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(71) Applicant: **NANOBİZ TEKNOLOJİ ANONİM ŞİRKETİ** [TR/TR]; Üniversiteler Mah. İhsan Doğramaci Blv. Galyum 27/218, Çankaya/Ankara (TR).

(72) Inventor: **ÖKTEM, Hüseyin Avni**; Mutlukent Planlamacilar Sitesi 2025. Sokak No:4, Beysukent, Çankaya/Ankara (TR).

(74) Agent: **YALCINER, Ugur G. (YALCINER PATENT & CONSULTING LTD.)**; Remzi Oguz Arik Mah. Tunus Cad. No:85/3-4, 06680 Cankaya/Ankara (TR).

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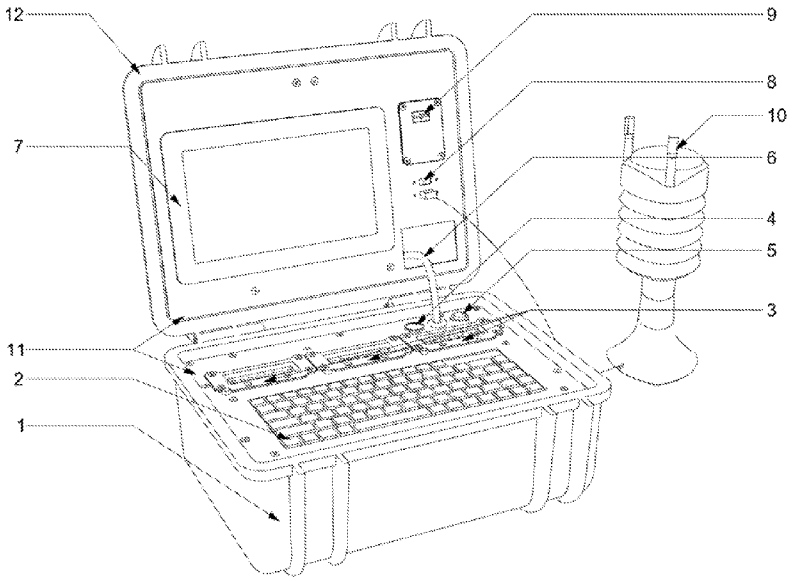

FIGURE 1

(57) Abstract: This invention defines the portable apparatus/device, method and their usage areas in accordance with the concept of the Internet of Things, which can be used to identify biological agents such as bacteria, bacterial spore, fungus (mold), yeast, virus, algae and pollen, parasite, parasite egg, meat species and genetically modified organisms using nucleic acid-based techniques outside the laboratory.

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PORTABLE DEVICE, KIT AND USAGE AREAS FOR DIAGNOSIS BASED ON ISOTHERMAL NUCLEIC ACID AMPLIFICATION

TECHNICAL FIELD RELATED TO INVENTION

The invention relates to devices, apparatus, test kits that can be used in the diagnosis of various biological agents with nucleic acid-based methods in settings other than equipped laboratories, and to their usage areas.

THE STATE OF THE ART (PRIOR ART)

There are widely used techniques such as ELISA, polymerase chain reaction (PCR), reverse transcription-polymerase chain reaction (RT-PCR) in the detection and diagnosis of biological agents.

Techniques used in the detection of biological agents with 100% accuracy, in other words, identification of biological agents are known as nucleic acid (NA) based techniques. These techniques are based on the principle of detection by amplifying the regions that are located on the nucleic acid (DNA or RNA) samples obtained from the target biological agent and are specific to the target agent. Techniques such as PCR, RT-PCR, isothermal amplification are widely used for this purpose, and they are still regarded as the "gold standard" techniques used in the identification of biological agents in many fields.

In order to obtain nucleic acid from the sample containing the target agent for the application of nucleic acid-based techniques, different requirements must be met such as pre-enrichment, nucleic acid isolation, preparation of different reagents for the tubes to be used in the reaction, reagents that need to be stored at -20 degrees such as enzymes, primers, precise pipetting at the microliter level, preferably a sterile environment to prevent possible contamination. Due to these requirements, a well-equipped molecular biology laboratory is required to apply NA-based techniques and expert personnel are required to make the above-mentioned preparations. Another important issue in NA-based analyzes is the problems that may occur during the transfer of samples collected from the field to the laboratory for analysis (such as sample deterioration, contamination) and the result may be delayed due to elapsed time.

Accordingly, different problems can be experienced in different sectors. For example, in a patient, treatment can be started late, as in the COVID19 pandemic, contamination and disease can become widespread and the damages can reach enormous dimensions since isolation and treatment are started late in veterinary practices. In the food sector, significant losses can occur due to delays in shipment or withdrawal of shipped goods.

Due to the reasons stated above, the application of nucleic acid-based methods outside the laboratory has not become widespread, and with the current state of the art, these analyzes can often be performed by expert personnel in a fully equipped laboratory. Therefore, there is an important need for high-accuracy molecular tests to be performed in the field.

SUMMARY OF THE INVENTION

This invention defines devices, apparatus, kits and their areas of use that make it possible to perform NA-based analyzes on the bedside or pen side in the field.

