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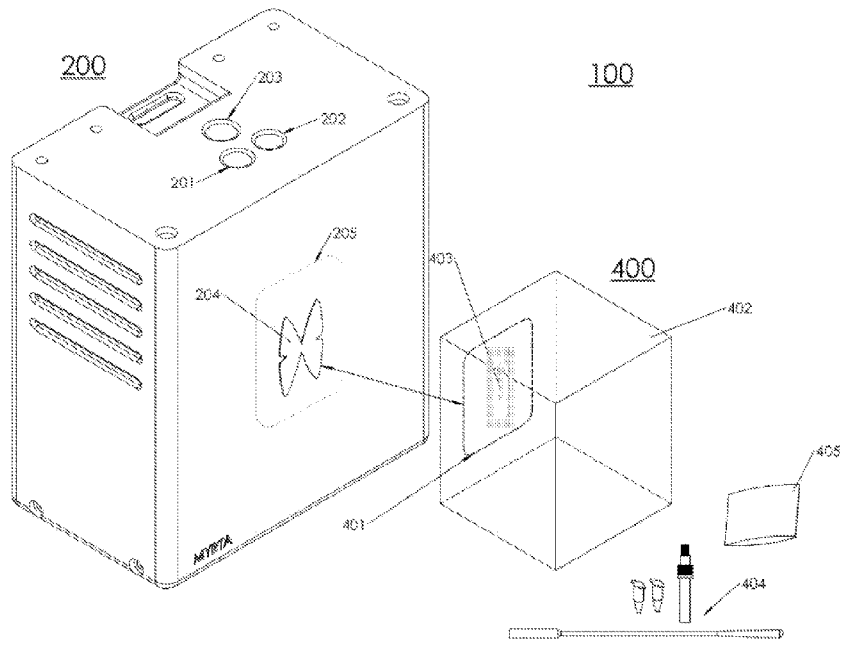
(54) Title: SYSTEM FOR IN VITRO MOLECULAR DIAGNOSTIC

Fig. 1




(57) Abstract: A system for in vitro molecular diagnostic of an analyte is described. The system includes a test kit and a diagnostic device. The system provides automatic conveyance of kit information to the diagnostic device, including diagnostic protocols, simultaneous with the conveyance of other information regarding the test. The system can sequentially run different molecular diagnostics without programming the diagnostic device between diagnostics because of the information received by the diagnostic device from the test kit. This system allows these different molecular diagnostics to be run without connection to the internet and a remote server.

*[Continued on next page]*

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— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

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— *with international search report (Art. 21(3))*

# SYSTEM FOR IN VITRO MOLECULAR DIAGNOSTIC

**[0000]** This application claims the benefit of priority to United States Provisional Patent Application No. 63/394,785 filed August 3, 2022, entitled "SYSTEM FOR IN VITRO MOLECULAR DIAGNOSTIC" which is incorporated by reference in its entirety.

## Background

**[0001]** Near-field communication (NFC) is a contactless communication technology that operates in the 13.56 MHz frequency range. For this reason, it is considered a type of RFID (radio frequency identification) technology. This technology works within a limited distance, typically 4.0 inches or less. Because of this, it is considered as a relatively secure communication tool. Therefore, industries like banking, finance, and healthcare use this technology in various ways. For example, many smart phones and credit cards use this technology. From tapping a credit card at a gas station to purchasing clothes in a dress store, NFC technology may play a role (see, Karpischek, S., Michahelles, F., Resatsch, F., & Fleisch, E. (2009). Mobile sales assistant: An NFC-based product information system for retailers. Proceedings - 2009 1st International Workshop on Near Field Communication, NFC 2009, 20–23, and Kang, S. G., Song, M. S., Kim, J. W., Lee, J. W., & Kim, J. (2021)), Near-Field Communication in Biomedical Applications. *Sensors (Basel, Switzerland)*, *21*(3), 703, provides a review on uses of NFC technology for biomedical applications.

**[0002]** In most of the common applications, near-field communication takes place between an active device (reader / writer device) and a target device which may be active or passive. An active device (meaning a powered device) can work in a reader/writer mode. For example, in the "reader mode", the NFC enabled device can read information stored on an NFC tag. These NFC tags are passive devices (i.e. NFC tags do not have a power source).

**[0003]** NFC tags can be embedded in labels, packaging, logo, and the like with the appropriate information depending on the application. As passive devices, NFC tags draw power from the NFC reader device. When the NFC reader device is positioned close to a tag, the NFC reader device energizes the NFC tag by magnetic induction. Once this happens, data is transferred from the NFC tag to the NFC reader device. There are different types of NFC tags (Type 1 to Type 5) and some can be re-written. The difference in the types refer to various levels of storage capacity, read/write speeds and data transfer capabilities. The use of NFC communications in biomedical applications is increasing as described in Dr. Shyman Thangaraju (2013), Near Field Communication in Medical Devices, White Paper HCL Technologies, (April 2013).

