sample analysis effectively and correctly. The maintenance module could also allow automated or semi-automated ordering of supplies or service.

A database **538** can be included in the processing circuitry **530**. The database can record images, patient sample analysis data, patient data, statistical data, test conditions, and other data. The network module **534** can communicate with the database **538** exporting and/or importing data. The database **538** can be stored on removable and/or permanent data storage within the reader **500**. The database can also occur in whole or in part remote from the reader.

Statistical data of the database **538** can be used during analysis of a patient sample by the sample processing module **532** to assist and/or perform the analysis of a patient sample. Additionally, the database **538** can include statistical analysis techniques and/or algorithms that can be used by the sample processing module **532** to determine, calculate or otherwise analyze the patient sample. The database **538** can also include specific information, such as prior patient analysis results. Such results can be used to determine if the detected condition is new and/or an existing condition. Additionally, the severity of the condition can be tracked for a particular patient to assess their treatment progress.

The cartridge **560** can contain the patient sample for analysis. The cartridge **560** can be inserted in the cartridge interface **504** and the patient sample analyzed or transferred to the reader **500** for analysis by the components, elements and/or systems of the reader **500**. The cartridge **560** can include a blood collection device or system **562**, an electrophoresis strip **564**, a buffer **566**, a temperature control device and/or system **568** and a verification element **569**.

Blood collection **562** of the cartridge **560** can include a device and/or system for collecting, storing, and/or analyzing a patient's blood sample, which can include a passive or active blood collection device or system, a blood sample storage chamber, a blood sample analysis chamber and/or other chambers, devices and/or systems to assist or facilitate the collection of a blood sample and analysis of the blood sample.

Active blood sample collection can include the use of a needle, capillary tube or pipette. In an example embodiment, the cartridge **560** can include a needle that can be actuated to deploy from the cartridge **560**, piercing a patient's skin and extracting a sample that is drawn into the cartridge **560** and stored for analysis. A further active blood sample collection **562** can be a pipette-like system. The user or other can apply pressure to a bulb or deformable portion of the cartridge **560**, the release of pressure on the bulb or deformable portion can draw at least a portion of a patient blood sample into the cartridge **560**. The patient can be lanced, poked or pierced to cause bleeding, the blood can be sampled to draw at least a portion of the blood into the cartridge **560** for analysis.

The blood collection **562** can include a lancet or a piercing instrument that can pierce skin to cause bleeding. The blood can be collected using the cartridge **560** to obtain the patient blood sample. Collection of the blood sample can include retraction of the lancet or piercing instrument, carrying a portion of the patient blood into the cartridge **560** for analysis. The blood collection **562** can also include a sealed chamber that has a negative internal pressure. A needle can pierce the patient and pierce the sealed chamber, the negative pressure of the sealed chamber causing blood to flow into the sealed chamber due to the pressure differential.

The blood collection **562** can also include a capillary tube that can passively collect a blood sample using capillary action. The patient is caused to bleed, such as by a lancet or other inducing technique, and the capillary tube is placed in the blood to draw a sample into the capillary tube of the cartridge **560** for analysis.

The cartridge **560** can include a filter to filter the patient sample within the cartridge **560**. The filter can be placed to filter the patient sample as it is drawn into the cartridge **560** through, before and/or after the blood collection **562**. In another example, the filter can filter the sample after it has been stored in the cartridge **560**. As previously described, the filter can include structural and/or chemical features to filter a patient sample as necessary or desired.

Preparation of the patient sample can include lysing of the patient sample. The reader **500** can also include mechanical lysing. Mechanical lysing can assist with the lysing of cells of a patient blood sample within a cartridge **560** or the lysing of the patient blood sample within the reader **500**. Mechanical lysing can include a physical disruptor, or portion thereof, an agitator, a sonicator that can apply sound energy to the patient sample, filtering of the patient sample and/or other mechanical lysing device or system. The mechanical lysing can interface with and/or engage the cartridge **560** to facilitate the lysing of the patient sample. The mechanical lysing can be mechanically powered, such as by a wound spring, or electrically powered, such as by a reader **500** power source **510**.

Alternative methods of lysing can include chemical lysing of the patient sample. Chemical lysing can include mixing the patient sample with one or more compounds and/or substances to cause lysing of the patient sample. For example, the patient sample can be mixed with a dilutant, such as water, that is selected to cause lysing of the patient sample. As with mechanical lysing, a requisite amount of time can elapse before analysis of the patient sample is performed in order to allow adequate lysing of the patient sample to occur.

The electrophoresis strip **564** of the cartridge **560** is a piece of material on or through which the electrophoresis test occurs. The electrophoresis strip **564** can be a variety of shapes, such as a strip, and composed of a variety of different materials, such as cellulose acetate, glass fibers or agarose gels. The cartridge **560** can include an opening in which the electrophoresis strip **564** is positioned and/or accessible to one or more systems/components of the reader **500**, such as the electrophoresis module **506** and/or electrophoresis band detection module **508**. Alternatively, the cartridge **560** can include a transparent or translucent portion(s) about electrophoresis strip **564** through which suitable imaging of the electrophoresis strip **564** can be performed to obtain the electrophoresis results.

