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(54) POINT OF CARE DIAGNOSTIC PLATFORM

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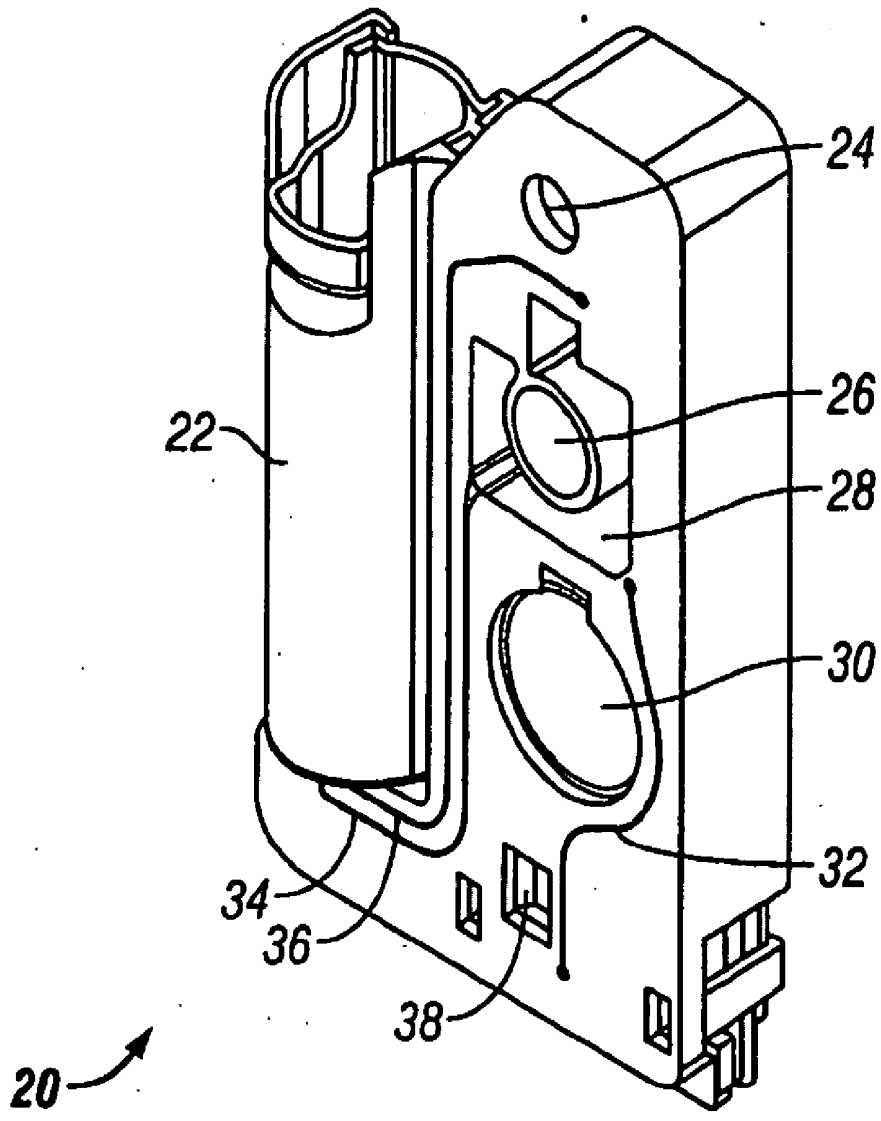
(57) **ABSTRACT**

Disclosed is a point of care diagnostic system that includes an analytic cartridge adapted to receive a blood draw tube such that the cartridge can directly accept a blood sample from the blood draw tube. The cartridge is adapted to perform an assay on the blood sample and to produce an indication of an assay result entirely within the cartridge.



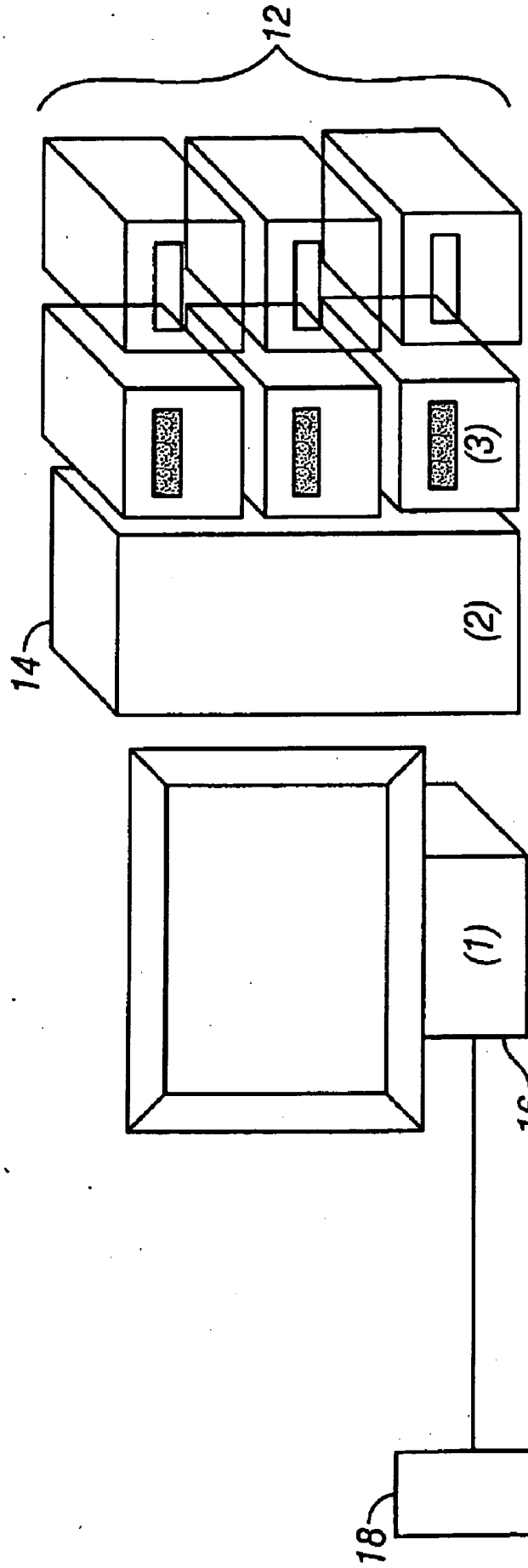


FIG. 1(a)

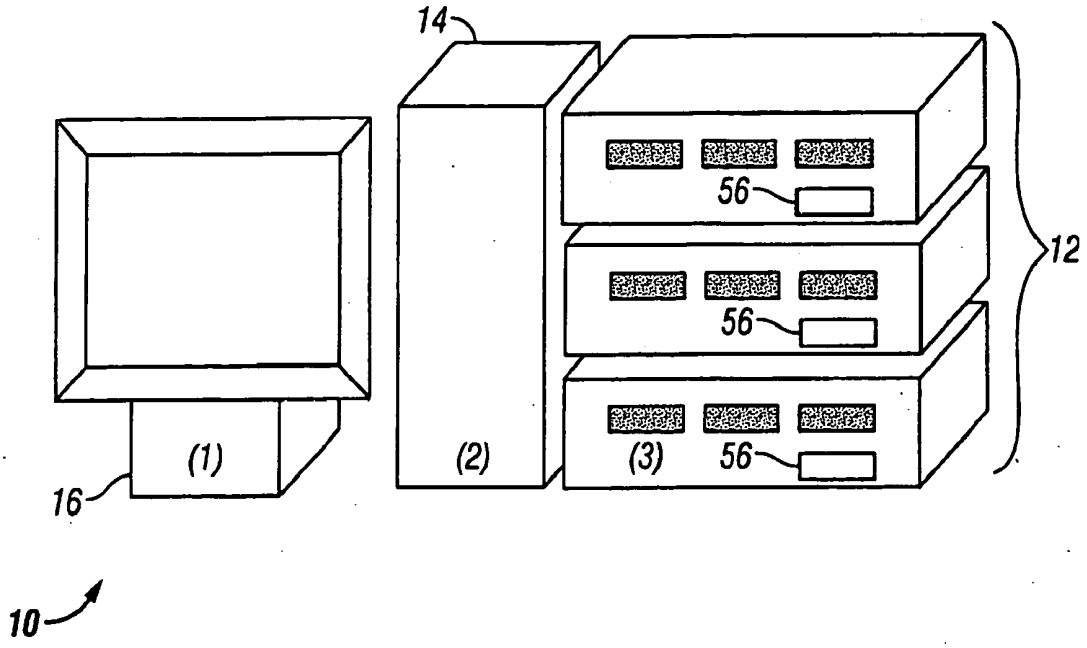


FIG. 1(b)