Two basic versions of the device are defined in the invention. One of them is designed in a format that the screen, keyboard and electronics can be carried in a single bag. The other device version being described contains all of the above-mentioned components in a case that is small enough to be carried by hand. The device can also perform NA-based tests using the kits defined in this invention, automatically analyze the test results and display the results on the screen, and perform all functions required to transmit them to third parties by SMS, e-mail and voice calls in accordance with the Internet of Things (IoT) concept. The device of the invention can also exchange data by communicating with smart devices such as mobile phones and tablets.

The kits used in the devices are designed to contain all the reagents required to perform isothermal amplification-based nucleic acid tests for diagnosis of the target biological agent and the chemicals necessary for the release of nucleic acids from biological agents, all these components are contained in a single tube and are presented in reactive gel or dry format. By means of this kit format, when samples containing biological agents (such as nose/throat swabs, blood/serum samples taken from the patient) have sufficient agent concentration, they are applied directly to reaction tubes without any pre-preparation, pre-enrichment and/or nucleic acid purification, and the reaction is carried out by placing the tubes in the device defined in the invention, the result is automatically obtained, displayed on the screen of the devices, and can be transmitted to a central software and third parties via SMS, e-mail and

voice calls, including the GPS data of the location where the test is performed and sample information when desired. When desired, a portable meteorology station can be connected to the system and the meteorological data at the point where the analysis is made can be transmitted to the user or third parties defined in the system as stated above.

DEFINITIONS OF THE FIGURES EXPLAINING THE INVENTION

The figures and related explanations required to better understand the subject of the invention are as follows.

Figure 1. Portable device and parts in bag format

Figure 2. Exploded view of a portable device in bag format

Figure 3. View of the portable device in bag format from different angles (A. Top view, B. Front view, C. Screen view, D. Side view)

Figure 4. Hand-held device and its parts

Figure 5. Exploded view of the hand-held device

Figure 6. View of the hand-held device from different angles (A. Top view, B. Front view, C. Perspective view, D. Side view)

Figure 7. Reaction cartridge

Figure 8. View of the reaction cartridge from different angles (A. Front view, B. Back view, C. Perspective view, D. Side view)

DEFINITIONS OF THE ELEMENTS AND PARTS FORMING THE INVENTION

In order to explain the components of the applications developed in the invention better, the parts and pieces in the prepared figures are numbered separately and the explanation of each number is given below.

1. Portable bag
2. Keyboard
3. Reaction module
4. Turn on-off button
5. Socket

6. Data cable

7. Screen and computer

8. USB plugs

9. Barcode reader

10. Meteorological station

11. Connection panels

12. Carrying bag cover

13. Bag multi-electronic unit

14. Touch screen

15. Screen top cover

16. Screen bottom cover

17. Reaction module cover

18. Body upper part

19. Body lower part

20. Hand-held apparatus electronic unit

21. Rechargeable battery

23. Cartridge body

24. Reaction tubes

25. Cartridge cover

DETAILED DESCRIPTION OF THE INVENTION

The elements of the device forming the invention are shown in Figure-1-8. Two basic versions of the device are defined in the invention. One of them is designed in a format that the screen, keyboard and electronics can be carried in a single bag. The other device version being described contains all of the above-mentioned components in a case that is large enough to be carried by hand.

Figure 1 shows the diagnostic device in portable bag (1) format and its parts. Figure 2 shows the inside view of the diagnostic device in bag format. Figure 3 shows the diagnostic device in bag format view from different perspectives.

Figure 4 shows the diagnostic device in hand-held format. Figure 5 shows the diagnostic device in hand-held format view from different perspectives. Figure 6 shows the inside view of the diagnostic device in hand-held format. Figure 7 shows the cartridge used in the

diagnostic device and its parts. Figure 8 shows the cartridge used in the diagnostic device and its parts viewed from different perspectives.

The inventive test system, which includes two separate applications in a bag (LAMP4U®-BagLab) and hand-held (LAMP4U®-NanoLab) format, can perform highly sensitive molecular methods based on nucleic acid amplification, such as polymerase chain reaction (PCR) and loop-mediated isothermal amplification (LAMP) reactions without the need for any other device and/or laboratory infrastructure. Reaction tubes and disposable cartridge kits prepared to contain all the reagents required to perform the said reactions are also described in the present invention.

The biological agent diagnostic device of the invention includes;

- A housing apparatus suitable for hand carrying,
- A data input module where the user can input information,
- A data display module where the user can view information,
- Results and report module where the user can view the reaction results,
- Cartridges containing reaction tubes containing primer sets specific to the target agent to be diagnosed, reaction components in dry, liquid or gel form,
- At least one reaction module in which cartridges are placed, which performs the functions of heating and cooling the reaction tubes, detecting the reaction results, and
- An electronic unit containing electronic cards containing the driver units, analysis layers, power layers, embedded software required for operating the reaction blocks.

Detailed descriptions of the aforementioned systems and their parts are given below.

The term "hand-held case" defines the carrying bag (1) in the first embodiment of the invention and the device body in the second embodiment. The term "data input module where the user can input information" defines the keyboard (2) and the touch screen (14) in embodiments of the invention. The term "data display module where the user can view information" defines the screen and the computer (7) in the first embodiment of the invention and the touch screen (14) in the second embodiment of the invention.