A buffer **566**, for use with the electrophoresis strip **564**, can be included in the cartridge **560**. The buffer **566** can be a conductive solution that may also modify the chemical environment the test is run in, for example by controlling the pH, that is applied to the electrophoresis strip **564** prior to an electrophoresis test. Certain materials of the electrophoresis strip **564** can require the use of a buffer **566** to perform an electrophoresis test. A chamber of the cartridge **560** can store the buffer **566** and the reader **500** or user can cause the buffer **566** to be applied to the electrophoresis strip **564**. Alternatively, a buffer can be stored within the reader **500** and applied to the electrophoresis strip **564** prior to a test. The cartridge **560** can include various routing to transfer the buffer **566** from an internal chamber of the cartridge **560** or from the reader **500** to the electrophoresis strip **564**.

Additional sample treatment solutions and/or materials, such as a dilutant, can be included in the cartridge **560**. Dilutant can be used to dilute, treat and/or prepare the patient sample for analysis. The dilutant can be stored within the cartridge **560** separate from the patient sample and mixed automatically or manually. The dilutant can be preloaded in the same chamber, a mixing chamber or patient sample chamber in which the patient sample is stored within the cartridge **560**. The user could also add the dilutant or it could be stored in the reader.

The cartridge **560** can also include temperature control **558**, which can include active and/or passive temperature control systems and/or methods. Passive temperature control **558** can include insulation, structural design features and/or chemical design features. The passive temperature control **558** can maintain the temperature of the cartridge **560** to preserve a collected patient sample. Active temperature control **558** can include electronic elements, such as thermoelectric elements that can heat or cool at least a portion of the cartridge **560**, for example to regulate the temperature of the cartridge **560** or a portion thereof. Temperature control **558** can include heating and/or cooling the temperature of the cartridge before, during and/or after the collection of a patient sample and/or the analysis of the sample. The temperature control **558** interfaces with the reader **500** and/or an external device to regulate the temperature of the cartridge **560**.

FIG. **6** is a further example cartridge **600**, which can include a blood sample collector **610**, an electrophoresis strip **620**, a treatment chamber **630**, and/or a sample depositor **640**. The various components of the cartridge **600** can be arranged in various configurations depending on the analysis to be performed and/or other environmental and/or use considerations. In the example shown in FIG. **6**, the cartridges **600** components can be interchangeable allowing a complete cartridge **600** to be assembled from various components.

The blood sample collector **610** of the cartridge **600** can collect a blood sample from a patient. The collector **610** can include devices, components and/or systems to assist or perform the collection of the blood sample from a patient. The blood sample collector **610** can include a capillary tube **612** and/or a lancet **614**. The capillary tube **612** can use capillary action to draw a blood sample into the cartridge **600**. The lancet **614** can be used to pierce, puncture and/or cut a patient's tissue to cause bleeding, from which a blood sample can be taken.

The collected blood sample can be collected in a blood sample chamber of the cartridge **600**. The blood sample chamber can include a filter to filter the blood sample. The filter can be positioned within the blood sample chamber of the cartridge **600** such that the blood sample chamber is divided into a first and second portion, which are separated by the filter. The blood sample chamber can include structural and/or chemical features to assist with the storage of the blood sample and/or the analysis of the blood sample. Additionally, the blood sample chamber can be located within the cartridge **600** to assist with and/or facilitate the analysis of the blood sample using a reader.

An electrophoresis strip **620** can be included with the cartridge **600**. The electrophoresis strip **620** can include a strip of material **622** on or through which the test is conducted and a pair of electrodes **624** to apply the necessary voltage across the strip **622**. As previously discussed, the strip **622** can be made of a variety different suitable materials that can support an electrophoresis process. The electrodes **624** can be disposed at opposite ends of the strip **622** to apply a voltage across the strip **622** as part of the electrophoresis testing process. The cartridge **600** can include external contacts that are connected to the electrodes **624** and can interface with a reader device to supply electric power to the electrodes **624**. Alternatively, the electrodes **624** and/or the cartridge **600** can include an inductive power mechanism to facilitate the wireless transmission of power to the cartridge **600** and/or the electrodes **624**.

The treatment chamber **630** can store one or more materials for use in the electrophoresis process, including a buffer **632** and markers **634**. The buffer **632** can be a solution that is applied to the strip **622** prior to an electrophoresis test. The cartridge **600** can include internal structures to facilitate the transfer of the buffer **632** from the treatment chamber **630** to the strip **622**. An example buffer can include Tris/Borate/EDTA (TBE) buffer. The buffer solution is electrically conductive and assists with application of a voltage across the strip **622** by the electrodes **624**. Markers **634** can be various compounds/components that can be mixed with the blood sample prior to the test. The markers **634** can have an optical property, such as a color, and known electrophoresis properties, such as moving a known distance along an electrophoresis strip in a set amount of time at a known voltage level. Markers **634** can be selected to move at the same rate as a compound/component of the blood sample or at a different rate. A marker **634** moving at the same rate as a compound/component of the blood sample can be used assist with visualizing a final position of a band associated with that particular compound/component. Alternatively, a marker **634** can be selected so that at the conclusion of an electrophoresis the marker is positioned between two bands of compounds/components of the blood sample or before or after all bands. The marker positioned between or after the two bands can assist with distinguishing the bands from each other during analysis and/or evaluation of the band data.