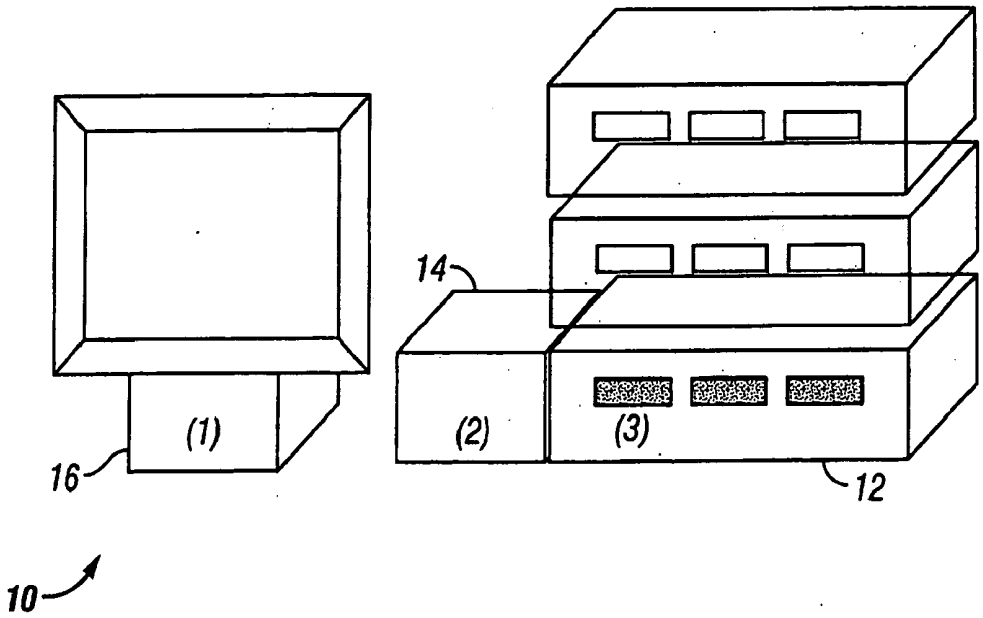


FIG. 1(c)

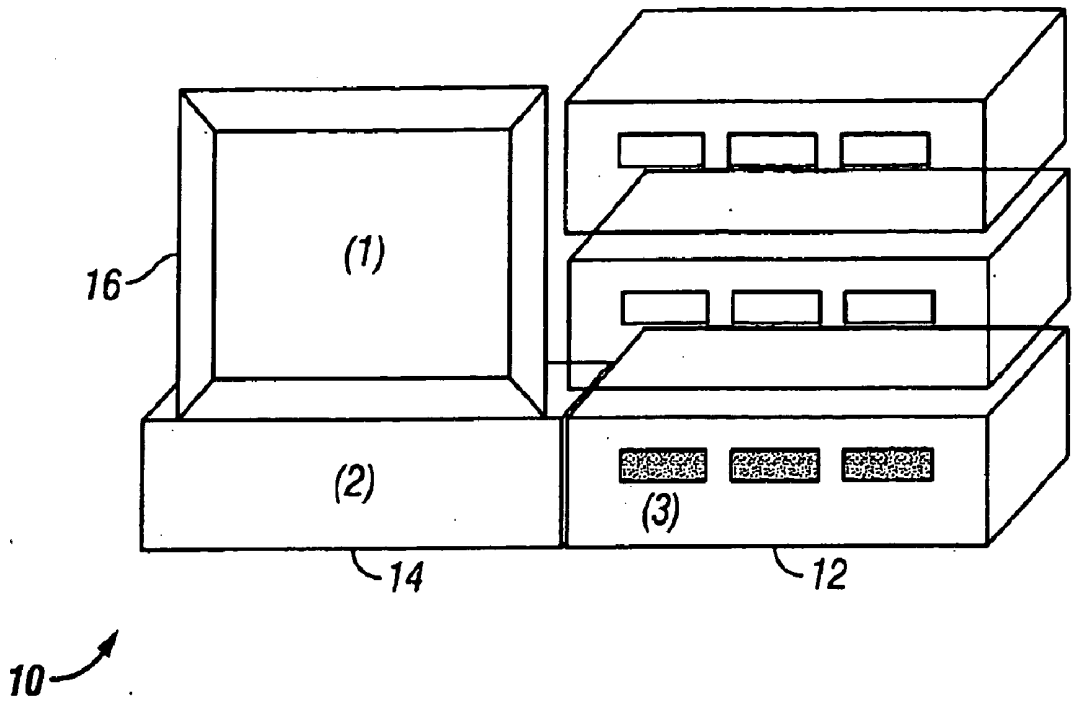


FIG. 1(d)

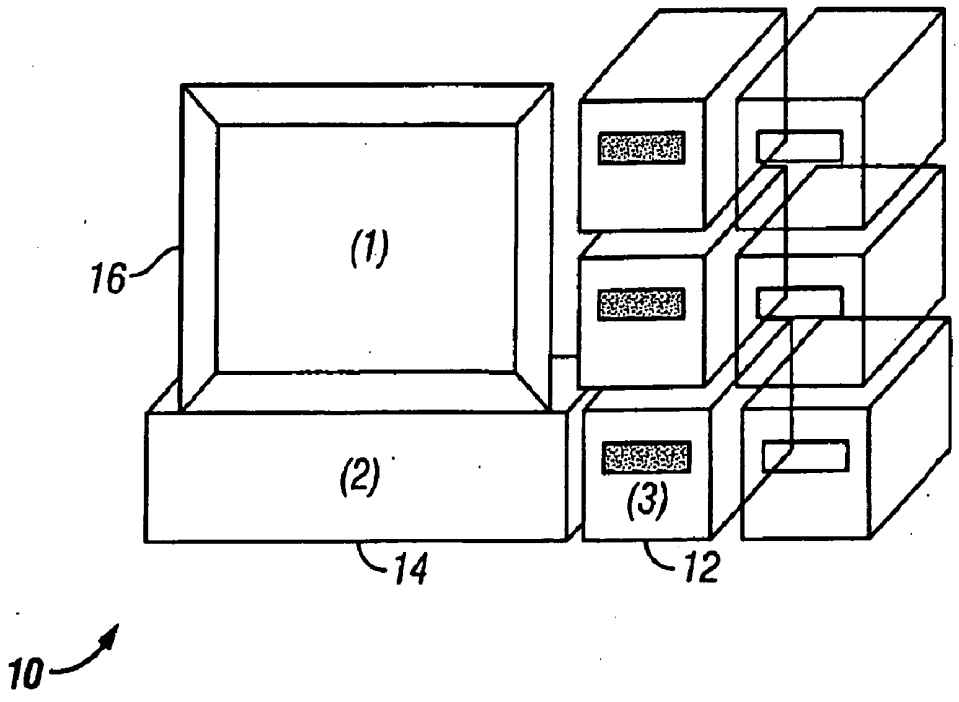


FIG. 1(e)