**[0004]** Conventional systems for in vitro molecular diagnostics include manual programming of the diagnostic device to specify the diagnostic protocol for the diagnostic device to run on a biological sample to detect the presence or absence of an analyte. This manual programming does not convey other information about the biological sample, such as the name of the sample collection kit, the kit id number, date of manufacture of the kit, batch number of the kit, and / or serial number of the kit. Moreover, this manual programing must be updated or changed to run different diagnostic protocols. It is therefore desirable to deploy NFC communications in molecular diagnostic systems in in vitro settings that allow for automatic conveyance of diagnostic protocols to a diagnostic device, simultaneous with the conveyance of other information regarding the biological sample.

## Summary

**[0005]** In aspects, a system for in vitro molecular diagnostic of an analyte, the system including a test kit, the test kit comprising a near field communication (NFC) tag, wherein the NFC tag includes kit information, the kit information including a diagnostic protocol information configured for analyzing the

analyte with a diagnostic device; a container configured for receiving testing components; and the testing components, configured for preparation of a biological sample to analyze the presence or absence of the analyte via in vitro molecular diagnostic using the diagnostic device; the diagnostic device for analyzing the analyte using the diagnostic protocol instructions, wherein the diagnostic device has an embedded NFC reader.

**[0006]** In aspects, the system of paragraph [0005], wherein the test kit further includes instructions for collection of the biological sample.

**[0007]** In aspects, the system of paragraph [0005], wherein the NFC tag is attached to an outside side of the container.

**[0008]** In aspects, the system of paragraph [0005], wherein the testing components include a biological sample collection swab for collection of the biological sample; a sample collection tube for receiving the biological sample collection swab, the sample collection tube includes a buffer analyzing the biological sample; one or more tubes for receiving the biological sample, where the one or more tubes includes reagents configured for conducting the molecular diagnostic.

**[0009]** In aspects, the system of paragraph [0005], wherein the embedded NFC tag of the container further includes test kit information, the test kit information comprising a name of the test kit, a test kit id, a date of test kit manufacture, a test kit serial number, and a result reporting format.

**[0010]** In aspects, the system of paragraph [0009], wherein the kit information further comprises a test kit batch number, and a test kit expiry date.

**[0011]** In aspects, the system of paragraph [0005], wherein the diagnostic device is a thermal cycler for polymerase chain reaction (PCR) molecular diagnostic.

**[0012]** In aspects, the system of paragraph [0011], wherein the diagnostic protocol information is cycling conditions for PCR molecular diagnostic.

**[0013]** In aspects, a method of use of a system for in vitro molecular diagnostic of an analyte, the method including activating a diagnostic device of the system, where the activation comprises bringing a near field communication (NFC) tag of a test kit within proximity of a NFC reader of the diagnostic device,

wherein the NFC reader receives a molecular diagnostic protocol information from the NFC tag; initiating a molecular diagnostic protocol of the received molecular diagnostic protocol information on a collected biological sample prepared in accordance with instructions of the test kit; reporting an analysis of the molecular diagnostic protocol to determine the presence or absence of the analyte.

**[0014]** In aspects, the system of paragraph [0013], wherein the diagnostic device is a thermal cycler for polymerase chain reaction (PCR) molecular diagnostic.

**[0015]** In aspects, the system of paragraph [0014], wherein the molecular diagnostic protocol information comprises cycling conditions for PCR molecular diagnostic.

**[0016]** In aspects, the system of paragraph [0013], wherein in activating the NFC reader further receives kit information from the NFC tag, the kit information comprising a name of the test kit, a test kit id, a date of test kit manufacture, a test kit serial number, and a result reporting format.

**[0017]** In aspects, the system of paragraph [0014], wherein the kit information further comprises a test kit batch number, and a test kit expiry date.

## Figures

**[0018]** Fig. 1 represents a system for in vitro molecular diagnostic of an analyte.

**[0019]** Fig. 2 represents a NFC tag of the test kit.

**[0020]** Fig. 3 represents a schematic of the operating system for the diagnostic device.

**[0021]** Fig. 4 represents a method of using the system for in vitro molecular diagnostic of an analyte.

## Detailed Description

**[0022]** A system for in vitro molecular diagnostic of an analyte is described. The system includes a test kit and a diagnostic device. The system provides automatic conveyance of kit information to the diagnostic device, including diagnostic protocols, simultaneous with the conveyance of other

information regarding the test (i.e. information about the test kit (test kit information) that may include the name of the test kit, the test kit id number, date of manufacture of the test kit, batch number of the test kit, and / or serial number of the test kit). The system can sequentially run different molecular diagnostics without programming the diagnostic device between diagnostics because of the information received by the diagnostic device from the test kit. For example, a COVID-19 molecular diagnostic may be run on the diagnostic device according to the method described herein, and immediately thereafter an influenza A molecular diagnostic may be run on the diagnostic device according to the method described herein. This system allows these different molecular diagnostics to be run without connection to the internet and a remote server.