The treatment chamber **630** can be composed of multiple chambers to isolate the various treatment materials from

each other. The cartridge **600** can include various structures to transfer materials from the treatment chamber **630** to various other portions of the cartridge **600**. The movement of materials from the treatment chamber **630** can initiated by a reader, user interaction with the cartridge **600** and/or another initiation event or source. A passive process, such as gravity or a capillary action, can be used to move the material from the treatment chamber **630**. Alternatively, an active process can be used, such as a pressure differential. A user or reader can power the active transfer process to move the materials from the treatment chamber **630**.

The various chambers of the cartridge **600** can be interconnected and/or in fluid communication, allowing and/or facilitating the movement and/or transfer of fluid, with one or more of the chambers of the cartridge **600** and/or a connection to an external fluid source. The fluid communication between chambers can allow the blood sample, the treatment chamber **630** and/or other fluids to flow or be transferred from chamber to chamber(s) and can include passageways like flexible, rigid, and semi-rigid pipes and tubes. Flow control elements, such as valves, can be positioned along one or more of these passageways to regulate the fluid communication between chambers. The flow control elements can be manually actuated, such as by a reader or user applying pressure to the cartridge **600** or actuating the flow control element, or electrically actuated, such as by a signal from the reader or a user initiated signal or trigger.

The cartridge **600** can also include a sample depositor **640**, or a portion of a sample depositor system. The sample depositor **640** can deposit an amount of the collected blood sample onto the strip **622** in a controlled manner. A controlled manner can include the amount of blood sample deposited, the area over which the blood sample is deposited, the shape of the area and/or other blood sample deposition characteristics. For the electrophoresis testing, confining the deposited blood sample in a thin, or narrow, line initially can assist with the resultant band fidelity due to the uniform nature from which the compounds/components disperse from the initial deposition of the blood sample onto the strip **622**. Example depositors **640** can include a shaped orifice(s) through which an amount of the blood sample can be metered, a shaped applicator that applies a portion of the blood sample to the strip **622** and/or other means. The sample depositor **640** can operate alone, or in conjunction with a reader, to deposit a controlled amount and shape of the patient blood sample onto the strip **622**.

FIG. **7** is an example patient sample analysis process **700** of a reader, processing circuitry, a device or system external to a reader and/or a combination thereof. The reader can receive a cartridge containing a patient sample **702**, such as the insertion of a cartridge within a cartridge interface, the reader, and/or an external device connected to the reader or an external device or system. The cartridge can be optionally verified **704** to determine the validity of the cartridge and/or the patient sample within. The reader can then identify the analysis to be performed on the patient sample based on a cartridge feature **706**, such as structural feature of the cartridge. That is, the reader can recognize or identify the cartridge type and a corresponding analysis that can be performed on the patient sample contained within. Alternatively, the reader can receive an input regarding the analysis to be performed on the patient sample **708**. The input can include a user selecting an analysis, communication from an external system or device indicating the analysis performed or other input directing the reader to perform an analysis of the patient sample. Optionally, a portion of the patient sample can be transferred from the cartridge into a sample chamber **710** of the reader so that the patient sample can be analyzed within the sample chamber. Additionally, the patient sample can optionally be prepared for analysis **712**, which can include applying a buffer to an electrophoresis strip, adding one or more markers to the patient sample or other preparation performed on or to the patient sample prior to patient sample analysis. The patient sample is then analyzed **714** by the reader and its systems and/or an external device or system. The patient sample analysis data is then output **716**, such as transmitted to a reader and/or an external device or system. The output **716** can include measurement, images and interpretive data, such as the presence or absence of a condition, disease and/or infection within the patient sample, including detailed information, such as the type and degree of the disorder, condition, disease and/or infection.

FIG. **8** illustrates an example cartridge **800** and various patient sample analysis devices/systems in relation to the cartridge **800**. The patient sample analysis devices/systems can be included on a reader into which the cartridge **800** is inserted or received, the cartridge **800** can be inserted or received in a specific alignment or orientation in relation to the patient analysis devices/systems of the reader. Additionally, one or more portions of or a complete patient sample analysis device/system can be included with the cartridge **800**.

A blood sample collector **802** can be included on the cartridge **800**. The blood sample collector **802** can include a capillary or other tube, through which a patient's blood sample can be transferred into the cartridge **800**. A capillary tube can use capillary action to draw the blood sample into the cartridge **800**. A tube can be part of a pipette or pipette-like device or system of the cartridge **800**, application and release of pressure on, or deformation of a portion of the cartridge **800** can cause a blood sample to be drawn through the blood sample collector **802**, or portion thereof, due to a pressure differential between the surrounding environment and an internal portion or chamber of the cartridge **800**.

The blood sample collector **802** can include a lancet or needle that can be used to cause a patient to bleed and/or with which to take the blood sample from the patient. The lancet or needle can be releasably or permanently affixed to the blood sample collector **802** or can extend and/or retract automatically and/or manually from the blood sample collector **802** to assist or facilitate the collection of a blood sample from a patient.