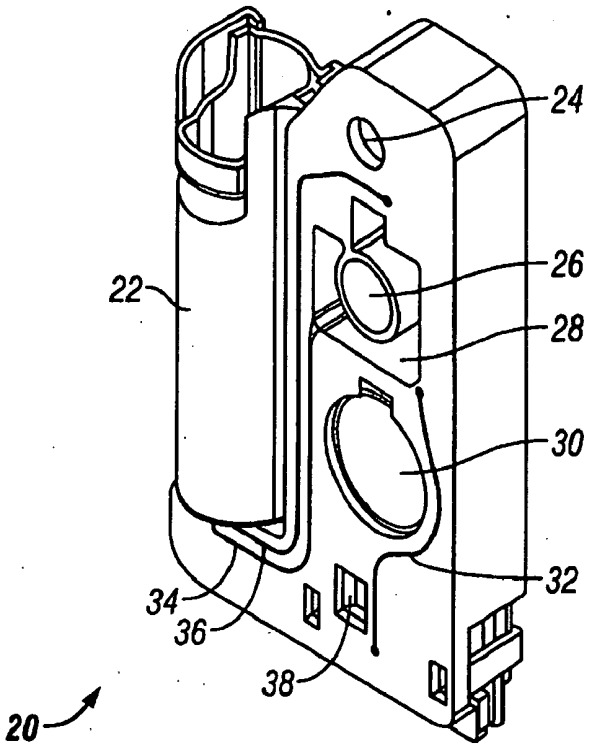


FIG. 2

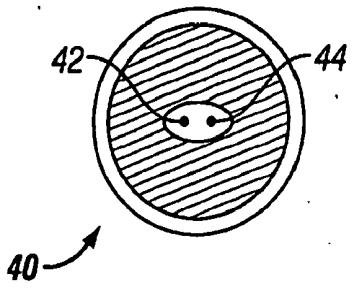


FIG. 3

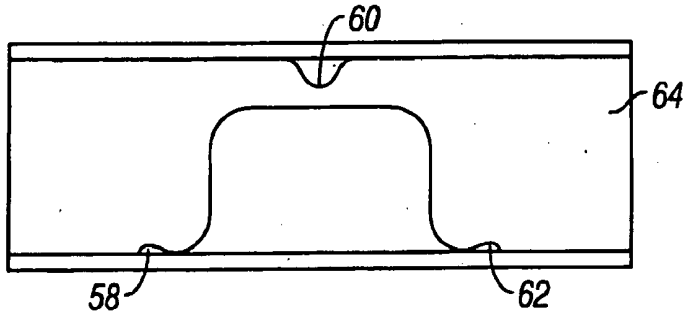


FIG. 7

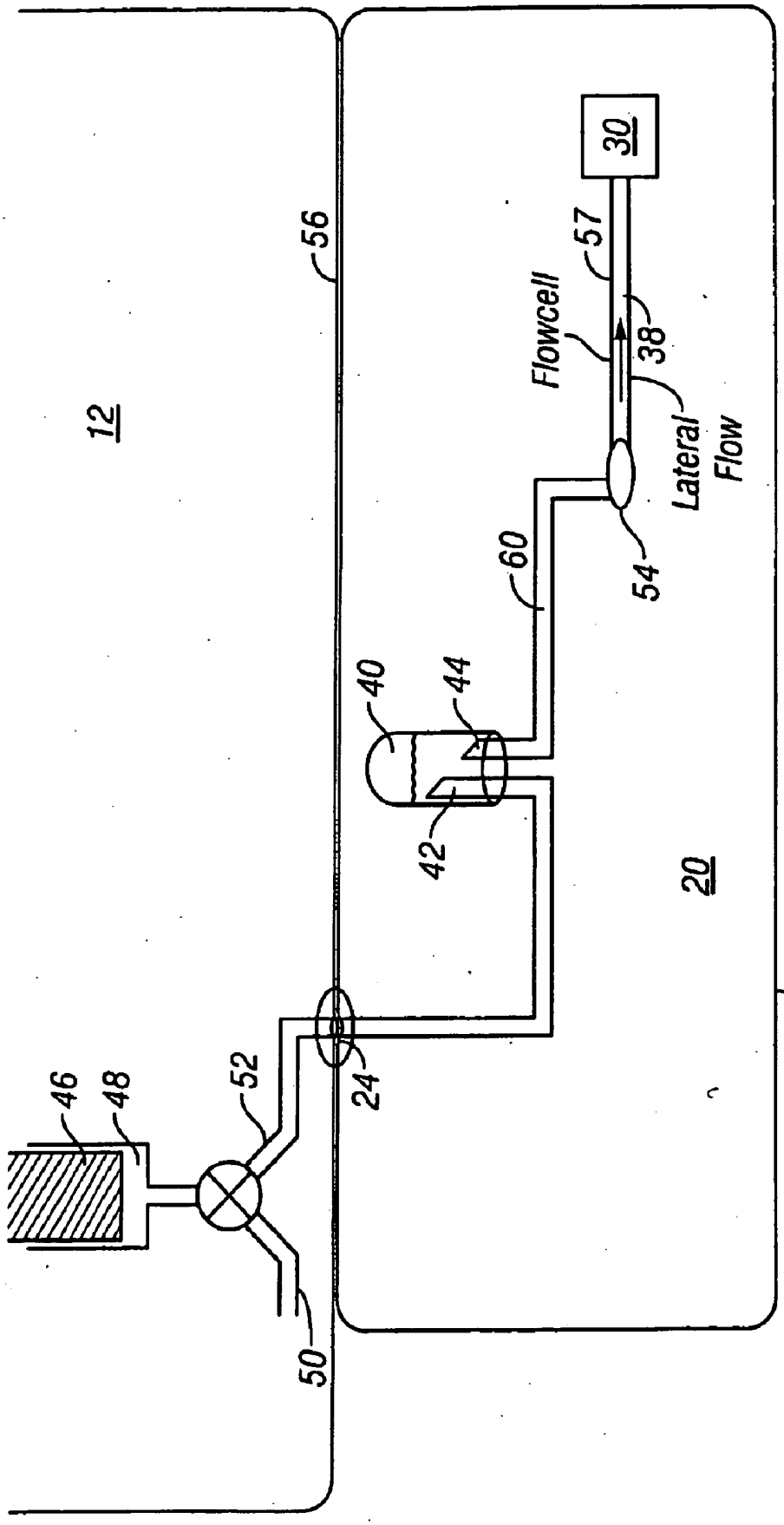

12
56
30
57
Flowcell
38
Lateral Flow
54
60
40
44
42
20
24
52
46
48
50
Cartridge

FIG. 4

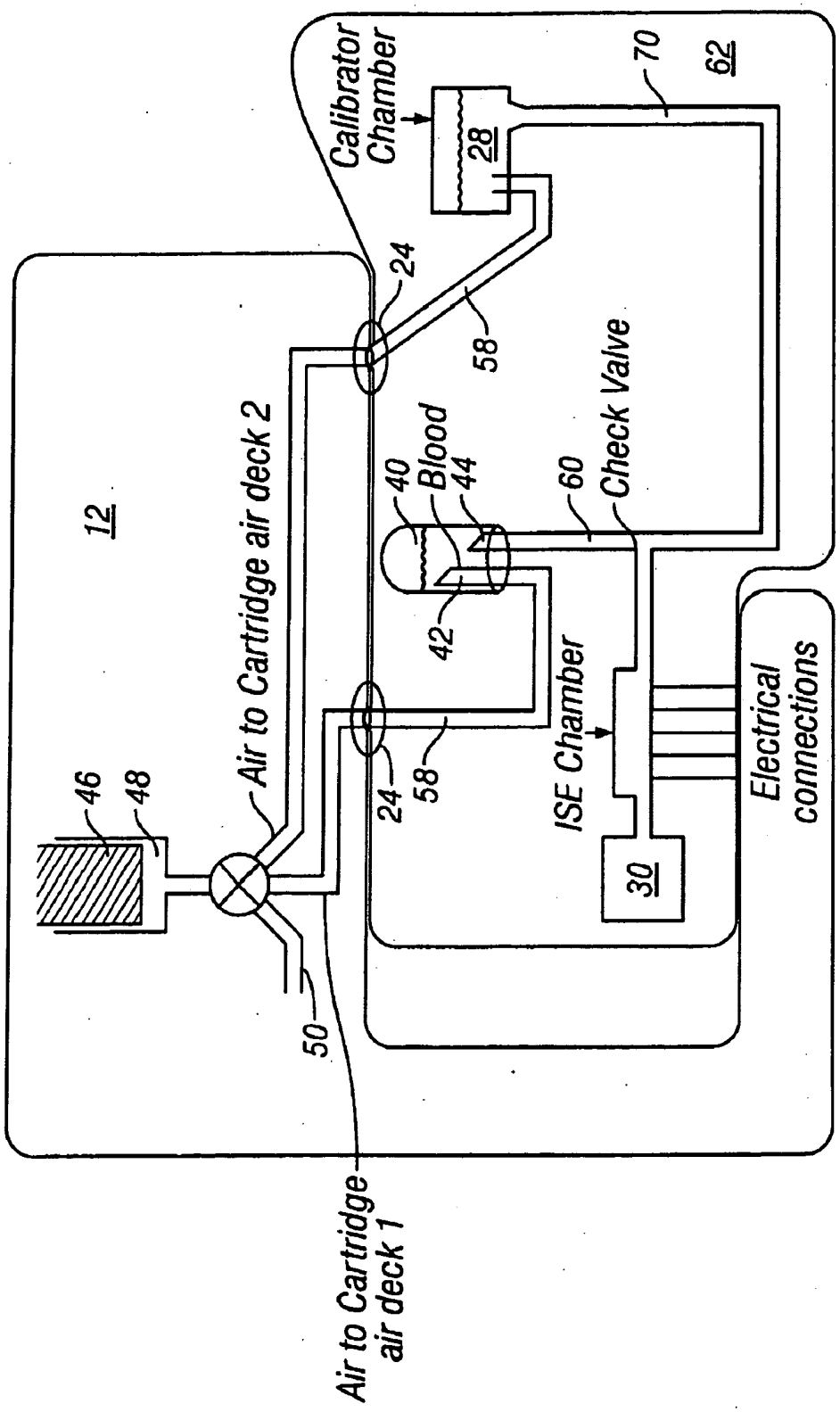

Calibrator Chamber
28
70
62
24
58
Check Valve
60
Blood
40
44
42
12
Air to Cartridge air deck 2
ISE Chamber
30
Electrical connections
46
48
24
58
50
Air to Cartridge air deck 1