**[0023]** As used herein biological samples may be a nasal swab, nasopharyngeal swab, buccal swab, throat swab, or urogenital or anal swab that are collected using a cotton tipped swab or flocked nylon swab. Or for example, the collected biological sample may be a biological sample in a viral transport media (VTM) or universal transport media (UTM) to prevent degradation of the nucleic acids when detection will not occur simultaneous to collection. Or for example, the collected biological sample may be blood collected on a glass rod.

**[0024]** As used herein analyte means a nucleic acid, such as DNA or RNA, for detection to determine the presence or absence of the nucleic acid, which may be used to diagnose a condition of interest, such as a viral or bacterial infection, cancer, or a genetic mutation.

**[0025]** Fig. 1 represents the system 100 for in vitro molecular diagnostic of an analyte, where the system includes a test kit 400 and a diagnostic device 200. The test kit of the system includes the components required to obtain a biological sample for an analyte of interest. For example, the test kit may be for obtaining a biological sample to detect the presence or absence of deoxyribose nucleic acid (DNA) or ribonucleic acid (RNA) of COVID-19. The test kit includes a container

402, an NFC tag 403, test components 404, and instructions 405. The test kit of the system may include a label 401. The container 402 of the system is configured for containing the test components 404 and instructions 405 and for having the NFC tag 403 and label 401 attached to it.

**[0026]** The NFC tag 403 of the system is a passive tag and is encoded with the kit information. The kit information includes the diagnostic protocol for the diagnostic device to detect the presence or absence of the analyte from the collected biological sample. The kit information may further include information on the test kit, such as the name of the sample collection kit, the kit id number, date of manufacture of the kit, batch number of the kit, and / or serial number of the kit.

**[0027]** The NFC tag 403 is attached to the container 402, such as on the front of the container 402. Preferably, the NFC tag 403 is attached to the container underneath the label 401 (as shown in Fig. 1), such that the NFC tag 403 is not visible to users of the kit. Typically, the NFC tag is thin enough (0.2 to 0.8 mm range) and therefore fits under the label 401. Alternatively, the NFC tag 403 can be attached to any of the test components 404 if the size of the test components 404 permits such attachment.

**[0028]** The test components 404 of the test kit are configured for obtaining a biological sample that may be directly used in the diagnostic device. The test components 404 may include a swab for collection of the biological sample from the nose or mouth, a sample collection tube containing buffers configured for carrying out the molecular diagnostic in a volume from 0.5 to 2.0 milliliters (mL), reagents for carrying out the molecular diagnostic analysis for the analyte, and one or more tubes configured for carrying out the molecular diagnostic (e.g. polymerase chain reaction (PCR) tubes), where preferably the reagents are in the one or more tubes. As

shown in Fig. 4, the test components 404 are outside the container 402 (e.g. the test components are ready to use), however, the test components 404 reside in the container for storage prior to and after use.

**[0029]** For example, when the test kit 400 is configured to detect the presence or absence of COVID-19, the test components 404 include the following: reagents specific for PCR, where the reagents are lyophilized. The lyophilized reagents are found in two colored standard 0.2 mL PCR tubes configured for use with the diagnostic device. The first tube is a first color and contains all the PCR reagents necessary to amplify a region of the human Cox-1 gene. This can be considered as the internal positive control of the reaction. If the sample presented to the tube is a human sample, say from a nasal swab, this reaction has to work for the test to be considered functional (i.e. PCR was successfully run on the biological sample). Similarly, the second tube of a second color has all the PCR reagents necessary to amplify a region of the RdRp gene of the Coronavirus, if present in the sample introduced to the tube. In the case of the Cox-1 internal positive control in the first tube, the probe designed to detect Cox-1 is labeled with the Cy5 dye. Similarly, the probe designed to detect the RdRp gene in the second tube is labeled with the 6-FAM dye. These probes are conventional probes and described as TaqMan probes for wide use, such as those use for (detection of specific polymerase chain reaction product by utilizing the 5'---3' exonuclease activity of Thermus aquaticus DNA polymerase (see, P M Holland, R D Abramson, R Watson, and D H Gelfand in Proc Natl Acad Sci U S A. 88(16): 7276–7280 (1991).

**[0030]** In the example of the test kit 400 for detection of COVID-19, the test kit 400 will also have a sample collection tube in the test components 404. This sample collection tube will have 0. 6 mL of a buffer that is suitable for a nasal swab biological sample. The test kit 400 will also

have a swab provided that can be used to collect nasal samples following the instructions provided to the user.

**[0031]** The label 404 of the test kit 400 is configured to cover the NFC tag 403, such as a printed paper label or the like. The label 404 may contain writing that includes the name of the test kit.