In an embodiment of the present invention, the device in Bag format (LAMP4U®-BagLab) is contained in a portable bag (1) that is impact resistant and waterproof (IP67). The dimensions of the portable bag (1) are 40-45 cm x 30-35 cm x 17-23 cm in width-length-height,

respectively. Bag dimensions can also be smaller, such as 30-55 cm x 25-30 cm x 5-10 cm, provided that their functions remain the same. Bag dimensions are not limited to these.

The portable device in bag format includes a keyboard (2) where the user can input information, at least one reaction module (3), in which the cartridges used for diagnosis are placed and that performs the functions of heating, cooling, illuminating the reaction tubes, determining reaction results, turn on-off button (4), socket for energy connection (5), data cable (6) providing communication of screen and computer (7) with the electronic units (13), USB sockets (8) for connecting different devices such as touch screen and computer (7), meteorology station (10), barcode reader (9) to identify cartridges to the system, bag multi-electronic unit (13) including heating and cooling of at least one reaction module (3), image and signal capture, signal processing, communication, GPS data determination, communication units, connection panels (11) for connecting touch screen-computer-electronic units to the bag body (1) and bag cover (12) and screws for mounting.

In the second embodiment of the present invention, in the hand-held format system (LAMP4U®-NanoLab), it includes the touch screen (14), the screen upper cover (15), the screen lower cover (16), the reaction module cover (17), the body upper part (18), the body lower part (19), at least one reaction module (3), which performs the functions of heating, cooling, illuminating the reaction tubes, determining the reaction results, the hand-held apparatus electronic unit (20) including heating, cooling of at least one reaction module (3), image and signal capture, signal processing, communication, GPS data determination and communication units, the rechargeable battery (21) and screws for mounting.

The device in both embodiments can wirelessly communicate with smart devices such as mobile phones or tablets via radio frequency (RF) or internet connection and can be controlled in accordance with the IoT concept.

Reaction cartridges (Figure 7) contain the cartridge body (23), disposable reaction tubes (24), cartridge cover (25), barcode or QR code positioned on the cartridge. The cartridges include reaction tubes (24) containing chemicals required for the release of acids into the environment in the biological agents and all reaction components required for the diagnosis of biological agents by isothermal nucleic acid amplification method such as primer sets, enzyme, salt, detergent, buffer, dNTP molecules, ions, betaine, EDTA, signal-generating colored or fluorescent molecules and buffer chemicals in dry or gel format and a barcode printed label.

The operating principles of diagnostic systems have been created to be extremely simple, by means of the software they contain and simple user interfaces. An individual reaction tube has been created for each biological agent to be diagnosed. These reaction tubes contain all components that can amplify the target biological agent-specific gene region or gene regions by isothermal nucleic acid (DNA or RNA) amplification and make it possible to measure the amplified nucleic acids by changes in color change, fluorescence or magnetic properties. There are chemicals and other materials in the tube that make it possible to release nucleic acids from the biological agent into the reaction environment. These components are described in the examples below.

Reaction tubes were prepared to contain all components in dried or gel format for single use. By means of these features, reaction tubes make it possible to get results by adding the biological agent directly to the reaction tube without the need for any nucleic acid purification from the biological agent to be diagnosed. In addition, in the case of nucleic acid purification from a biological agent, the purified nucleic acids can be added to the reaction tube and a diagnosis can be made.

After the sample of the target biological agent to be determined is added to the reaction tubes, the tubes are placed in the carrier cartridge or the samples are added to the reaction tubes while the tubes are in the carrier cartridge. The label on the cartridge contains information on the preparation date of the reaction tubes, the expiry date, which biological agent or agents is/are to be diagnosed. This information is also processed into the barcode and/or QR code on the label. Experimental parameters to be used in the diagnosis of the target biological agent are also processed on the barcodes. In this way, before the cartridge is placed in the devices, barcode is scanned with a barcode reader or smart device, and after the cartridge is placed in the reaction module (3), the analysis can be started by commanding via the touch screens. Reactions can also be started with the information inputted on the device screens without reading the barcode. The analysis results are determined by the sensing units in the reaction module (3) and processed by the components in the electronic unit, and the result is displayed to the user after the reaction. The results obtained with these processes are simultaneously transmitted to users registered in the system via e-mail, SMS and voice calls via the communication module in the electronic unit.

Molecular test systems based on nucleic acid amplification such as PCR and LAMP are methods used to determine biological agents (such as COVID19) with high sensitivity and accuracy. However, a well-equipped infrastructure and expert personnel are required for the

application of these methods. In the most commonly used PCR method, nucleic acids (RNA or DNA) must first be isolated from the material to be tested. This process requires both time (60-100 minutes) and a separate nucleic acid purification kit and various laboratory devices such as centrifuge, vortex, micropipette and spectrophotometer. In addition, the reagents must be carefully pipetted in special sterile cabinets (biosafety cabinets) in order to prevent contamination from the environment during the preparation of the reaction tubes. After the necessary amount of nucleic acid is added to the reaction tubes, the reaction is started by placing the tubes in devices called thermal cycle devices. The reaction may take 80 to 120 minutes to result. At the end of this period, it is concluded that the reaction is positive or negative and necessary reporting procedures are carried out. As can be understood from here, this process takes approximately 3-4 hours and cannot be performed outside of the laboratory.