FIG. 5

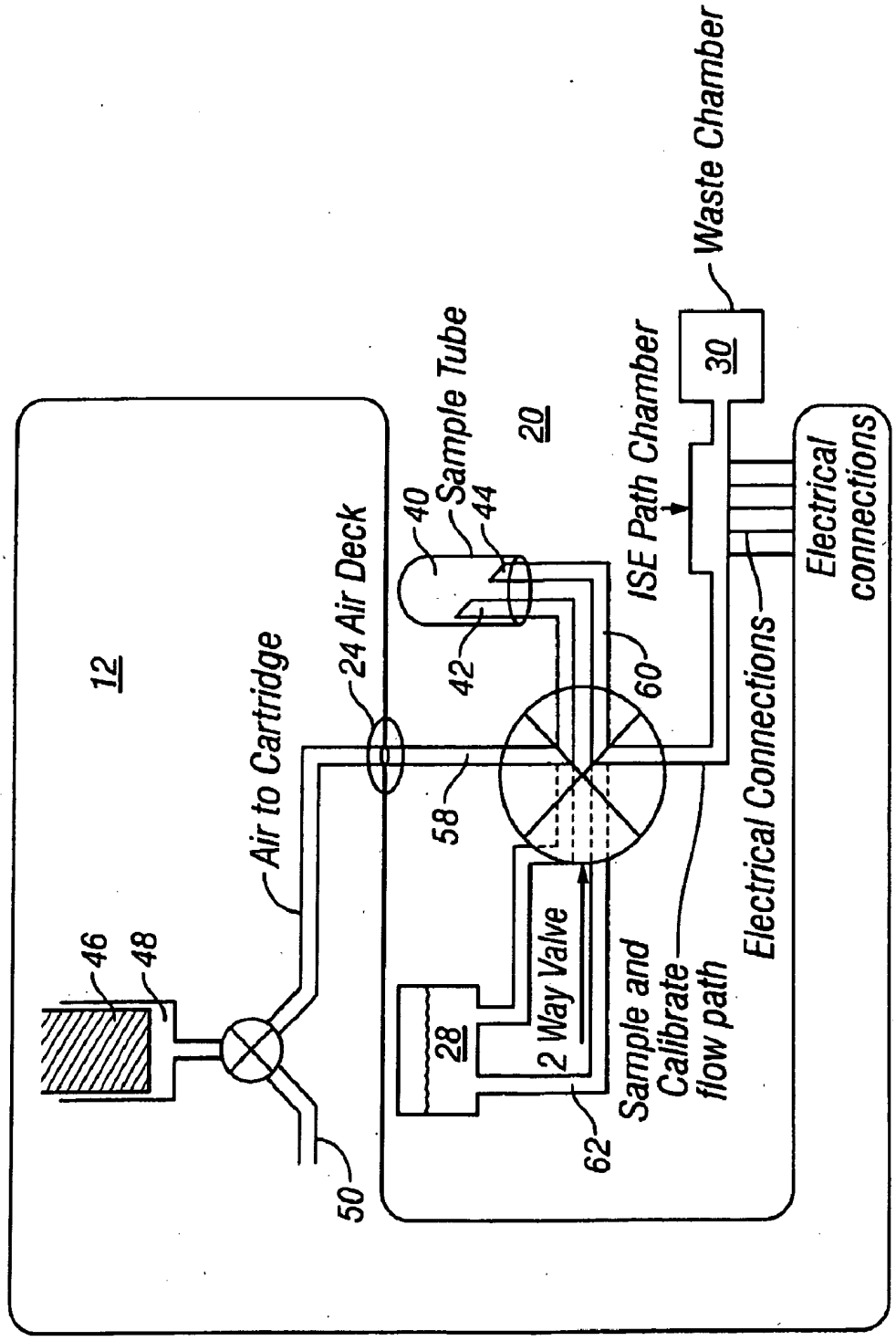

12
Air to Cartridge
24 Air Deck
Sample Tube
40
44
42
20
ISE Path Chamber
60
30
Waste Chamber
Electrical connections
Electrical Connections
58
46
48
28
2 Way Valve
Sample and Calibrate flow path
62
50

FIG. 6

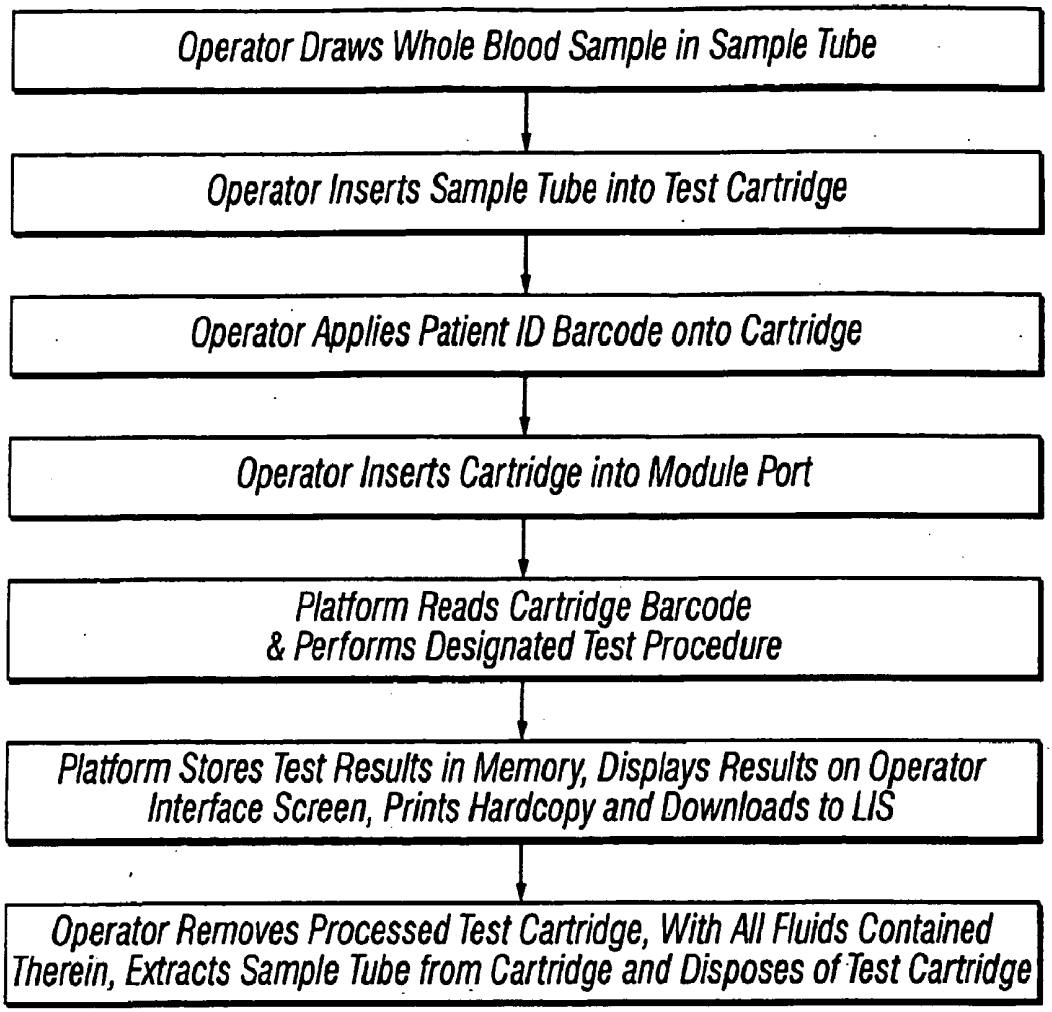

Operator Draws Whole Blood Sample in Sample Tube
Operator Inserts Sample Tube into Test Cartridge
Operator Applies Patient ID Barcode onto Cartridge
Operator Inserts Cartridge into Module Port
Platform Reads Cartridge Barcode & Performs Designated Test Procedure
Platform Stores Test Results in Memory, Displays Results on Operator Interface Screen, Prints Hardcopy and Downloads to LIS
Operator Removes Processed Test Cartridge, With All Fluids Contained Therein, Extracts Sample Tube from Cartridge and Disposes of Test Cartridge