**[0032]** The instructions 405 of the test kit 400 include instructions for collecting the biological sample for analysis of the analyte that is the subject of the test kit 400 and for operating the diagnostic device 200 to conduct the molecular diagnostic analysis for the presence or absence of the analyte. As shown in Fig. 4, the instructions 405 are outside the container 402 (e.g. the test components are ready to use), however, the instructions 405 reside in the container for storage prior to and after use.

**[0033]** The diagnostic device 200 of the system 100 is configured for conducting molecular diagnostics on the biological sample collected via the test kit 400. The diagnostic device includes an NFC reader 205. For example, the diagnostic device may be the device of the LIMITED WELL THERMAL CYCLING DEVICE PCT/US21/64256, where the device further includes the NFC reader 205. The NFC reader 205 is a conventional NFC reader that can read any corresponding NFC tag, where the operational software of the diagnostic device is programmed to respond to the NFC reader 205 commands. The NFC reader 205 is connected to the controlling board of the diagnostic device 200 as shown in Fig. 3. The NFC reader 205 creates a 13.56 MHz RF field with an antenna 204. The antenna 204 is attached the diagnostic device.

**[0034]** Fig. 2 represents the NFC tag 403. The NFC tag 403 is a conventional NFC tag. For example, the NFC tag 403 may be 1.5 inches in length and 0.75 inches wide and is 0.2 mm thick. The NFC tag 403 includes an integrated circuit (chip and antenna) 101 that is encoded with the

kit information, including the diagnostic protocol information and may be encoded with the test kit information. The back side of the tag is typically covered with a removable paper 102, which when removed will expose an adhesive allowing the tag to be attached to a suitable location.

**[0035]** To encode the NFC tag 403 with the data needed for the operating system of the diagnostic device to conduct in vitro molecular diagnostic of an analyte the following protocol may be used. The diagnostic device is conventionally programmed with the diagnostic protocol information using a user interface. Once the molecular diagnostic protocol information and kit information is programmed, the NFC tag is energized with the NFC reader (in writer mode) and the memory blocks are then written to the NFC tag 403 to program the NFC tag 403 with the particular molecular diagnostic protocol and kit information. This is a conventional procedure, but where the specific diagnostic protocol information is recognized only by the diagnostic device having the corresponding operating system configured for reading and executing the information from the NFC tag 403.

**[0036]** In this particular example, and as illustrated in Figure 1, the type of NFC tag used has 2528 bits of memory with NXP ICODE SLIX2 IC and supports the ISO 15693 and ISO 18000-3 Mode 1 protocols. The tag form factor is a wet inlay on printable PET (Polyethylene Terephthalate) with permanent pressure sensitive adhesive for the attachment of the NFC tag 403 to the container 402, for example.

**[0037]** Fig. 3 represents a schematic of the operating system 350 for the diagnostic device 200. The operating system of the diagnostic device includes the NFC antenna 204, such as a conventional ferrite backed NFC antenna, a printed circuit board (PCB) 300, a resistive heating element 310, and a power supply 312, where the operating system 350 is configured to operate the diagnostic device based on the diagnostic protocol and kit information from the NFC tag.

**[0038]** The PCB 300 includes an NFC reader 205, such as a 13.56 Mega Hertz (MHz) RFID reader, an oscillator 302, such as a 27.12 MHz oscillator, a crystal 304, such as a 25.00 MHz crystal, a microcontroller 306 (where the microcontroller has a central processing unit and storage medium (such as electrically erasable programmable read-only memory (EEPROM)), such as an ARM 32-bit microcontroller, and an analog to digital converter (ADC) 308, such as an 8 channel 16 bit ADC. The power supply 312 is a shielded power supply that converts alternating current to direct current from wall power 120 or 240 volt alternating current (represented by 314).

**[0039]** Fig. 4 represents a method of detecting the presence or absence of an analyte using the system 100. In 402 a diagnostic device is activated. The activation includes bringing the NFC tag 403 of the test kit 400 into proximity of the NFC reader 205 of the diagnostic device 200. During activation the NFC reader 205 reads the NFC tag 403 and the diagnostic device 200 activates, which may be indicated by a beeping of the diagnostic device 200 and flashing of a light on the diagnostic device. The activation further includes the NFC reader 205 reading the kit information, including the diagnostic protocol information and the test kit information from the NFC tag 403.

**[0040]** In 404, the molecular diagnostic protocol is initiated on a collected and prepared biological sample. Once a user has collected and prepared the biological sample according to the instructions of the test kit 100, the molecular diagnostic protocol is initiated, such as through pressing a "start" button on the diagnostic device 200. For example, the biological sample may be collected and prepared according to the procedure of SAMPLE EXTRACTION TUBE FOR METHOD FOR DETECTION OF RNA OR DNA U.S. Application No. 63/354,162. Once the diagnostic device 200 is initiated, the molecular diagnostic protocol begins.