Alternatively, a patient blood sample can be obtained by other means or methods, and a portion of the patient blood sample can be transferred into the cartridge **800** through the blood sample collector **802** or through another input into the cartridge **800**. For example, a blood sample can be drawn from a patient, for use in multiple analysis and/or diagnostic services, using a traditional method such as a needle and vacuum sample tube. From this collected blood sample, a portion of the sample to be analyzed using the cartridge **800** and/or a reader can be transferred into the cartridge **800** for analysis. In this manner, the patient is pierced a minimal number of times, drawing enough blood to run necessary diagnostic tests and analyses, including those using the reader and/or cartridge **800**.

The cartridge **800** can be divided into multiple portions and each portion can include one or more internal chambers that can contain a fluid, such as a buffer, dilutant, a marker, a blood sample, or a combination of the blood sample and the marker. One or more internal chambers can also be empty allowing fluids to be introduced and/or mixed within

in preparation for analysis and/or additional or alternate purposes. The internal chamber can be interconnected, such as by conduits or tubes, to allow fluid communication between the various chambers. Flow control devices can regulate flow of fluids and/or gases from one or more chamber to another chamber(s). Internal chamber(s) within the cartridge **800** can span across one or more portions of the cartridge **800**. That is, a single internal chamber occupies space in both the first portion and second portion of the cartridge **800**.

The cartridge **800** can include a sample chamber **810** in which the collected blood sample can be stored and/or prepared for analysis. The sample chamber **810** can be divided into multiple portions, or sub-chambers, to separate the collected blood sample from various treatment materials, such as one or more markers. A first portion can receive the blood sample, which can then be passed through a filter, passively or actively and/or in response to an input, such as by a reader into which the cartridge **800** is inserted, into a second portion of the sample chamber **810** in which the treatment of the blood sample can be performed. The portions of the sample chamber can also be separated by a barrier that prevents and/or controls the flow of the blood sample between the portions of the chamber due to the geometry of the barrier, including openings disposed through the barrier. The barrier can be impermeable and block the flow of the blood sample between the portions of the sample chamber **810** until the barrier is selectively removed, such as by moving the barrier, including by inductively moving or controlling the barrier, or destroying the barrier, including puncturing the barrier, to allow the flow of the blood sample between the portions of the sample chamber **810**. Alternatively, the barrier can be dissolvable, completely, or partially, to allow the flow and/or control the flow of the blood sample between the portions of the sample chamber **810**. The barrier can also be semi-permeable to control the flow, such as a flow rate, of the blood sample between the portions of the sample chamber **810**. In an example, a filter placed between the portions of the sample chamber **810** can be a semi-permeable barrier that controls the flow of the blood sample between the portions of the chamber **810**.

A collected sample can be stored within the sample chamber **810** or stored in a different chamber and then transferred into the sample chamber **810** in preparation for analysis. Additional materials or fluids can be added to the sample chamber **810** to mix with a sample in preparation for analysis. Additionally, the sample chamber **810** can be preloaded with various materials or fluids that can be mixed with the sample in preparation for analysis, including stabilizing or preserving the sample, dilution of the sample, markers, reagents and/or other processes or procedures.

The prepared sample, such as by the addition of one or more markers to the collected blood sample, can then be transferred to the electrophoresis section **820** of the cartridge **800**. The electrophoresis section **820** can be in fluid communication with the sample chamber **810** to allow the prepared sample to be transferred for testing purposes. One or more flow controls can be used to control the flow of the prepared sample between the chamber **810** and section **820**. The flow can be controlled by a reader when the cartridge **800** is placed therein. Alternatively, other sources, such as a user or the cartridge **800** itself can control the flow of the treated sample.

The electrophoresis section **820** of the cartridge **800** includes an electrophoresis strip **822** and electrodes **824** and **826** disposed at either end. In the example shown in FIG. **8**, an electrophoresis test is in process or completed as evidenced by the displayed banding. Prior to the initiation of the test, a buffer can be applied to the electrophoresis strip **822**, such as by a buffer solution stored in the sample chamber **810**, the electrophoresis section **820**, a reader or another source. Alternatively, the electrophoresis strip **822** can have a buffer pre-applied, such as during a manufacturing process of the cartridge **800**, by a user prior to a test or from another source. In a further embodiment, as described previously, the electrophoresis strip **822** can have a portion of the buffer applied in dry state, such as during a manufacturing process, that can be hydrated by the addition of a dilutant, such as deionized water, prior to the electrophoresis process to wet the electrophoresis strip **822** in a buffer solution.

The blood sample, treated or untreated, can be transferred from the sample chamber **810** and a measured portion can be deposited onto the electrophoresis strip **822** in a controlled manner at an initial position **830**. Once the blood sample has been deposited on the electrophoresis strip **822**, a voltage can be applied to/across the electrophoresis strip **822** using the electrodes **824** and **826**. One electrode is positively charged and the other is negatively charged, creating a voltage and causing current to flow between the two electrodes **824**, **826**. The voltage/current between the electrodes **824**, **826** causes portions of the deposited blood sample to move across the electrophoresis strip **822** at varying rates due to physical, electrical and/or chemical properties of each of the portions. The voltage/current is applied at a set or varying rate for a set amount of time to complete the test.