FIG. 8

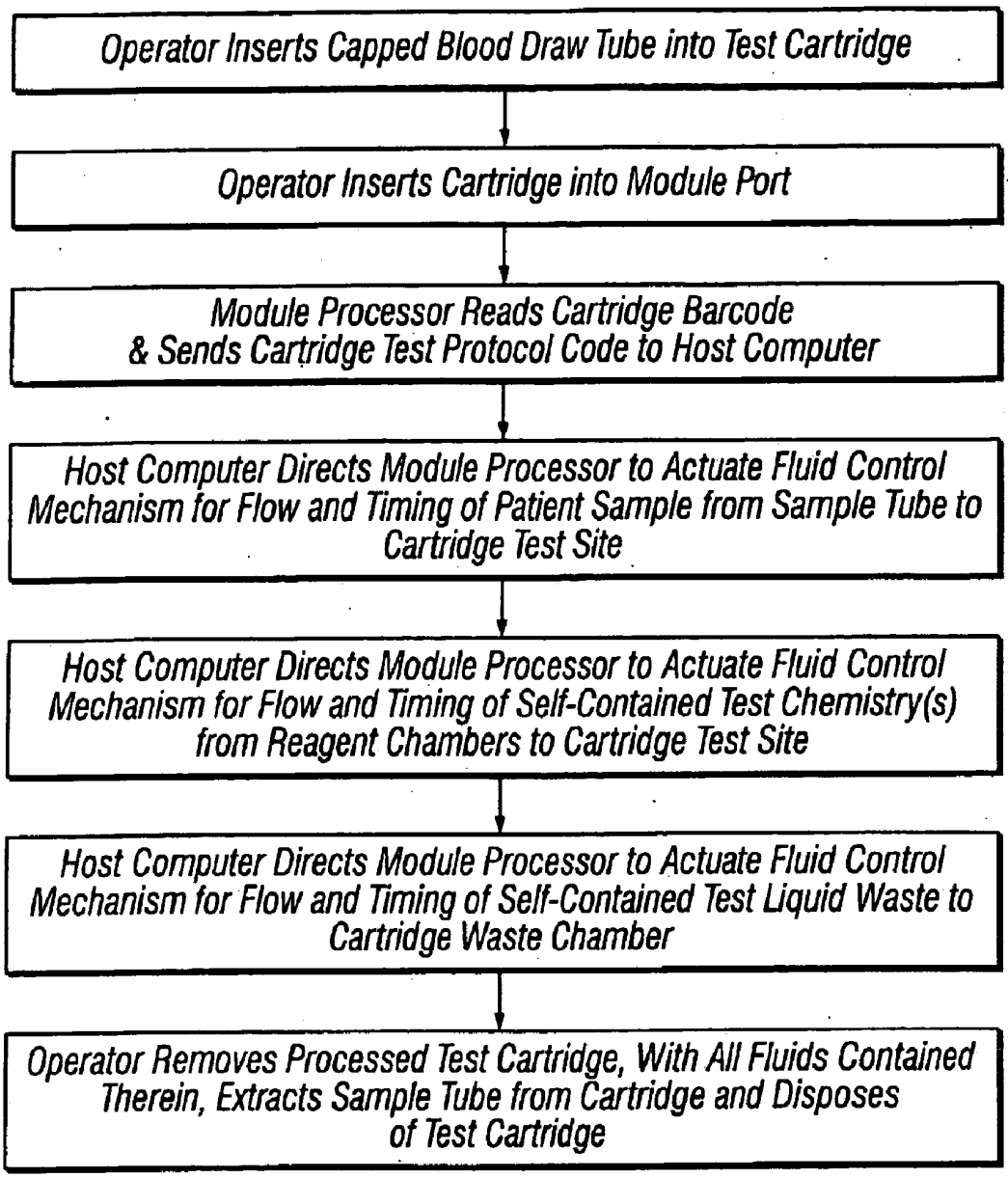

Operator Inserts Capped Blood Draw Tube into Test Cartridge
Operator Inserts Cartridge into Module Port
Module Processor Reads Cartridge Barcode & Sends Cartridge Test Protocol Code to Host Computer
Host Computer Directs Module Processor to Actuate Fluid Control Mechanism for Flow and Timing of Patient Sample from Sample Tube to Cartridge Test Site
Host Computer Directs Module Processor to Actuate Fluid Control Mechanism for Flow and Timing of Self-Contained Test Chemistry(s) from Reagent Chambers to Cartridge Test Site
Host Computer Directs Module Processor to Actuate Fluid Control Mechanism for Flow and Timing of Self-Contained Test Liquid Waste to Cartridge Waste Chamber
Operator Removes Processed Test Cartridge, With All Fluids Contained Therein, Extracts Sample Tube from Cartridge and Disposes of Test Cartridge

FIG. 9

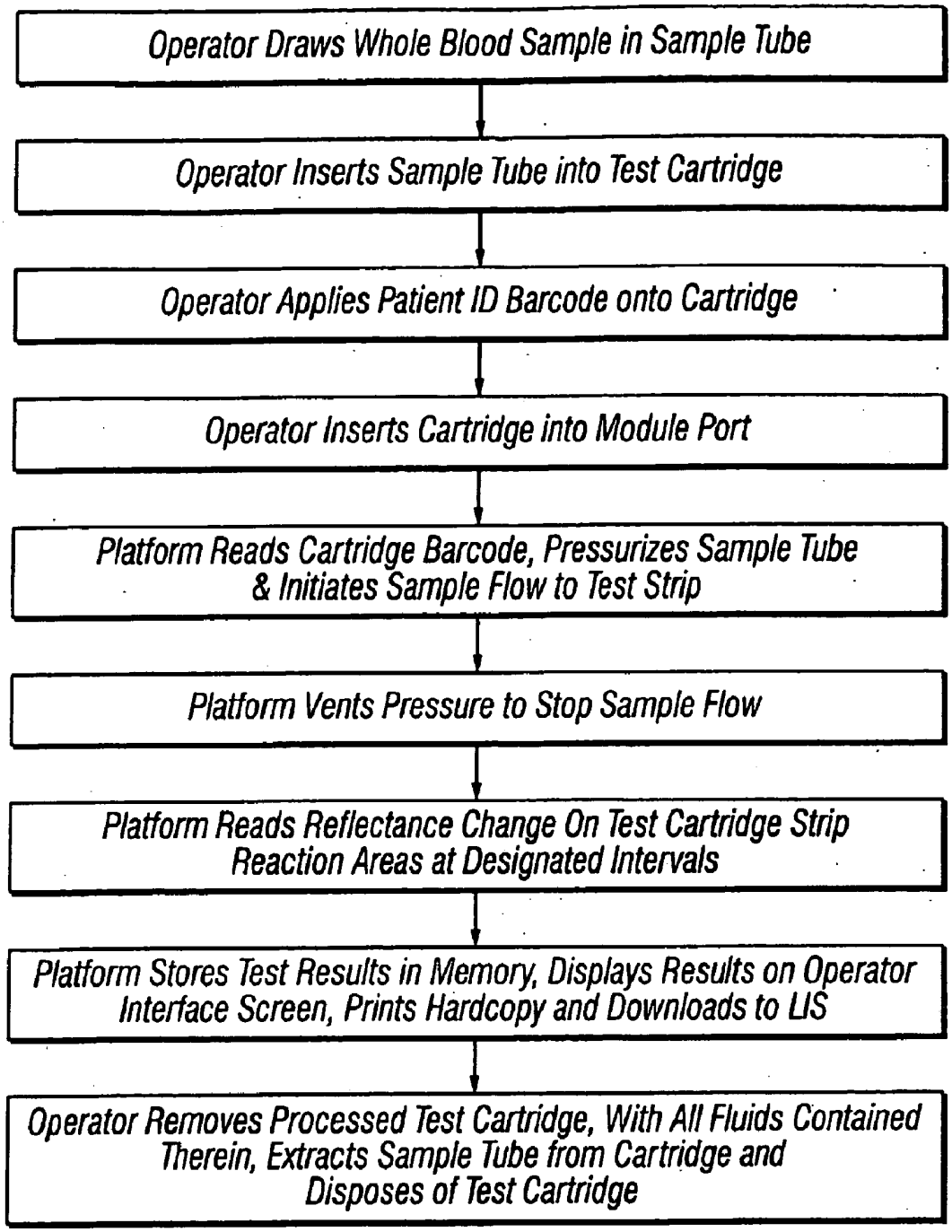

Operator Draws Whole Blood Sample in Sample Tube
Operator Inserts Sample Tube into Test Cartridge
Operator Applies Patient ID Barcode onto Cartridge
Operator Inserts Cartridge into Module Port
Platform Reads Cartridge Barcode, Pressurizes Sample Tube & Initiates Sample Flow to Test Strip
Platform Vents Pressure to Stop Sample Flow
Platform Reads Reflectance Change On Test Cartridge Strip Reaction Areas at Designated Intervals
Platform Stores Test Results in Memory, Displays Results on Operator Interface Screen, Prints Hardcopy and Downloads to LIS
Operator Removes Processed Test Cartridge, With All Fluids Contained Therein, Extracts Sample Tube from Cartridge and Disposes of Test Cartridge