By means of the simple-to-use apparatus and disposable kits defined in the invention, it is possible to perform molecular tests in the field and at the bedside. Since the ready-to-use kits contain all the components necessary for the release of nucleic acids from the biological agents in the sample and for the amplification reaction to be performed, it is sufficient to directly add the samples taken from the patient to the reaction tubes in order to perform the test. Then, the reaction tubes are placed in the cartridge, and the cartridge is placed in the reaction module (3) in the portable devices, and the reactions can be started using the touch screens (7, 14) of the devices. The reactions are completed in 45-60 minutes and the results are displayed to the user on the screen. In addition, the results can be transmitted to the addresses registered in the system as SMS, voice calls and e-mails when requested.

In this way, highly sensitive molecular tests can be performed at the bedside without any processing in the field or at the bedside, and the obtained test results can be accessed instantly. It is also possible to automatically report test results to people and authorities in remote locations.

By means of these simple usage features, devices and kits have the potential to be used for different purposes in different sectors such as medicine, environment, agriculture, animal husbandry, but not limited to the examples below.

For example, one of the most important requirements in order to get ahead of the COVID-19 (SARS-CoV-2) pandemic, which is still happening worldwide, is that people infected with the virus can be tested quickly and with high accuracy. For this purpose, samples are taken from individuals in health units, at sample collection stations established on the field or working with the logic of "drive-in", but molecular tests cannot be performed at the point where the

sample is taken due to the reasons explained above, following the collection of a certain number of samples, the samples are transferred to the centers where molecular tests can be performed, tests are carried out and in the light of the obtained findings, the results of the person tested can be obtained. In case of infection, the patient is tried to be reached based on the records taken from the person. In some cases, since these processes take a few days, the person infected with the virus continues to spread the virus around during this process and the pandemic continues to grow.

Since LAMP4U© devices and kits can be used outside the laboratory, it makes it possible to perform molecular tests, especially at sample collection and test stations to be established in the field, first-level health institutions such as family health centers, non-fully-fledged hospitals and even at the bedside at home. In this way, people with virus infection can be diagnosed quickly by applying molecular tests and based on this diagnosis, appropriate triage can be made and necessary precautions can be taken and the spread of the pandemic can be prevented. Similarly, apparatus and kits have the potential to be used in land border crossings, ports, airports, military units, refugee camps, road control points, field hospitals, and temporarily established health units.

Another field in which LAMP4U© devices and kits can be widely used is the agriculture sector. For example, with samples taken from greenhouses and fields, the system will be able to quickly detect biological agents (such as mold, bacteria, fungi, viruses) that can cause disease and by taking the necessary precautions, a large-scale disease and therefore product loss can be prevented. It can also be used to determine whether there is a genetically modified organism (GMO) in different plant samples and/or plant products.

Similarly, a pathogen detected in different samples collected from poultry houses and barns where animals are densely sheltered will enable to take precautions with early warning. An important application in this regard is the fast and accurate detection of calf diarrhea. By using kits and devices on stool samples to be taken from animals with suspected disease, it will be possible to determine the disease agent very quickly and to initiate the necessary treatments. Likewise, it can be used to determine the disease agents that occur in fish and pond waters in fish farms.

The system of the invention identifies the biological agents such as spore, bacteria, virus, fungus (mold), yeast, algae, pollen, parasite, parasite egg in samples taken directly or processed after collection or in samples such as tissue, blood, serum, saliva, urine, sweat,

milk, honey, egg, body fluid, semen, sperm, vaginal fluid, stool, hair, feather, in soil, fresh water, sea water, environmental samples taken from the air; processed or unprocessed red meat, white meat, water products, such as fish and shrimp; in food products such as vegetables, fruits, grains, legumes, honey, molasses, jam; in plant parts such as leaves, roots, stems and flowers; flying-walking insects, snakes, lice, fleas and insects such as ticks; in poultry, ovine and bovine animals; in domestic animals (pets) such as horses, donkeys, cats-dogs-birds; in humans by a method based on nucleic acid amplification (such as loop-mediated isothermal amplification).

Examples of some of the studies carried out in order to demonstrate the applicability of the concept are given below.

EXAMPLE 1: Identification of *E.coli* O157:H7 bacteria by LAMP method without DNA isolation.

In this study, the amplification of gene regions specific to *E.coli* O157:H7 (EC) bacteria, which is an important pathogenic microorganism in foods, was studied by the loop-mediated isothermal amplification (LAMP) method. 2 microliter samples from the liquid samples that were grown in LB medium overnight and reduced to a bacterial concentration of 10^5 cfu/ml without any DNA isolation were added to the ready-to-use reaction tubes containing the components shown in Table 1. Then, the reaction module (3) was heated to 66°C. Initially, the reaction tubes are purple colored. As a result of the reaction, amplification and color change occurred in the tubes where EC was added. There was no color change in the tubes in which only water was added.