As shown in FIG. **8**, the blood sample has separated into 4 distinct bands **832**, **834**, **836** and **838**. Each band corresponds to a particular compound/component of the blood sample and the compounds/components can be identified based on their movement along the electrophoresis strip **822**. Additionally, markers **840***a* and **840***b* were included in the deposited blood sample to assist with the band analysis/evaluation. In the example shown, marker **840***a* is positioned between bands **832** and **834**. The positioning of marker **840***a* between the two bands **832**, **834** can assist with differentiating each of the bands **832**, **834** during analysis/evaluation of the band data. The other marker **840***b* is shown positioned with band **838**. Marker **840***b* was selected to have the same electrophoresis properties as the compound/component associated with band **838**, such that the marker **840***b* and band **838** would progress along the electrophoresis strip **822** together. Marker **840***b* can assist with determining the location of the band **838** and the distance the band has moved from the initial point **830**. Markers can be selected based on their movement along the electrophoresis strip relative to the one or more compounds/components of the blood sample. In an embodiment, the markers can be selected to move with the one or more components/compounds of the blood sample, move separate from the one or more components/compounds of the blood sample (i.e., move at a different rate), or a combination thereof. While the bands are shown as distinct lines in the example of FIG. **8**, in actuality each band will have a width and often decreasing intensity along that width, much like the tail of a brushstroke.

An optical imaging device **850** can image the electrophoresis strip **822** along with the bands **832**, **834**, **836**, **838** and markers **840***a*, **840***b* present along its length. Using the captured image data, the optical imaging device, or another system/device such as a reader, can analyze the image to identify the compounds/components associated with each of the bands **832**, **834**, **836**, **838** and their relative proportions. The captured image data can be used to determine a location

of each of the bands **832**, **834**, **836**, **838** and an intensity associated with each band. The intensity of the band can be calculated from the image data or can be determined using alternative methods, such as measuring a light transmission through the electrophoresis strip **822** and bands **832**, **834**, **836**, **838** thereon. By plotting the intensity and position information, the proportion of each of the compounds/components represented by the bands **832**, **834**, **836**, **838** can be determined by determining an area under the curve for each of the bands **832**, **834**, **836**, **838** represented on the plot.

To assist with accurate analysis of the blood sample, a known sample quantity can be collected and/or used for analysis using an electrophoresis analysis process. The electrophoresis results indicate a relative proportion of one or more components/compounds present within the sample. Using the known sample quantity and the proportions, the actual amounts, or estimates thereof, of each of the one or more components/compounds present within the patient sample can be determined.

Imaging of the electrophoresis strip **822** and the bands and markers thereon can be performed using a set or varying spectrum of light and/or optical imaging devices and techniques, to capture a variety of information for use in analysis of the bands. In various lighting conditions and spectrums, different aspects of the bands can be more easily ascertained, such as band position and intensity. Additionally, the markers can be selected to fluoresce in certain lighting conditions, making it easier to determine a position of a marker relative to a band on the electrophoresis strip **822**. Multiple captured images can be composited and/or used for the analysis process to increase the effectiveness and/or accuracy of the band analysis/evaluation.

In an alternative embodiment, the imaging of the electrophoresis strip **822** and the bands thereon can be performed using a generic optical imaging device, such as a digital camera. The cartridge **800** can be imaged using the digital camera, such as by a cell phone camera, and the captured image can be transferred to a device and/or system for analysis and/or evaluation. Such functionality can also be a secondary analysis/evaluation, or verification, method to support the optical imaging module/device of a reader.

FIG. **9** illustrates an example diagnostic system **900** that includes a cartridge **910** and reader **920**, such as described herein, the reader connected **940** to an external device **930**, such as a computing device, including a laptop, phone, tablet, a server, remote computer, or other external device. The connection **940** between the reader **920** and the external device **930** can be a physical connection, such as a universal serial bus (USB) connector, such as shown in FIG. **9**, or can be a wireless connection, such as an IR, Bluetooth® and/or WiFi electrical coupling, or a combination thereof. The connection **940** allows communication between the reader **920** and the external device **930**. In an example, the reader **920** can perform analysis of a patient sample contained within the cartridge **910**, data from the various analysis systems and/or elements of the reader **920** can be transmitted through the connection **940** to the external device **930** for processing. The external device **930** can then display or transmit the processed results, or portion thereof, to a user and/or can optionally transmit the processed results back to the reader **920** for display and/or transmission of the analysis results, or a portion thereof, to the user. In a further example, the reader **920** and external device **930** can both process all or a portion of the patient sample analysis data. The external device **930** can also control one or more aspects of the reader **920**, such as the analysis able to be performed by the reader **920**, authorized users of the reader **920** or other aspects of the reader **920** and its performance. Additionally, the external device **930** can be in the proximity of the reader **920**, such as nearby, or can be remote from the reader **920**, such as in another room or in another location including in another country. The external device **930** can communicate with and/or be connected to multiple readers and or other external systems, such as remote servers or databases.

FIG. **10** is an example reader network **1000**. Various reader devices **1002***a*, **1002***b*, **1002***c* . . . **1002***n* are connected to external devices and/or systems, such as a server **1020** and/or computing device **1030**, by a network **1010**. The readers **1002***a*, **1002***b*, **1002***c* . . . **1002***n* can send and/or receive data, instructions, and other information to and/or from the external devices and/or systems **1020**, **1030**. The network **1010** can include physical and/or electronic connections to facilitate communication from the readers **1002***a*, **1002***b*, **1002***c* . . . **1002***n* to the external devices and/or systems **1020**, **1030**.