FIG. 10

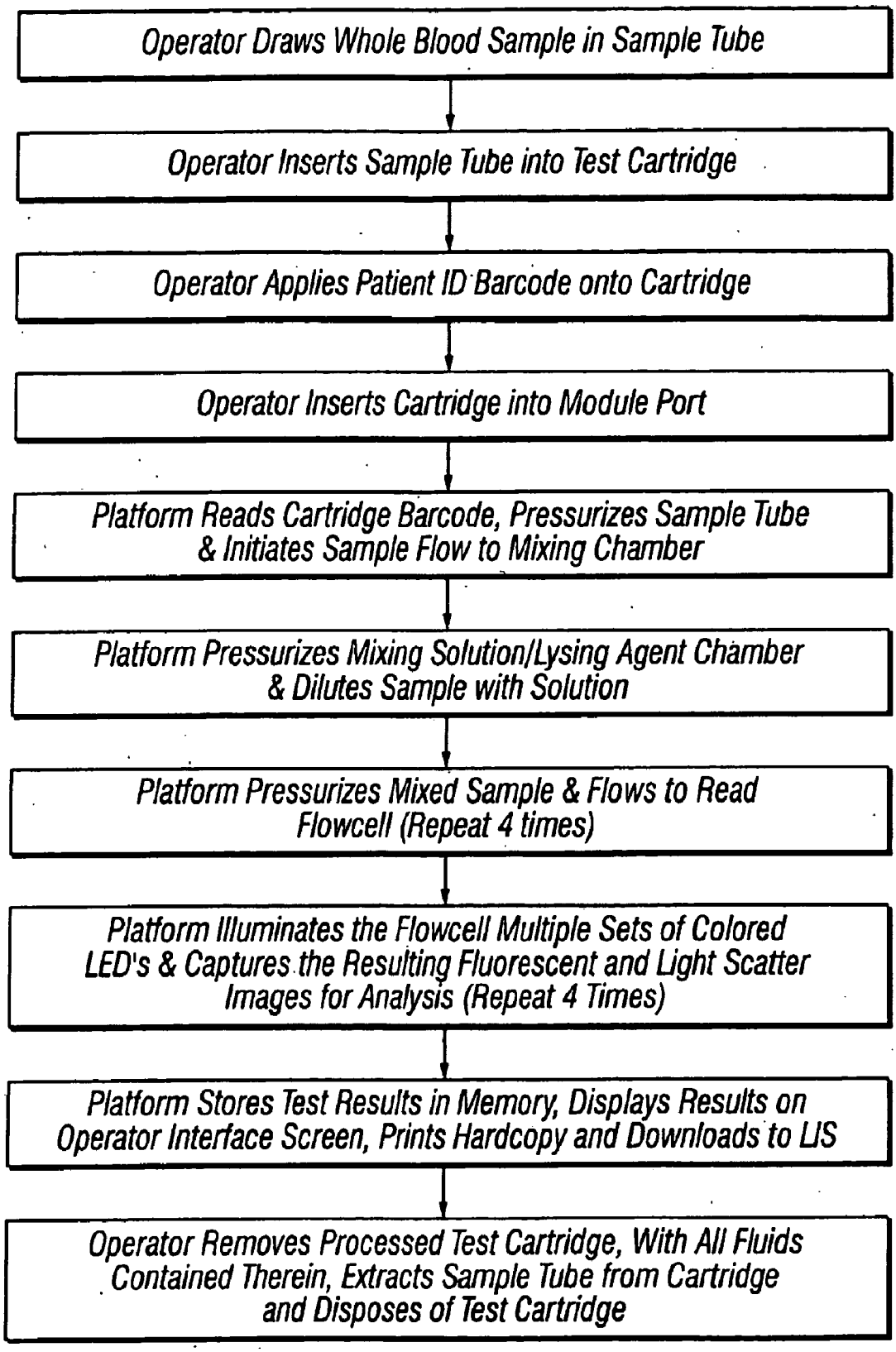

Operator Draws Whole Blood Sample in Sample Tube
Operator Inserts Sample Tube into Test Cartridge
Operator Applies Patient ID Barcode onto Cartridge
Operator Inserts Cartridge into Module Port
Platform Reads Cartridge Barcode, Pressurizes Sample Tube & Initiates Sample Flow to Mixing Chamber
Platform Pressurizes Mixing Solution/Lysing Agent Chamber & Dilutes Sample with Solution
Platform Pressurizes Mixed Sample & Flows to Read Flowcell (Repeat 4 times)
Platform Illuminates the Flowcell Multiple Sets of Colored LED's & Captures the Resulting Fluorescent and Light Scatter Images for Analysis (Repeat 4 Times)
Platform Stores Test Results in Memory, Displays Results on Operator Interface Screen, Prints Hardcopy and Downloads to LIS
Operator Removes Processed Test Cartridge, With All Fluids Contained Therein, Extracts Sample Tube from Cartridge and Disposes of Test Cartridge

FIG. 11

POINT OF CARE DIAGNOSTIC PLATFORM

REFERENCE TO PRIORITY DOCUMENTS

[0001] This application is a continuation of co-pending U.S. patent application Ser. No.10/746,127, filed Dec. 23, 2003, which claims priority of U.S. Provisional Patent Application Ser. No. 60/470,725, filed May 14, 2003. Priority of the aforementioned filing dates is hereby claimed, and the disclosures of the aforementioned patent applications are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates generally to a point of care diagnostic system that has a plurality of modules and associated cartridges, and more particularly, to a point of care diagnostic system that includes a plurality of modules that share common QC protocols.

[0004] 2. Description of the Related Art

[0005] Blood and other body fluid tests are important diagnostic methods in patient care and treatment. The reliability and the accuracy of the tests are critical in correctly diagnosing the patient and administrating proper treatment. The Food and Drug Administration (FDA) has established numerous quality standards for the various blood or body fluid tests. Monitoring the test process is beneficial in producing reliable and accurate test results.

[0006] One way of monitoring the test process is periodically performing the monitoring test on standard test samples. The monitoring test results are compared with expected results to verify the accuracy of the test processes or correct the test instrument or process when appropriate. In this approach, the test processes are assumed to generate consistent result between the monitoring tests.

[0007] Another way of monitoring the test process is including standard test samples in the test process. This approach is suitable for a test process that performs tests on multiple samples. The test results on the standard test samples are compared with expected results to verify the accuracy of the test processes. In this approach, the test processes on real samples are assumed to generate result consistent with those on standard test samples.

[0008] These monitoring processes are time and cost inefficient. They are deficient in meeting the needs of point of care, e.g., hospital emergency room/department, test processes. In addition to being reliable and accurate, an emergency room test process should be simple to operate and generate diversity of analytical results fast.

[0009] Accordingly, there is a need for a point of care diagnostic platform that has a plurality of modules coupled to common host computer. There is another need for a point of care diagnostic platform with a plurality of modules that share common QC protocols. Yet there is another need for a point of care diagnostic platform with a plurality of modules coupled to a host computer and an external communication system. There is still another need for a point of care diagnostic platform with a plurality of modules, and a plurality of analytic cartridges, where each cartridge is associated with a module and is configured to directly accept a blood sample from a standard blood draw tube. Yet there is a further need for a point of care diagnostic platform that has a plurality of modules, a host computer coupled to the modules, a common external communication interface, with each module sharing the common external communication interface.

SUMMARY OF THE INVENTION

[0010] Accordingly, an object of the present invention is to provide a point of care diagnostic platform that includes a plurality of modules that share common QC protocols.

[0011] Another object of the present invention is to provide a point of care diagnostic platform with a plurality of module coupled to a common host computer.

[0012] Yet another object of the present invention is to provide a point of care diagnostic platform with a plurality of modules, a host computer coupled to the plurality of modules and an external communication system.

[0013] Still another object of the present invention is to provide a point of care diagnostic platform with a plurality of modules, and a plurality of analytic cartridges, where each cartridge is associated with a module of the plurality of modules and is configured to directly accept a blood sample from a standard blood draw tube.

[0014] Another object of the present invention is to provide a point of care diagnostic platform with a plurality of modules; a host computer coupled to the plurality of modules and a common external communication interface, with each module sharing the common external communication interface.

[0015] A further object of the present invention is to provide a point of care diagnostic platform with a plurality of modules coupled to a common external communication interface such as a least one of WAN or a LAN.

[0016] Another object of the present invention is to provide a point of care diagnostic platform with a plurality of modules coupled to a common external communication interface that is coupled to a wireless network.

[0017] A further object of the present invention is to provide a point of care diagnostic platform with a plurality of modules coupled to a hospital information network or a laboratory information network.

[0018] Yet another object of the present invention is to provide a point of care diagnostic platform with a plurality of modules and a plurality of analytic cartridges that are each bar-coded with information for test protocols, and lot expiration dates.

[0019] Still a further object of the present invention is to provide a point of care diagnostic platform with a plurality of modules and a plurality of analytic cartridges that retain and seal fluids.

[0020] Yet another object of the present invention is to provide a point of care diagnostic platform that has a plurality of modules and a plurality of analytic cartridges, where all fluids in a cartridge, including a patient sample, remain within the cartridge.

[0021] These and other objects of the present invention are achieved in a point of care diagnostic platform includes a plurality of modules. A plurality of analytic cartridges are

provided. Each cartridge is associated with a module and is configured to directly accept a blood sample from a standard blood draw tube.

[0022] In another embodiment of the present invention, a point of care diagnostic platform includes a plurality of modules. A host computer is coupled to the plurality of modules and a common external communication interface. Each module shares the common external communication interface.

[0023] In another embodiment of the present invention, a point of care diagnostic platform includes a plurality of modules each sharing the same QC protocols. A plurality of analytic cartridges are included. A host computer is coupled to the plurality of modules. The host computer is coupled to an interface. Each module has a corresponding interface component.

[0024] In another embodiment of the present invention, a point of care diagnostic platform includes a plurality of modules. A plurality of analytic cartridges are provided that each are bar-coded with information for test protocols, and lot expiration dates.

[0025] In another embodiment of the present invention, a point of care diagnostic platform includes a plurality of modules. A plurality of analytic cartridges are provided that retain and seal fluids.

[0026] In another embodiment of the present invention, a point of care diagnostic platform includes a plurality of modules. A plurality of analytic cartridges are provided. All fluids in the cartridges, including patient samples, remain within the cartridges.

[0027] In another embodiment of the present invention, a point of care diagnostic platform is provided that includes a plurality of modules. A plurality of analytic cartridges are provided. Each cartridge has wet and dry chemistries and at least one substrate that carriers a chemistry.

[0028] In one aspect, there is disclosed a point of care diagnostic system that includes an analytic cartridge adapted to receive a blood draw tube such that the cartridge can directly accept a blood sample from the blood draw tube. The cartridge is adapted to perform an assay on the blood sample and to produce an indication of an assay result entirely within the cartridge.

BRIEF DESCRIPTION OF THE DRAWINGS

[0029] FIG. **1**(*a*) is a block diagram illustrating one embodiment of a point of care diagnostic platform of the present invention, with a user interface, host computer, multiple single-cartridge test processing modules and an external communication system.

[0030] FIG. **1**(*b*) is a block diagram illustrating another embodiment of a point of care diagnostic platform of the present invention, with multiple multi-cartridge test processing modules.

[0031] FIG. **1**(*c*) is a block diagram illustrating another embodiment of a point of care diagnostic platform of the present invention, with the host computer being integrated with multiple, multi-cartridge modules.

[0032] FIG. **1**(*d*) is a block diagram illustrating another embodiment of a point of care diagnostic platform of the present invention, with the host computer and user interface both integrated with multiple, multi-cartridge modules.

[0033] FIG. **1**(*e*) is a block diagram illustrating another embodiment of a point of care diagnostic platform of the present invention, with the host computer and user interface integrated with multiple, single-cartridge modules.

[0034] FIG. **2** is a cross-sectional view of one embodiment of a cartridge that can be utilized with the point of care diagnostic platform of the present invention.

[0035] FIG. **3** is a cross-sectional view of a sample tube that can be utilized with cartridges of the present invention.

[0036] FIG. **4** is a schematic diagram illustrating one embodiment of the docking, and the relationship between a cartridge and a module of the present invention.

[0037] FIG. **5** is a schematic diagram illustrating another embodiment of the docking, and the relationship between a cartridge and a module of the present invention.

[0038] FIG. **6** is a schematic diagram illustrating another embodiment of the docking, and the relationship between a cartridge and a module of the present invention.