Table-1

Reaction Mixture (25 µL) components	
Solution name	**Amount**
Isothermal reaction buffer (10X)	2,5 µL
$MgSO_4$ (100 mM)	1,5 µL
Enzyme (8U/µL)	1 µL
dNTP (10 mM)	3,5 µL

FIP/BIP primer mixture (40 µM)	1 µL
F3/B3 primer mixture (5 µM)	1 µL
LF/LB primer mixture (10 µM)	1 µL
Betaine (5 M)	5 µL
Hydroxyl Naphthol Blue HNB (3 mM)	1 µL
Agarose gel solution (1,5%)	6.5 µL
Other Conditions	
Reaction temperature	66°C
Reaction time	1 hour

With these experimental results, it has been shown that using the LAMP method, the biological agent (EC) applied in reaction tubes where all the components required for the reaction are combined in a reactive gel format, can be detected by monitoring the color change that occurs after the reaction without any DNA isolation.

EXAMPLE 2: Identification of *Salmonella* bacteria by LAMP method without DNA isolation.

2 microliters samples that were grown in LB medium overnight at 42°C and contain *Salmonella* cells at a concentration of $1*10^4$ cfu/ml were added without any pre-preparation and/or DNA purification to the ready-to-use reaction tubes containing the components shown in Table 2 and dried by lyophilization. Then the electronic unit heated the reaction module (3) to 65°C. As a result of the reaction, amplification and color change occurred in the tubes where *Salmonella* was added. There was no color change in the tubes in which only water was added (without *Salmonella*). The color change in the tubes was detected by the sensing unit in the reaction module (3) and it was shown that *Salmonella* was detected on the screen by processing. By means of the Nanotakip software, this result was sent to the phone number registered in the system via e-mail and SMS.

This example shows that the signal (color change) generated as a result of the reaction is determined by the sensing unit, processed by the electronic processor and control unit within the electronic unit, the results are displayed and can be transmitted to the registered persons by SMS and E-mail by the software.

Table-2

Reaction mixture (25 µl) components	
Solution name	**Amount**
Isothermal reaction buffer (10x)	2,5 µl
$MgSO_4$ (100 mM)	1,5 µl
Enzyme (8U/µl)	1 µl
dNTP (10 mM)	3.5 µl
FIP/BIP primer mixture (40 µM)	1 µl
F3/B3 primer mixture (5 µM)	1 µl
LF/LB primer mixture (10 µM)	1 µl
Betaine (5M)	8 µl
HNB (3 mM)	1 µl
Water	3.5 µl
Other conditions	
Reaction temperature	65°C
Reaction time	1 hour

As shown in the examples above, with this invention, it is possible to diagnose biological agents in the air in real-time and to generate an early warning.

EXAMPLE 3: Diagnosis of COVID-19 (SARS-CoV-2) Virus reference material by Reverse transcriptase (RT)-LAMP method without RNA isolation.

Two microliters of the reference material from Acuplex™ SARS-CoV-2 reference material (Material code 0505-0119) in particle structure supplied from SERACARE company is placed in a 200 microliter plastic PCR tube and kept at 95° C for 15 minutes in the heat block and then, added directly to the ready-made reaction tubes containing the components shown

in Table 3 without any RNA isolation. The reaction tubes were purple before the reaction. The color change was observed in the amplified tubes as a result of the reaction performed for 60 minutes without any loop process at a constant 63°C in a standard thermal cycler. There was no color formation in the tube in which water was added (no reference material added) as expected.

As a result of the experiments shown in this example:

a) It is shown that molecular tests of COVID-19 (SARS-CoV-2) can be performed in 60 minutes without any RNA isolation step with the devices and methods defined by this invention.

b) It is shown that the reaction results can be detected by the naked eye as a result of the color changes in the reaction tubes without the need for any additional equipment.

c) It is shown that the reaction can be carried out even with a device that can keep the temperature constant at 63-65ºC (such as a heat block) without the need for a complex and expensive device.

Table-3

Reaction mixture (25 µl) components	
Solution name	**Amount**
Isothermal reaction buffer (10x)	2,5 µl
$MgSO_4$ (100 mM)	1,5 µl
Bst (8U/µl)	1 µl
RT enzyme (AMV, 10 U/µl or M-MuLV 200 U/µl)	3 or 1,25 µl
dNTP (10 mM)	3,5 µl
FIP/BIP primer mixture (40 µM)	1 µl
F3/B3 primer mixture (5 µM)	1 µl
LF/LB primer mixture (10 µM)	1 µl
Betaine (5M)	5 µl
EDTA	1 µl

HNB (3 mM)	1 µl
Water	1.5 or 2,25 µl
Other conditions	
Reaction temperature	63ºC
Reaction time	1 hour

EXAMPLE 4: Diagnosis of COVID-19 (SARS-CoV-2) Virus in Clinical Samples with or without RNA isolation by Reverse transcriptase (RT) -LAMP method.