**[0041]** For example, when COVID-19 is the analyte, the molecular diagnostic protocol includes the following procedures of this paragraph. The sample is heated for 3 minutes at 95 degrees Celsius (°C) in a sample well (represented by 203 in Fig. 1) after which the diagnostic device cools the heating block and beeps and flashes the light on the front of the diagnostic device 200. Once the user acknowledges this by pressing on the START button once, the diagnostic device 200 will stop beeping, change the light color to white and the button color to green. Following the instructions 405 of the test kit 400, the user takes the next steps in sample preparation of providing aliquots of the heated sample to the two PCR tubes. Upon completion of this step the START button of the diagnostic device is selected. Once the START button is selected, the color of the light changes and becomes violet, the block inside is heated to 42°C for 10 minutes followed by 95°C for 5 minutes. This is followed by 40 cycles at 90°C for 10 second and 54°C for 10 seconds. While the 40 cycles are happening, the light on the color bar on the device can change to various colors and becomes a status bar that is slowly filled from left to right. Once the 40 cycles are complete (the light status bar will be full), the block is cooled down to room temperature (25°C).

**[0042]** In 406, the analysis of the molecular diagnostic protocol is reported. Reporting the analysis include the diagnostic device 200 indicating the presence or absence of the analyte of interest based on the data collected from the molecular diagnostic reaction and in accordance with kit information received from the NFC tag 403.

**[0043]** For example, when COVID-19 is the analyte, the operating system of the diagnostic device 200 compares the data from the control and the test reactions (wells represented by 201 and 202 in Figure 1) and determines an outcome according to the information received from the NFC tag 403. If the test well and the control well had signal above background, the operating

system is programmed to turn the light to red and flash the light until the user presses the START button once. This means the sample tested was positive for the analyte (COVID-19). If the test well did not have signal above background and the control well had signal above background, then the operating system is programmed to turn the light to green and flash the light until the user presses the START button once. This means the sample tested was negative for the analyte (COVID-19). If the signal in the test tube was above or below background and the control well was also below background, then the operating system is programmed to turn the light to orange and flash the light until the user presses the START button once. This means the sample did not run as expected and therefore no result was available. In this instance the molecular diagnostic must be rerun. In all cases, hitting the START button at this stage resets the machine and the machine is ready to scan another NFC tag and receive another kit information, including the diagnostic protocol and test kit information.

**[0044]** For further example, the reporting may further include providing the analysis to a spreadsheet like format which can be obtained by the user connecting the diagnostic device 200 through a USB connection to a standard computer.

## Claims

1. A system for in vitro molecular diagnostic of an analyte, the system comprising:

a test kit, the test kit comprising

a near field communication (NFC) tag, wherein the NFC tag includes kit information, the kit information comprising

a diagnostic protocol information configured for analyzing the analyte with a diagnostic device;

a container configured for receiving testing components; and

the testing components, configured for preparation of a biological sample to analyze the presence or absence of the analyte via in vitro molecular diagnostic using the diagnostic device;

the diagnostic device for analyzing the analyte using the diagnostic protocol instructions, wherein the diagnostic device has an embedded NFC reader.

2. The system of claim 1, wherein the test kit further includes instructions for collection of the biological sample.
3. The system of claim 1, wherein the NFC tag is attached to an outside side of the container.
4. The system of claim 1, wherein the testing components comprise

a biological sample collection swab for collection of the biological sample;

a sample collection tube for receiving the biological sample collection swab, the sample collection tube includes a buffer analyzing the biological sample;

one or more tubes for receiving the biological sample, where the one or more tubes includes reagents configured for conducting the molecular diagnostic.

5. The system of claim 1, wherein the embedded NFC tag of the container further includes test kit information, the test kit information comprising a name of the test kit, a test kit id, a date of test kit manufacture, a test kit serial number, and a result reporting format.
6. The system of claim 5, wherein the kit information further comprises a test kit batch number, and a test kit expiry date.
7. The system of claim 1, wherein the diagnostic device is a thermal cycler for polymerase chain reaction (PCR) molecular diagnostic.
8. The system of claim 7, wherein the diagnostic protocol information is cycling conditions for PCR molecular diagnostic.
9. A method of use of a system for in vitro molecular diagnostic of an analyte, the method comprising:

   activating a diagnostic device of the system, where the activation comprises bringing a near field communication (NFC) tag of a test kit within proximity of a NFC reader of the diagnostic device, wherein the NFC reader receives a molecular diagnostic protocol information from the NFC tag;

   initiating a molecular diagnostic protocol of the received molecular diagnostic protocol information on a collected biological sample prepared in accordance with instructions of the test kit;

   reporting an analysis of the molecular diagnostic protocol to determine the presence or absence of the analyte.
10. The method of claim 9, wherein the diagnostic device is a thermal cycler for polymerase chain reaction (PCR) molecular diagnostic.
11. The method of claim 10, wherein the molecular diagnostic protocol information comprises cycling conditions for PCR molecular diagnostic.
12. The method of claim 9, wherein in activating the NFC reader further receives kit information from the NFC tag, the kit information comprising a name of the test kit, a test kit id, a date of test kit manufacture, a test kit serial number, and a result reporting format.