[0039] FIG. **7** is a cross-sectional view of one embodiment of a cartridge utilized with the present invention, illustrating air, sample and reagent flow channels.

[0040] FIG. **8** is a flow chart illustrating an overall methodology of the point of care diagnostic platform of the present invention.

[0041] FIG. **9** is a flow chart illustrating one embodiment of a cartridge processing procedure implemented with the point of care diagnostic platform of the present invention.

[0042] FIG. **10** is a flow chart illustrating one embodiment of an immunoassay operating procedure implemented with the point of care diagnostic platform of the present invention.

[0043] FIG. **11** is a flow chart illustrating one embodiment of a hematology operating procedure implemented with the point of care diagnostic platform of the present invention.

DETAILED DESCRIPTION

[0044] As illustrated in FIG. **1**(*a*), one embodiment of the present invention is a point of care diagnostic platform, denoted generally as **10**, and its method of use. Point of care diagnostic platform **10** includes a plurality of modules **12**. A variety of different modules can be included but not limited to, immunoassay, hematology, electrolyte, molecular diagnostic, coagulation, blood gas, chemistry and the like. The modules **12** can share at least a portion of a common functionality of operation such as fluid movement, sample introduction, and the like. In one embodiment, each module **12** contains common functionalities, and unique technologies that correspond to one or more selected chemistries. In the FIG. **1**(*a*) embodiment, modules **12** are multiple single-cartridge test processing modules.

[0045] Platform **10** can deliver a multitude of discreet testing capabilities in a standardized manner. Modules **12** can have common operation platforms. Examples of common operation systems are user interface, quality control, calibration, training, connection to various laboratory infor-

mation systems, hospital information systems, emergency room information systems, wireless communication and the like.

[0046] A host computer **14** is coupled to the plurality of modules **12** and also to a user interface **16**. Each module **12** is coupled to the user interface **16**. Host computer **14** has a variety of different capabilities, including but not limited to user interface, quality control, calibration, training, connection to various laboratory information systems, hospital information systems, emergency room information systems, wireless communication and the like. User interface **16** is coupled to each module **12** User interface **16** provides uniform (automated and standardized) connectivity to the plurality of modules **12** as well as communication to other hospital and laboratory information systems. It will be appreciated that standardized includes industry standards as documented by the Connectivity Industry Consortium. User interface **16** establishes a database of analyzed samples and provides the operator with quality control options for the plurality of modules **12**. This is achieved by centralizing and tracking the collective output of the plurality of modules **12**. In one embodiment, user interface **16** includes capability for at least one of a cardiac, fertility, kidney, coagulation, electrolyte and hematology panel, molecular diagnostics and chemistry panels, and the like.

[0047] Each module **12** has a corresponding interface component for module control and sample results acquisition. In one embodiment, host computer **14** is also coupled to an external communication system **18**. A variety of different external communication systems are suitable including but not limited to a, WAN, LAN, wireless network, hospital information network, laboratory information network, and the like. Platform **10** can be connected directly or indirectly to a emergency room/department patient management network

[0048] In one embodiment, each module **12** shares common QC protocols. The QC protocols include but are not limited to the following, module electronic verification, real-time process monitoring, patient record-keeping, periodic liquid control results monitoring, and the like. The QC protocols are initiated in the same manner regardless of the module **12** that is tested. Electronic monitoring of the process at each module **12** is continuous and transparent to the operator and do not require operator attention. Results are stored in module specific databases. Each module can utilize specific electronic and/or optical parameter monitoring. Changes in the electronic and optical parameters are tracked during the operation of the module **12** involved, and the outputs compared to expected thresholds/changes. These changes are indicative of correct internal operation during sample processing.

[0049] In another embodiment, illustrated in FIG. **1**(*b*), multiple, multi-modules are provided, where a module **12** can be utilized with more than one cartridge. In FIG. **1**(*c*) host computer **14** is integrated with multiple, multi-cartridge modules **12**. In the FIG. **1**(*d*) embodiment, host computer **14** and user interface **16** are both integrated with multiple, multi-cartridge modules **12**. In the FIG. **1**(*e*) embodiment, host computer and user interface **16** are integrated with multiple, single-cartridge test processing modules **12**.

[0050] Point of care diagnostic platform **10** includes a plurality of cartridges **20**, illustrated in FIG. **2**. Cartridges **20** include but are not limited to cardiac, fertility, kidney, coagulation, electrolyte and hematology panel, molecular diagnostics and chemistry panels, and the like.

[0051] Each cartridge **20** can include a dock **22** for receiving a sample tube, an air dock **24** that can be engaged by a module **12**, a rotary valve **26**, which can also be engaged by a module **12**, a calibration chamber **28**, waste chamber **30**, sample/calibration flow path **32** which is coupled to a detector, sample out flow **34**, sample pressure channel **36** and a flow cell **38** which is a detection chamber.

[0052] Cartridges **20** can have wet and dry chemistries and at least one substrate that carriers a chemistry. Examples of various wet and dry chemistries are listed in Table 1.

TABLE 1

Cartridge	Wet Reagents	Dry Reagents
electrolytes	calibration fluid	ion specific electrodes
immunology	—	Capture antibody Conjugate antibody
hemolotogy	Lysing solution/white blood cell - nuclear label Hemoglobin dye	—
Chemistry	Various	Various
Coagulation	—	Initiator
Blood gas	—	Electrode
Molecular	Nucleic acid label	Nucleic acid capture Amplification reagents

[0053] Cartridges **20** are associated with a corresponding module **12**. In one embodiment, cartridges **20** can directly accept a blood sample from a standard blood draw, sample tube **40** which can include a pressure needle **42** and a sampling needle **44**, as shown in FIG. **3**. This can be achieved by, (i) piercing the cap of the standard blood draw tube **40** needles **42** and **44**, which deliver low pressure air to force the sample through the other needle into the cartridge **20**, penetrating the cap with a single needle and withdrawing fluid directly using a vacuum, and the like. Cartridges **20** can be configured to retain and seal fluids. This can be achieved by using selective pressurization of reagent and sample reservoirs, which forces the fluids into cartridges **20** and through flow cell **38** into waste chamber **30**, that can be an integral part of cartridges **20**. All fluids in cartridges **20**, including patient samples, can remain within the cartridge **20**.

[0054] As illustrated in FIG. **4**, modules **12** can be configured to be engaged with the cartridges **20** to produce pneumatic movement of fluids in the cartridges **20**. The pneumatic pressure is applied by an external pump **46** through the dock **22** on cartridge **20**, FIG. **2**, which is engaged by module **12**. Module **12** can include a valve, **48**, a vent **50** to atmosphere and a channel **52** that is coupled to cartridge **20**. The pneumatic pressure is directed to specific reservoirs and samples in cartridge **20** using valve **48** mechanism to cause selective reagent flow. Cartridge **20** includes a sample application area **54**. Optics **56** are included in module **12** and an optical window **57** is included in cartridge **20**. At the cessation of reagent flow, excess pressure is vented through vent **50** to atmosphere to stop the flow. Platform **10** can provide self-testing of modules **12**, to provide for monitoring and detection of fluid flow. Various electrical and optical properties of the samples and reagents

allow continuous monitoring of flow cell contents and are compared to expected transition values, as illustrated in FIG. **5**.

[**0055**] FIG. **6** illustrates a cross-sectional view of one embodiment of a cartridge **20**. Cartridge **20** can have a number of different flow channels, including but not limited to air, sample and reagent flow channels **58**, **60** and **62**. Flow channels **58-62** can be created by depressions in both the top and bottom surfaces of the cartridge **20**. Flow paths **58-62** can then be sealed with a vapor barrier **64**.

[**0056**] Referring again to FIG. **4**, pressurization of specific sample or reagent containers provided by pump **46** are selectively directed to sample and reagents containers in sequence, providing an outflow directed by a valve to detection chamber **38** or other location, as needed, in sequence and with precise timing. The sample and reagents can flow through an area of controlled temperature to prepare them for precise analysis prior to or during introduction to detection chamber **38**. After analysis the reagents and sample remain in the cartridge **20** in waste region **30**, although the sample tube **40** can be removed by the operator for subsequent use if desired.

[**0057**] Each module **12** can include a processor **56** (FIG. **1**(*b*). Host computer **16**, in combination with a processor **56**, determines a test protocol for a cartridge **20**. A fluid control mechanism in the cartridge **20** is then actuated that permits a flow of a patient sample with liquid chemistries and waste materials. This can occur without exposing an operator of platform **10** and the patient, to a transfer of a patient sample into the cartridge **20** without exposure to the chemistries. Cartridges **20** are designed to isolate biohazards in a cartridge **20** from an operator of the cartridge **20** or the patient. Blood samples from patients are introduced to the cartridges **20** while isolating biohazards in the cartridge from an operator.

[**0058**] In one embodiment, cartridges **20** are designed to work with whole blood. This eliminates the requirement of a secondary process to remove the cellular components which may interfere with the testing. This additional separation is both time consuming and error prone. In the cartridge, the separation of cells is done automatically by providing a barrier which is penetrated by the analyte to be measured by excludes the cells from analytical contact, except in the case of hemotalogy, where the cells themselves are the subject of measurement.

[**0059**] Cartridges **20** can include electronic identifiers, including but not limited to bar-coded identifiers, with information for test protocols, and lot expiration dates. Cartridges **20** can also include serialized identification.