Studies were carried out on nasal and throat swab samples in viral transport fluids (VTM or VNAT) that were reported as positive for SARS-CoV-2 by qRT-PCR method in the hospital laboratory taken from patients who applied with COVID-19 disease complaints in Ankara City Hospital. Different experiments were carried out with the reaction mixtures given in Table 3 and samples with known Ct (cycle threshold) values of qRT-PCR method.

a) RNA purification was performed with silica column or magnetic sphere-based kits of different brands on clinical samples contained in VTM or VNAT. 4 microliters of the purified RNA samples were added to reaction tubes, and the reaction was performed in the devices described in the present invention. Color change was observed in the tubes to which RNA was added. No color change was observed in the tubes to which water was added.

b) Clinical samples in VTM or VNAT that are known to be positive by RT-PCR with Ct values below 25 are kept in the heat block at 95°C for 15 minutes, and 4 microliters were added directly to the ready-to-use reaction tubes containing the components shown in Table 4 without any RNA isolation. The experiment was carried out in reaction tubes using the devices described in the present invention. Color change was observed in the tubes to which the sample was added. No color change was observed in the tubes to which water was added (without RNA added).

The experiments in the examples (a) and (b) above gave results in 45 minutes at 63°C. The results of the experiment were reported to the e-mail address recorded on the devices and to the mobile phone as e-mail, SMS and voice call.

As a result of the experiments shown in this example:

a) With the devices and methods defined by this invention, it is shown that COVID-19 (SARS-CoV-2) molecular tests in clinical (patient) samples can be performed in 45 minutes without any RNA isolation step or after a standard RNA isolation method.

b) It is shown that the phones registered in the system can be notified automatically.

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Table-4

Reaction mixture (25 µl) components	
Solution name	**Amount**
Isothermal reaction buffer (10x)	2,5 µl
$MgSO_4$ (100 mM)	1,5 µl
Bst (8U/µl)	1 µl
RT enzyme (AMV, 10 U/µl)	3 µl
dNTP (10 mM)	3,5 µl
FIP/BIP primer mixture (40 µM)	1 µl
F3/B3 primer mixture (5 µM)	1 µl
LF/LB primer mixture (10 µM)	1 µl
Betaine (5M)	5 µl
EDTA	1 µl
HNB (3 mM)	1 µl
Water	1,5
Other conditions	
Reaction temperature	63ºC
Reaction time	45 minutes

CLAIMS

1. A biological agent diagnostic device, characterized by comprising

- A housing apparatus suitable for hand carrying,
- A data input module where the user can input information,
- A data display module where the user can view information,
- Results and report module where the user can view the reaction results,
- Cartridges containing reaction tubes containing primer sets specific to the target agent to be diagnosed, reaction components in dry, liquid or gel form,
- At least one reaction module in which cartridges are placed, which performs the functions of heating and cooling the reaction tubes, detecting the reaction results,
- An electronic unit containing electronic cards containing the driver units, analysis layers, power layers, and embedded software required for operating the reaction blocks.

2. The device according to claim 1, characterized in that the said hand-held housing device is a portable bag (1) or a compact body.

3. The device according to claim 2, characterized in that the device containing the portable bag (1) comprises

- A keyboard (2),
- At least one bag reaction module (3), in which the cartridges used for diagnosis are placed and which performs the functions of heating, cooling, illuminating the reaction tubes and determining the reaction results,
- A turn on-off button (4),
- A socket (5) for energy connection,
- A data cable (6) providing communication of screen and computer (7) with the electronic units (13),
- A touch screen and computer (7),
- A barcode reader (9) to identify cartridges to the system,
- Bag multi-electronic unit (13) including heating and cooling of at least one reaction module (3), image and signal capture, signal processing, communication, GPS data determination, communication units,

- Connection panels (11) for connecting touch screen-computer-electronic units to the bag body (1) and bag cover (12).

4. The device according to claim 2, characterized in that the device containing the portable compact body comprises;

- A touch screen (14)
- A screen upper cover (15) and screen lower cover (16),
- A reaction module cover (17),
- A body upper part (18) and body lower part (19),
- At least one reaction module (3) performing the functions of heating, cooling, illuminating the reaction tubes and determining the reaction results,
- A hand-held apparatus electronic unit (20) including heating and cooling of at least one reaction module (3), image and signal capture, signal processing, communication, GPS data determination, communication units,
- A rechargeable battery (21).

5. The device according to claim 1, characterized in that said data input module is a keyboard (2) or touch screen (14).

6. The device according to claim 1, characterized in that the data display module where the user can view information is touch screen and computer (7) or touch screen (14).

7. The device according to claim 1, characterized in that said cartridges comprise a cartridge body (23), disposable reaction tubes (24), cartridge cover (25) and barcode or data matrix positioned on the cartridge.

8. The device according to claim 1, characterized in that said components are buffer, salt, detergent, enzyme, primer sets, dNTP molecules, ions, betaine, EDTA, signal-generating colored or fluorescent molecules and buffer chemicals.

9. The device according to claim 1, characterized in that said electronic units can transmit the data containing the test results wirelessly to smart devices via radio frequency (RF) or internet connection.

10. The device according to claim 1, characterized in that as the sample to be diagnosed, at least one from the group consisting of environmental samples, air samples, meat products, water products, food products, plant parts, insects, parts from animals and humans, biological fluids, feces and tissue samples is selected.

11. The device according to claim 1, characterized in that said target agent to be diagnosed is spore, bacteria, virus, fungus (mold), yeast, algae, pollen, parasite or parasite egg.

12. The device according to claim 1, characterized in that it is used in the diagnosis of Covid19/SARS-CoV-2.

13. The device according to claim 1, characterized in that the cartridge in the device amplifies gene regions specific to the target agent to be diagnosed by isothermal polymerase chain reaction (PCR) (loop-mediated isothermal amplification (LAMP) or other isothermal PCR methods), conventional PCR or real-time PCR method.