13. The method of claim 10, wherein the kit information further comprises a test kit batch number, and a test kit expiry date.

Fig. 1

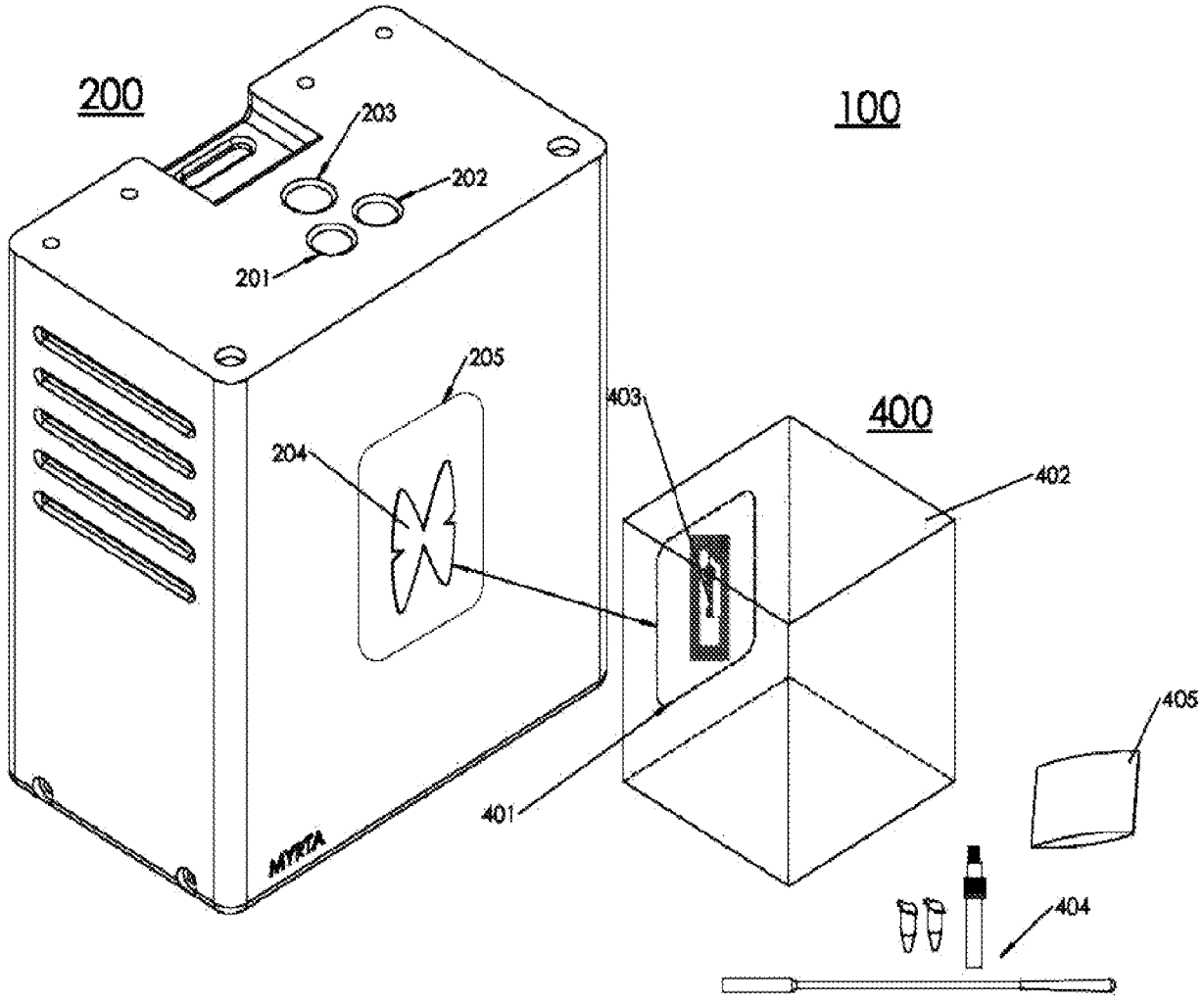


Fig. 2

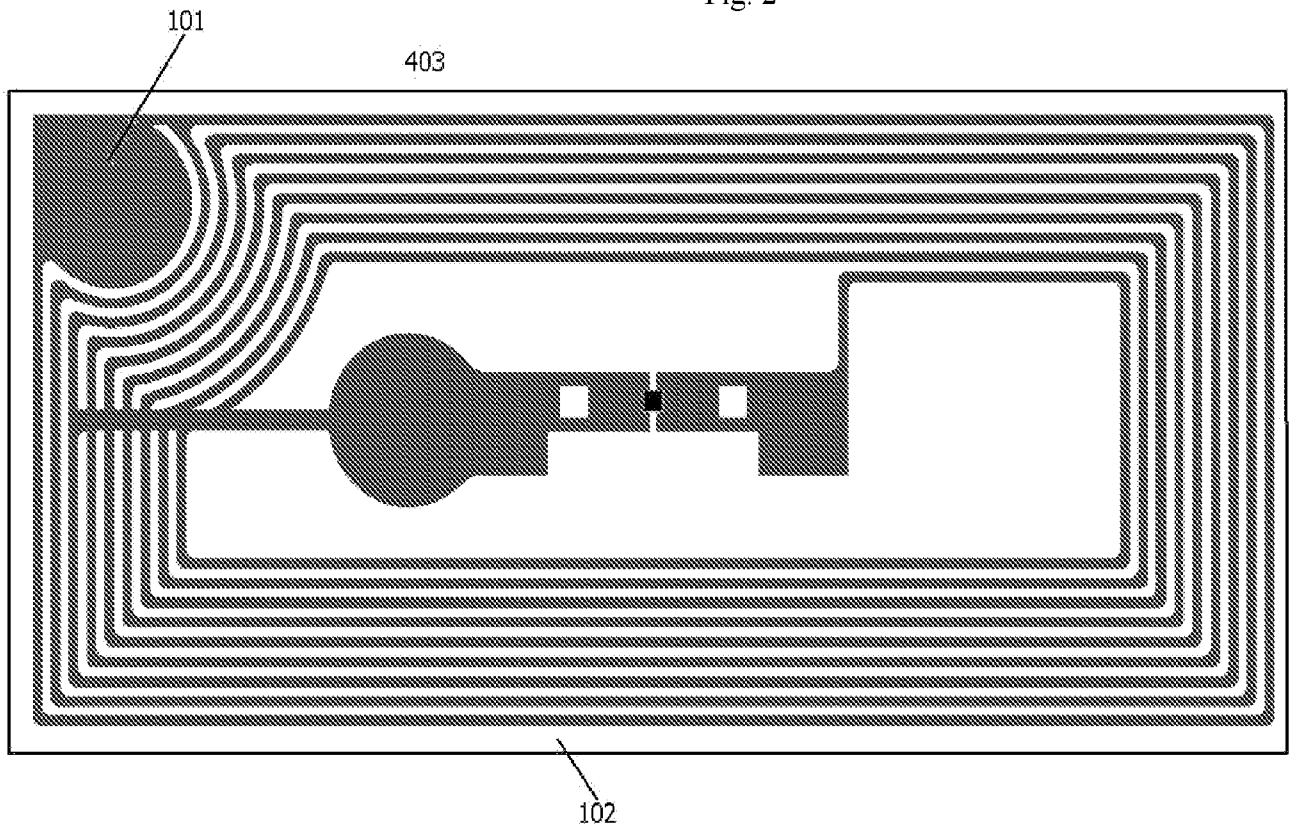


Fig.3

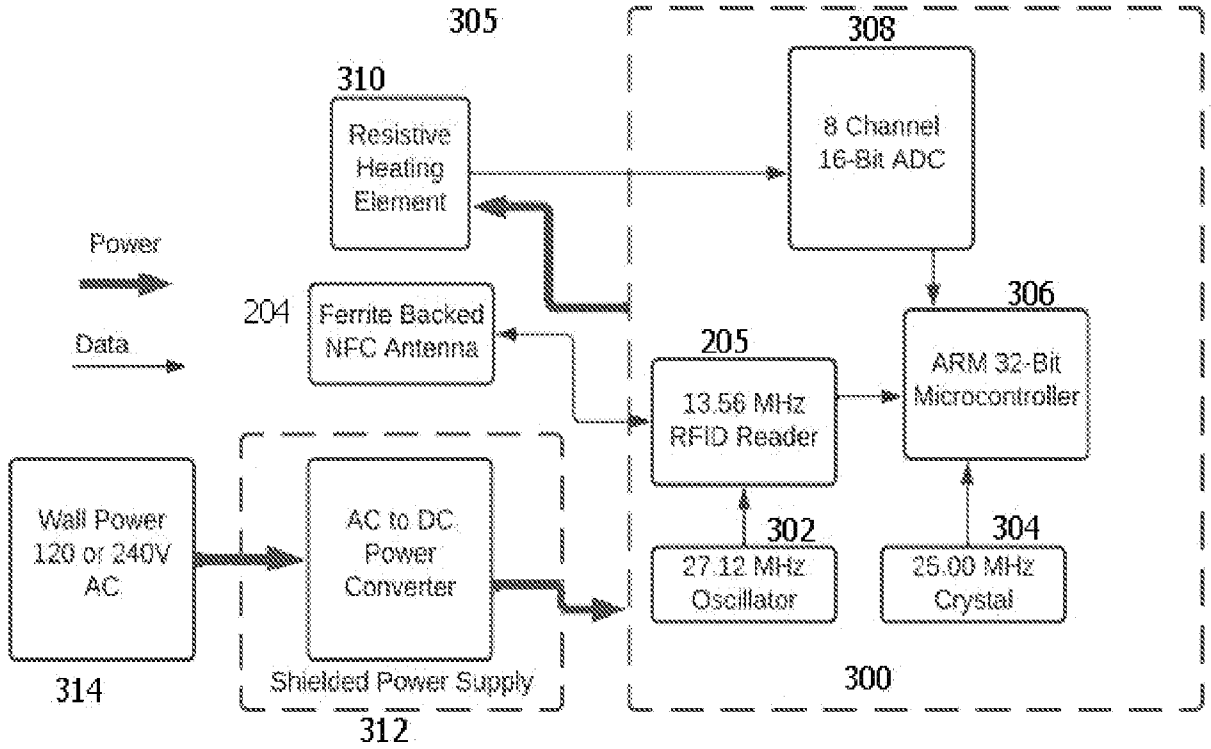
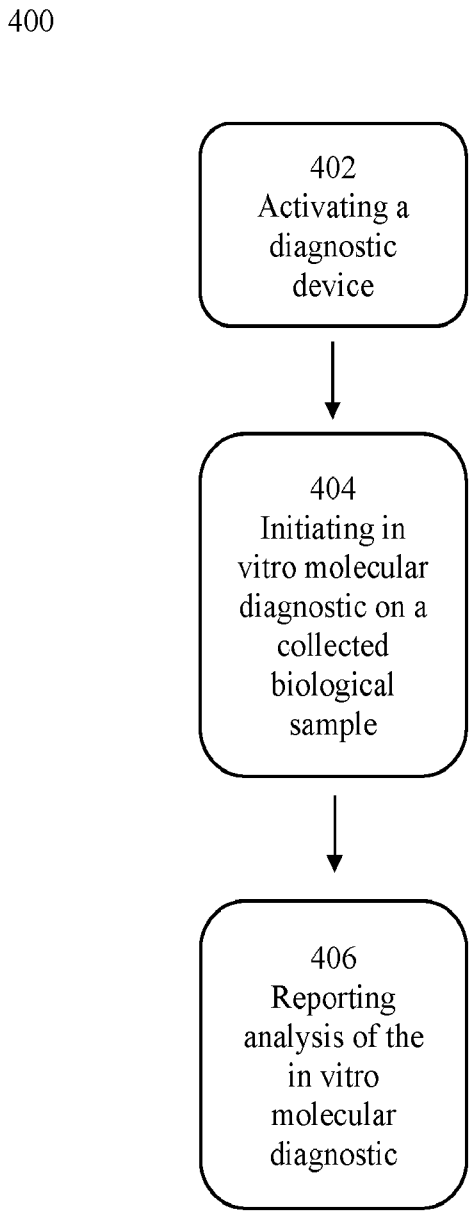

305
308
310
Resistive Heating Element
8 Channel 16-Bit ADC
Power
Data
204
Ferrite Backed NFC Antenna
306
205
13.56 MHz RFID Reader
ARM 32-Bit Microcontroller
Wall Power 120 or 240V AC
AC to DC Power Converter
302
304
27.12 MHz Oscillator
25.00 MHz Crystal
314
Shielded Power Supply
312
300

Fig. 4


400
402
Activating a diagnostic device