[**0060**] In one embodiment, placement of a cartridge **20** in a module **12** begins an initiation of the module **12**. When a cartridge **20** is inserted into a module **12** it can be sensed automatically. The bar code of cartridge **20**, with its unique sample, are read. This initiates the sequential operation of the fluid movement and detection.

[**0061**] In another embodiment of the present invention, platform **10** includes a plurality of modules **12** each sharing common QC protocols. A list of possible QC protocols is found in table 2.

TABLE 2

	Responsibility	Comments
Model POCT Platform Operating Procedures		
Action (per cartridge)		
1. Draw minimum of 1.5 ml whole blood Operator Exact volume sample in appropriate 5 ml vacutainer-type above minimum not draw tube, using standard draw procedure	Operator	Exact volume above minimum not critical
2. Push sample tube into cartridge tube dock and fully seat over needles	Operator	
3. Place patient ID bar code label in designated target area on tube dock	Operator	If ED bar code system used
4. Push cartridge into module port until fully seated over snap-type detents	Operator*	Platform in testing mode
5. LED (blue) above port flashes to indicate cartridge fully seated in port and cartridge further read in process	Platform	No LED, push cartridge further into port
6. LED steady illumination after 2 seconds if cartridge read OK (lot#, exp. Date, test type, patient ID) OPERATOR WALK AWAY and reuse sample		No steady LED, replace cartridge and reuse sample
7. Perform designated assay protocol		10–15 minutes
8. LED extinguishes, patient, test results, reference range and QC data stored in memory, displayed on screen and printed on attached printer		Downloaded to LIS when connected
9. Remove cartridge and discard in biohazardous solid waste (remove and sale sample tube if required)		

TABLE 2-continued

	Responsibility	Comments
Immunoassay		
Action		
1. Draw minimum of 1.5 ml whole blood Operator Exact volume sample in appropriate 5 ml vacutainer-type above minimum not draw tube, using standard draw procedure	Operator	Exact volume above minimum not critical
2. Push sample tube into cartridge tube dock and fully seat over needles	Operator	
3. Place patient ID bar code label in designated target area on tube dock	Operator	If ED bar code system used
4. Push cartridge into module port until fully seated over snap-type detents	Operator	
5. Pressurize sample tube and flow sample: 200 ul/test trip at 500 u./min	Platform	3X volume for (3) strip cartridge
6. Stop flow by: a. venting pressure to test strip manifold, or b. flow channel manifold if even distribution	Platform	Test strip manifold is a porous membrane
7. Read reflectance change on strip reaction areas at designated intervals	Platform	
Hemotology		
1. Draw minimum of 1.5 ml whole blood Operator Exact volume sample in appropriate 5 ml vacutainer-type above minimum not draw tube, using standard draw procedure	Operator	Exact volume above minimum not critical
2. Push sample tube into cartridge tube dock and fully seat over needles	Operator	
3. Place patient ID bar code label in designated target area on tube dock	Operator	If ED bar code system used
4. Push cartridge into module port until fully seated over snap-type detents	Operator	
5. Pressurize sample tube and flow sample to segment at 200 ul	Platform	
6. Stop flow by venting pressure to sample tube	Platform	
7. Pressurize diluent and flow to wash sample segment into mixing chamber	Platform	
8. Stop flow by venting pressure	Platform	How mix
9. Mix sample and diluent	Platform	
10. Pressurize mixed sample and flow to flowcell.	Platform	
11. Stop flow by venting pressure	Platform	
12. Repeat steps 10 and 11 (4) times	Platform	
13. Segment 50 ul of sample	Platform	
14. Mix with 500 ul of Hb reagent	Platform	
15. Flow mixed sample into flowcell: 100 ul at 1 ml/min	Platform	
Electrolytes		
1. Draw minimum of 1.5 ml whole blood Operator Exact volume sample in appropriate 5 ml vacutainer-type above minimum not draw tube, using standard draw procedure	Operator	Exact volume above minimum not critical
2. Push sample tube into cartridge tube dock and fully seat over needles	Operator	
3. Place patient ID bar code label in designated target area on tube dock	Operator	If ED bar code system used
4. Push cartridge into module port until fully seated over snap-type detents	Operator	
5. Pressurize sample tube and flow sample to segment: 300 ul at 2 ml/min.	Platform	
6. Stop flow by venting pressure	Platform	
7. Pressurize sample tube and flow sample through cartridge: 400 ul at 3 ml/min.	Platform	
8. Stop flow by venting pressure	Platform	

*Operation at Instrument

[0062] FIGS. **8** through **11** are flow charts illustrating point of care diagnostic platform **10** of the present invention. FIG. **8** is a flow chart illustrating an overall methodology of the point of care diagnostic platform of the present invention. FIG. **9** is a flow chart illustrating one embodiment of a cartridge processing procedure implemented with the point of care diagnostic platform of the present invention. FIG. **10** is a flow chart illustrating one embodiment of an immunoassay operating procedure implemented with the point of care diagnostic platform of the present invention. FIG. **11** is a flow chart illustrating one embodiment of a hematology operating procedure implemented with the point of care diagnostic platform of the present invention.

[0063] In the preceding example, all reagents and waste are contained in cartridge **20**. Fluids are moved in cartridge **20** via an external pump (in the module) coupled to cartridge **20** via an air dock. Likewise the reagents and sample are directed sequentially by valve(s) with-in the cartridge but activated through physical engagement to an external activator in the module. Cartridge **20** contains the fluid flow, fluid distribution fluid segmentation and sample dilution. A module **12** controls the fluid flow via a low pressure air connection and the fluid selection via one or more valve connections.

[0064] In another embodiment, platform **10** provides real time QC monitoring, and real time test result threshold detection, as disclosed in U.S. Provisional No. 60/470,725, incorporated herein by reference.

[0065] While embodiments of the invention have been illustrated and described, it is not intended that these embodiments illustrate and describe all possible forms of the invention. Rather, the words used in the specification are words of description rather than limitation, and it is understood that various changes may be made without departing from the spirit and scope of the invention.

What is claimed:

1. A point of care diagnostic system, comprising:

an analytic cartridge adapted to receive a blood draw tube such that the cartridge can directly accept a blood sample from the blood draw tube, the cartridge adapted to perform an assay on the blood sample and to produce an indication of an assay result entirely within the cartridge.

2. The system of claim 1, wherein the cartridge includes a dock for receiving a draw tube.

3. The system of claim 1, wherein the cartridge includes at least one flow channel fluidly coupled to a draw tube when the draw tube is mounted in the cartridge.

4. The system of claim 2, wherein the cartridge includes a calibration chamber fluidly coupled to the flow channel.

5. The system of claim 2, wherein the cartridge includes a waste chamber fluidly coupled to the flow channel.

6. The system of claim 1, wherein the cartridge includes wet and dry chemistries.

7. The system of claim 1, wherein the cartridge includes at least one of immunoassay, hematology, electrolyte, general chemistry and molecular diagnostic capabilities.

8. The system of claim 1, wherein the cartridge is barcoded.

9. The system of claim 8, wherein the cartridge is barcoded with information for test protocols, and lot expiration dates.

10. The system of claim 1, wherein fluids are retained and sealed in the cartridge.

11. The system of claim 1, wherein the cartridges include serialized identification.

12. The system of claim 8, wherein a sample ID barcode is attached to the cartridge for automatic patient identification.

13. The system of claim 1, wherein a sample contained in a draw tube is removable after analysis.

14. The system of claim 1, wherein the cartridge includes wet and dry chemistries and at least one substrate that carries a chemistry.

15. The system of claim 1, wherein the cartridge is configured to isolate biohazards in the cartridge from an operator of the cartridge.

16. The system of claim 1, wherein the cartridge is configured to provide introduction of a blood sample to the cartridge while isolating biohazards in the cartridge from an operator.

17. The system of claim 1, wherein the cartridge is configured to provide introduction of a blood sample to the cartridge without exposing an operator to patient material in the cartridge.

18. The system of claim 1, wherein the cartridge is configured to provide removal of a blood sample from a vial and introduction of the blood sample to the cartridge without exposing the patient or an operator to the blood sample.

19. The system of claim 1, wherein the cartridge is configured to provide that an operator is not exposed to contents in the cartridge.

20. The system of claim 1, wherein the cartridge is configured to work with whole blood.

* * * * *

专利名称(译)	护理点诊断平台		
公开(公告)号	US20070059204A1	公开(公告)日	2007-03-15
申请号	US11/517007	申请日	2006-09-06
当前申请(专利权)人(译)	FASTRAQ INC.		
[标]发明人	WITTY THOMAS R CASE ROBERT		
发明人	WITTY, THOMAS R. CASE, ROBERT		
IPC分类号	G01N21/00 G01N G01N21/05 G01N33/00 G01N33/53 G01N33/543		
CPC分类号	G01N21/05 G01N33/5302 G06F19/366 Y10T436/11 Y10T436/118339 Y10T436/117497 Y10T436/115831 G16H10/40		
优先权	60/470725 2003-05-14 US		
外部链接	Espacenet USPTO		

摘要(译)

公开了一种护理点诊断系统，其包括适于接收抽血管的分析盒，使得盒可以直接接受来自抽血管的血液样本。该盒适于对血液样品进行测定并且完全在盒内产生测定结果的指示。