The readers **1002***a*, **1002***b*, **1002***c* . . . **1002***n* can be readers for use with a cartridge, as previously discussed, or can include other diagnostic and/or patient sample processing or storage devices. The readers **1002***a*, **1002***b*, **1002***c* . . . **1002***n* can communicate with the external devices and/or systems **1020**, **1030** to transmit analysis data, receive analysis results and/or information, transmit status information, receive instructions, receive software updates and/or other communications or information exchanged between one or more readers **1002***a*, **1002***b*, **1002***c* . . . **1002***n* and/or external devices and/or systems **1020**, **1030**. The readers **1002***a*, **1002***b*, **1002***c* . . . **1002***n* can include a communication module to connect the reader **1002***a*, **1002***b*, **1002***c* . . . **1002***n* to the network **1010**. The communication module can also be an external device to which the reader **1002***a*, **1002***b*, **1002***c* . . . **1002***n* is connected.

Additionally, the readers **1002***a*, **1002***b*, **1002***c* . . . **1002***n* can communicate with one another directly through a physical or wireless electronic connection. The connection between readers **1002***a*, **1002***b*, **1002***c* . . . **1002***n* can include intervening network devices, such as a router, or can be direct from one reader to one or more readers, such as an ad-hoc or local network. A reader can be designated as a primary device to transmit instructions to and receive data from other readers designated as secondary. Alternatively, no priority can be established between the readers **1002***a*, **1002***b*, **1002***c* . . . **1002***n*. The readers **1002***a*, **1002***b*, **1002***c* . . . **1002***n* can perform the same and/or different patient sample analyses.

The network **1010** can include wired connections, such as through an Ethernet connection, fiber optic connection, and/or other physical cable or connection. The network **1010** can also include electronic communication protocols, systems and/or methods, such a satellite communication, microwave communication, Wi-Fi, and Bluetooth®. The network **1010** can include multiple communication devices and/or protocols to facilitate communication between one or more readers **1002***a*, **1002***b*, **1002***c* . . . **1002***n* and/or external devices and/or systems **1020**, **1030**.

An example external device and/or system can include one or more servers **1020** which can be remote from or local to the readers **1002***a*, **1002***b*, **1002***c* . . . **1002***n*. The server **1020** can include sample processing **1022**, medical records **1024**, reader control/modification **1026** and/or other information or systems to communicate with and/or receive information from a reader **1002***a*, **1002***b*, **1002***c* . . . **1002***n*.

Sample processing **1022** can include receiving data from a reader **1002***a*, **1002***b*, **1002***c* . . . **1002***n* and analyzing the data to perform the analysis of the patient sample. Remote

processing of the patient sample data can reduce the computing burden of the reader **1002***a*, **1002***b*, **1002***c* . . . **1002***n*. Additionally, remote processing can allow for more effective and efficient processing by consolidating the analysis in one or more locations, such as the server **1020**. Consolidation can allow for the use of computer learning and/or larger databases for use in analysis of the patient sample. Such data aggregation can be used to map and/or research trends, map the progression of disorders and/or various other data analyses. Additionally, updating the analysis process can be required at fewer locations, the server **1020**, rather than on each individual reader **1002***a*, **1002***b*, **1002***c* . . . **1002***n*.

The server **1020** can also include medical records **1024**. The analysis performed by the server **1020** or reader **1002***a*, **1002***b*, **1002***c* . . . **1002***n* can be appended to the relevant patient medical record **1024**. Medical records **1024** can be stored on the server **1020** or on an external device and/or system, to which the server **1020** and/or reader **1002***a*, **1002***b*, **1002***c* . . . **1002***n* can communicate the necessary data and/or analysis. The sample processing **1022** can also access the medical records **1024** to perform pattern analysis to determine trends, clusters, and potential preventative measures to reduce impact of a disease and/or condition in a certain region, population and/or demographic. Further, the pattern analysis can be used to determine spread of a disease and/or migration of a condition.

The server **1020** can also include reader control/modification **1026**. Reader control/modification **1026** can include reader calibration information, software updates to the reader **1002***a*, **1002***b*, **1002***c* . . . **1002***n*, ensuring proper and/or authorized use of a reader **1002***a*, **1002***b*, **1002***c* . . . **1002***n* and/or other control or operational changes to a reader **1002***a*, **1002***b*, **1002***c* . . . **1002***n*. Centralizing reader control/modification **1026** can assist with proper reader **1002***a*, **1002***b*, **1002***c* . . . **1002***n* usage, maintenance and/or functionality to provide efficient and effective patient sample analysis using a reader **1002***a*, **1002***b*, **1002***c* . . . **1002***n*.