404
Initiating in vitro molecular diagnostic on a collected biological sample
406
Reporting analysis of the in vitro molecular diagnostic

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2023/029331

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - INV. - G16H 10/40; G01N 33/48; G16H 10/65; G01N 21/75; G16H 50/30 (2023.01)
ADD. - C12Q 1/686; G01N 1/02; G01N 21/27 (2023.01)

CPC - INV. - G16H 10/40; G01N 33/48; G01N 21/75; G16H 50/30; G16H 10/65 (2023.08)
ADD. - C12Q 1/686; G01N 1/02; G01N 21/27 (2023.08)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History document

Electronic database consulted during the international search (name of database and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X<br>---<br>Y | US 2021/0263018 A1 (EXPERIMENT X LTD.) 26 August 2021 (26.08.2021) entire document | 1, 3<br>---<br>2, 4-13 |
| Y | US 2006/0246598 A1 (DAI et al.) 02 November 2006 (02.11.2006) entire document | 2, 9-13 |
| Y | US 2021/0069718 A1 (VISBY MEDICAL INC.) 11 March 2021 (11.03.2021) entire document | 4 |
| Y | US 2016/0204833 A1 (DELL PRODUCTS L.P.) 14 July 2016 (14.07.2016) entire document | 5, 6, 12, 13 |
| Y | US 2018/0135102 A1 (BECTON, DICKINSON AND COMPANY) 17 May 2018 (17.05.2018) entire document | 7, 8, 10, 11 |

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