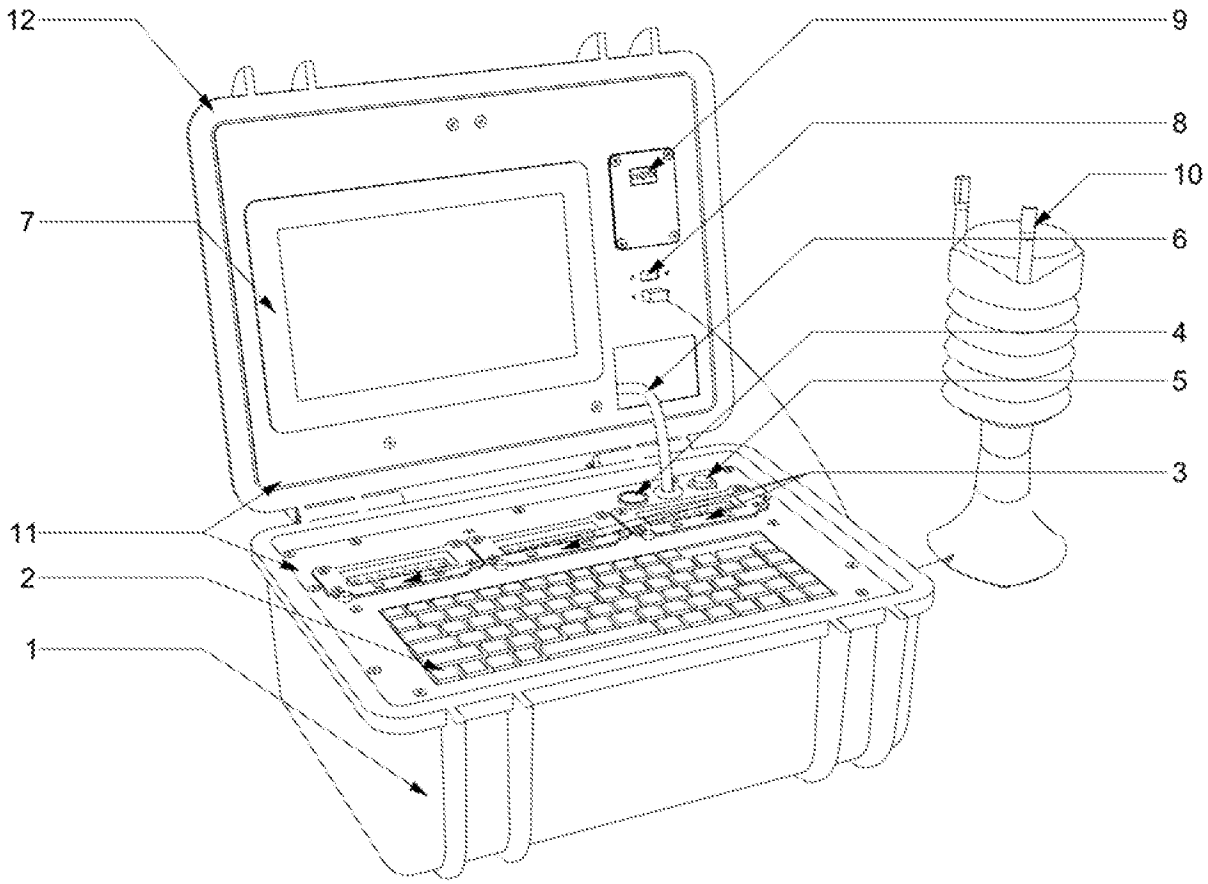


FIGURE 1

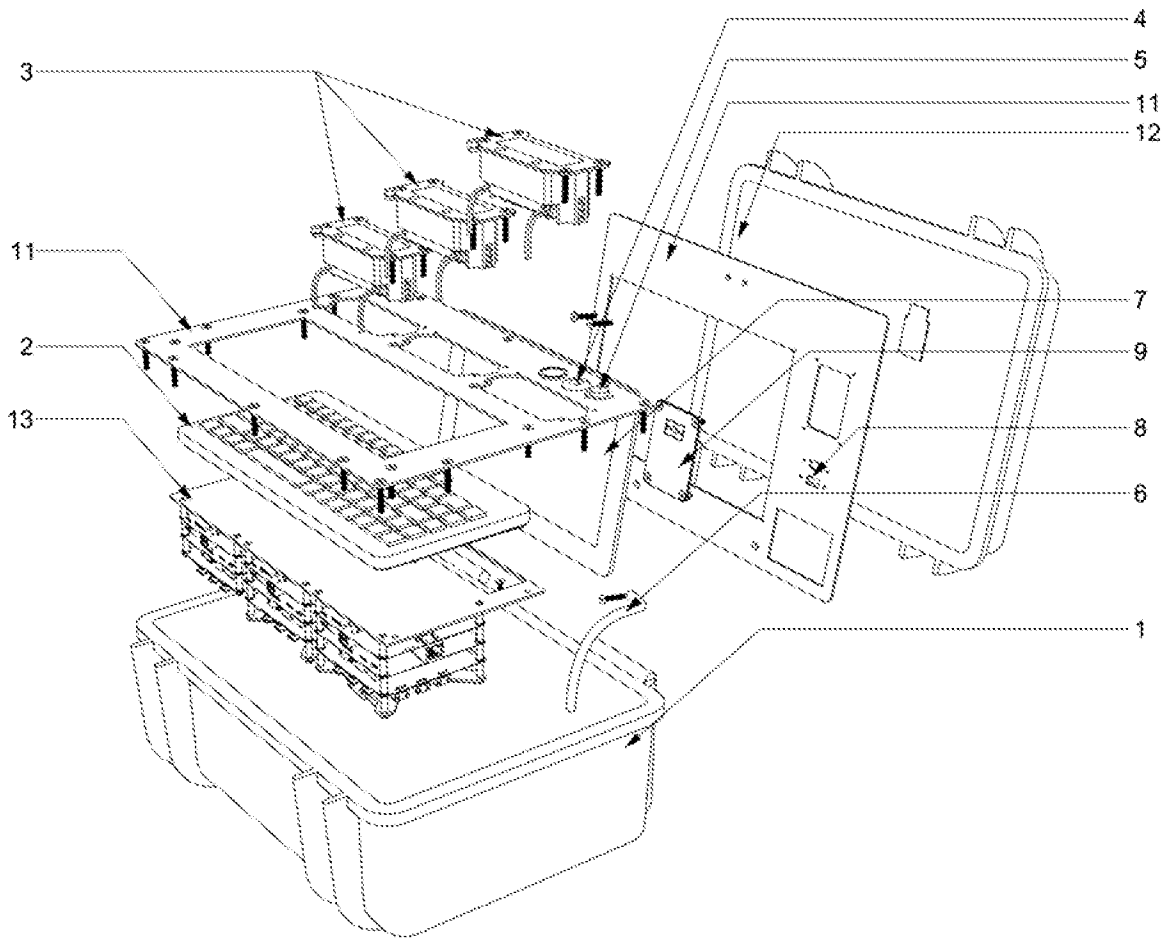
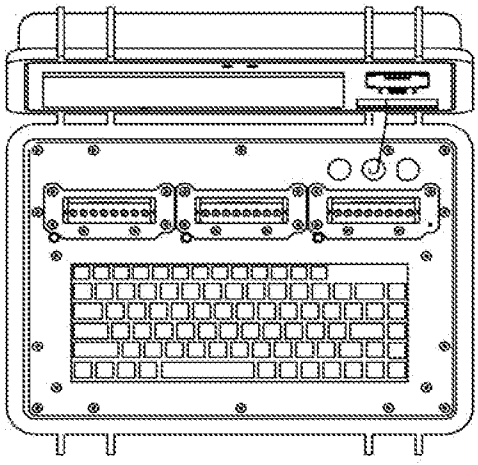
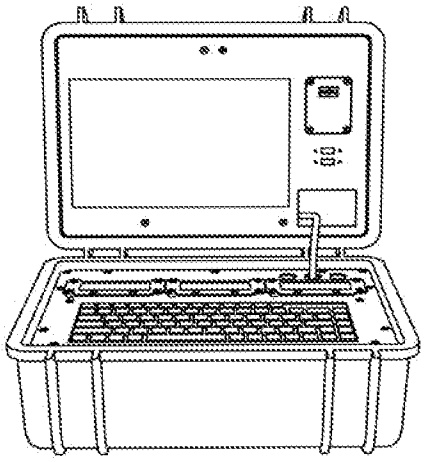