Another example external device and/or system can include one or more computing devices **1030**. The computing device **1030**, such as a mobile phone, computer, tablet, or other device, can be connected to one or more readers **1002***a*, **1002***b*, **1002***c* . . . **1002***n* through the network **1010**. The computing device **1030** can receive information from the reader **1002***a*, **1002***b*, **1002***c* . . . **1002***n* and perform some or all the sample processing and/or analysis **1032**, based on the received information. Additionally, the external device **1030** can act as an output to which the reader **1002***a*, **1002***b*, **1002***c* . . . **1002***n* transmits results, data and/or information regarding the patient sample analysis. As with the server, discussed above, the computing device **1030** can also include reader control/modification **1034**. The reader control/modification **1034** can provide an input through which instruction to a reader **1002***a*, **1002***b*, **1002***c* . . . **1002***n* can be entered. Additionally, the reader control/modification **1034** can include calibration and/or maintenance data and/or processes a user and/or reader **1002***a*, **1002***b*, **1002***c* . . . **1002***n* can perform to assist with maintenance and/or calibration of the reader **1002***a*, **1002***b*, **1002***c* . . . **1002***n*. The proper functioning and calibration of the reader **1002***a*, **1002***b*, **1002***c* . . . **1002***n* can assist with the efficient and effective analysis of patient samples. Additionally, the computing device **1030** can communicate with the server **1020** using the network **1010** or other communication means, systems and/or processes.

In an example, the computing device **1030** can store and/or transmit data from one or more readers **1002***a*, **1002***b*, **1002***c* . . . **1002***n* to the server **1020**. The data transmission can be in real-time or can be stored and transmitted when convenient or the computing device **1030** is again connected to a network **1010**. Additionally, the computing device **1030** can transmit the results of an analysis to a patient and/or a patient representative, such as a patient's physician. As with transmission of the data from the reader, the transmission of the patient analysis can be performed in real-time or at a later time, such as when the computing device **1030** is again connected to a network **1010**.

One of the functions of the reader network **1000** can include the sharing of the unique cartridge identifications of each of the cartridges analyzed by the readers **1002***a*, **1002***b* **1002***c* . . . **1002***n* of the network **1000**. Sharing the identification of each of the previously used cartridges can prevent the unauthorized reuse of a cartridge. Each reader **1002***a*, **1002***b* **1002***c* . . . **1002***n* can query the server **1020**, computing device **1030** and/or other readers to determine if a cartridge has been previously used as part of a cartridge verification process. In an embodiment, a list of cartridge identifications associated with previously used cartridges can be provided regularly to the reader **1002***a*, **1002***b* **1002***c* . . . **1002***n*, such as by the server **1020** or computing device **1030** via the network **1010**, to update the cartridge verification system of the reader **1002***a*, **1002***b* **1002***c* . . . **1002***n* to prevent reuse of cartridges. Alternatively, or additionally, a list of cartridge identifications associated with unused cartridges can be provided regularly to the reader **1002***a*, **1002***b* **1002***c* . . . **1002***n* to assist with cartridge verification.

The invention claimed is:

1. A point-of-care diagnostic system, comprising:

a cartridge having:

a blood sample chamber that is structured to receive a patient blood sample, the patient blood sample containing one or more hemoglobin types, and to store the patient blood sample within the blood sample chamber;

an electrophoresis strip structured to receive at least a portion of the patient blood sample from the blood sample chamber and to receive a selectively applied electric current;

a reader having:

a cartridge receptacle shaped to receive the cartridge and initiate an electrophoresis diagnostic process in response to receiving the cartridge;

an electrophoresis module structured to cause the selectively applied electric current to be applied to the electrophoresis strip of the cartridge, the electrophoresis strip having thereon received at least a portion of the patient blood sample;

an electrophoresis band detection module structured to detect one or more bands of at least a portion of the patient blood sample on the electrophoresis strip caused by the selectively applied electric current and to generate band detection data based on the one or more bands of the at least a portion of the patient blood sample;

a processor programmed to:

receive the band detection data;

analyze the band detection data to determine one or more band characteristics for each of the one or more bands, each of the one or more bands corresponding to one of the one or more hemoglobin types of the patient blood sample;

identify the one more hemoglobin types of the patient blood sample based on the one or more band detection characteristics of each of the one or more bands;

generate diagnostic results based at least in part on the one or more hemoglobin types of the patient blood sample; and

transmit the diagnostic results to an output.

2. The point-of-care diagnostics system of claim **1**, further comprising an integrated blood sample collector that includes one or more of:

a moveable lancet that, upon actuation, is structured to extend to produce the patient blood sample,

a retractable lancet that, upon actuation, is structured to extend to produce the patient blood sample and to retract into the cartridge after the blood sample is collected,

a stationary lancet that is structured to remain static to produce the blood sample and retracts into the cartridge after collecting the blood sample,

or a fixed lancet structured for a user to manually produce the patient blood sample.

3. The point-of-care diagnostics system of claim **1**, wherein the cartridge further includes at least one of a pre-loaded marker or buffer stored in one or both of the blood sample chamber and a treatment chamber in fluid communication with the blood sample chamber, the treatment chamber either located within one or the other of the cartridge and the reader or integrated within the blood sample chamber.

4. The point-of-care diagnostics system of claim **3**, further comprising one or both of a passive and an active mechanism that, when actuated, automatically causes one or more of the pre-loaded marker to mix with the patient blood sample or the buffer to be applied to the electrophoresis strip.

5. The point-of-care diagnostics system of claim **4**, wherein one or the other of the reader and the cartridge further include a mixing chamber in which the pre-loaded marker is mixed with the patient blood sample.

6. The point-of-care diagnostics system of claim **1**, wherein one or the other of the reader and the cartridge further include a sample depositor configured to selectively deposit a portion of the patient blood sample to the electrophoresis strip in a controlled manner.

7. The point-of-care diagnostics system of claim **6**, wherein the controlled manner includes a pre-determined volume of the patient sample and pre-determined deposit area having a defined shape.

8. The point-of-care diagnostics system of claim **1**, wherein the blood sample chamber of the cartridge further includes one or both of a pre-loaded anti-pathogen and a pre-loaded anti-foaming compound.

9. The point-of-care diagnostics system of claim **1**, wherein the electrophoresis strip includes electrodes that are releasably connected to the electrophoresis module when the cartridge is inserted in the reader.

10. The point-of-care diagnostics system of claim **1**, wherein the electrophoresis module includes electrodes that contact the electrophoresis strip of the cartridge after the cartridge is inserted in the reader.

11. The point-of-care diagnostics system of claim **1**, further comprising one or both of:

an actuator that is positioned to be actuated when the cartridge is received in the cartridge receptacle, and

a cartridge sensor that is configured to detect the presence of the cartridge within the cartridge receptacle, the cartridge sensor electrically coupled to the processor and configured to transmit cartridge data indicating the presence of the cartridge in the cartridge receptacle to the processor.

12. The point-of-care diagnostics system of claim **1**, wherein the electrophoresis module is further structured to stain the electrophoresis strip.

13. The point-of-care diagnostics system of claim **1**, wherein the processor is further programmed to automatically generate the diagnostic results.

14. The point-of-care diagnostics system of claim **1**, wherein the processor is further programmed to transmit the diagnostic results to a display.

15. The point-of-care diagnostics system of claim **1**, wherein the processor is further programmed to receive user input requesting the diagnostic results and, based on the received user input, is also further configured to transmit the output interpretive data to the display.

16. The point-of-care diagnostics system of claim **14**, wherein the display is integrated into the reader.

17. The point-of-care diagnostics system of claim **14**, wherein the display is integrated into a remote computing device.

18. The point-of-care diagnostics system of claim **1**, wherein a portion or all of one or both of the cartridge and the reader are temperature-controlled.

19. The point-of-care diagnostics system of claim **1**, further comprising an integrated power source in the reader, the power source electrically coupled to the electrophoresis module, the electrophoresis band detection module and the processor.

20. The point-of-care diagnostics system of claim **1**, further comprising an output configured to receive the diagnostic results and the output is integrated within the reader and includes one or more of a display, a visual indicator, an audible indicator, and a computing element remote from the reader.

21. The point-of-care diagnostics system of claim **20**, wherein the remote computing element is wirelessly connected to the reader or is connected to the reader via a wired electrical connection.

22. The point-of-care diagnostics system of claim **1**, wherein the processor includes processing circuitry that is integrated within the reader or at least a portion of the processing circuitry is integrated within the cartridge.

23. The point-of-care diagnostics system of claim **1**, wherein the processor includes processing circuitry that is wirelessly connected to the electrophoresis band detection module and is integrated partially or entirely in a computing element remote from the reader.

24. The point-of-care diagnostics system of claim **1**, wherein the processor is further programmed to determine the relative proportions of the one or more hemoglobin types in the patient blood sample and to generate the diagnostic results based at least in part on the relative proportions of the one or more hemoglobin types in the patient blood sample.

25. The point-of-care diagnostics system of claim **1**, further comprising an actuator electrically coupled to the processor, the actuator being structured to indicate that the cartridge is received within the cartridge receptacle, and the processor being further programmed to transmit instructions to the electrophoresis module to begin applying a voltage to the electrophoresis strip in response to the actuator indicating that the cartridge is received within the cartridge receptacle.

26. The point-of-care diagnostics system of claim **1**, wherein the processor is further programmed to measure the spacing from the application point and between each of the bands, and to automatically generate the diagnostic results to include the measurement of the spacing between each of the bands.

27. The point-of-care diagnostics system of claim 1, wherein the processor is further programmed to:

analyze the received band detection data to identify the one more hemoglobin types of the patient blood sample and determine the relative proportions of the one or more hemoglobin types in the patient blood sample,

automatically generate the diagnostic results that indicates the one or more hemoglobin types of the patient blood sample and relative proportions of the one or more hemoglobin types of the patient blood sample based on the received band detection data, and

automatically output the diagnostic results.

28. The point-of-care diagnostics system of claim 27, wherein the processor is further programmed to transmit the diagnostic results to one or both of a display integrated in the reader and a remote computing system.

29. The point-of-care diagnostics system of claim 1, wherein the processor is further programmed to automatically analyze the received band detection data to measure the spacing to and between each of the bands and to automatically generate the diagnostic results to include the measured spacing of each of the bands.

30. The point-of-care diagnostics system of claim 1, wherein the one or more band detection characteristics include an intensity and location for each of the one or more bands and the processing circuitry is further configured to correlate the band detection data of the blood sample with a level of each of the hemoglobin types of the blood sample.

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摘要(译)

一种即时诊断系统，包括一个盒式磁带和一个阅读器。药筒可包含患者样品，例如血液样品。将药筒插入读数器中并分析患者样品。读取器包含各种分析系统，例如电泳检测系统，其使用电泳测试来识别和量化血液样品的各种成分。读者可以处理来自各种患者样品分析的数据，以提供指示患者的病症，病症，疾病和/或感染的解释性结果。