FIGURE 2



A



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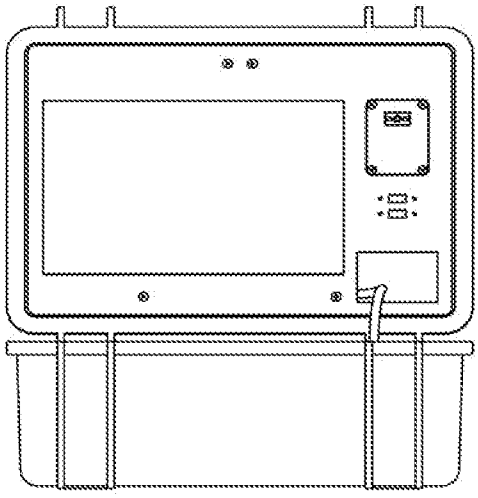
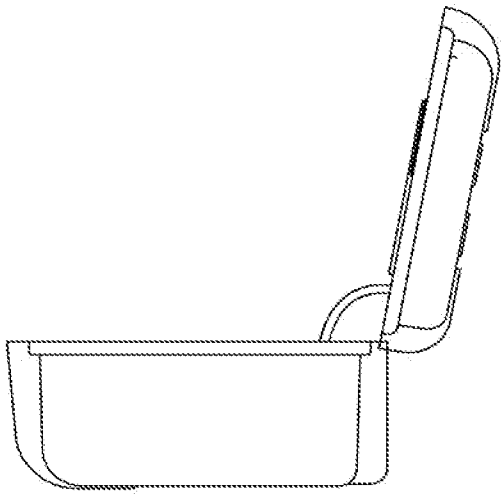


C



D

FIGURE 3

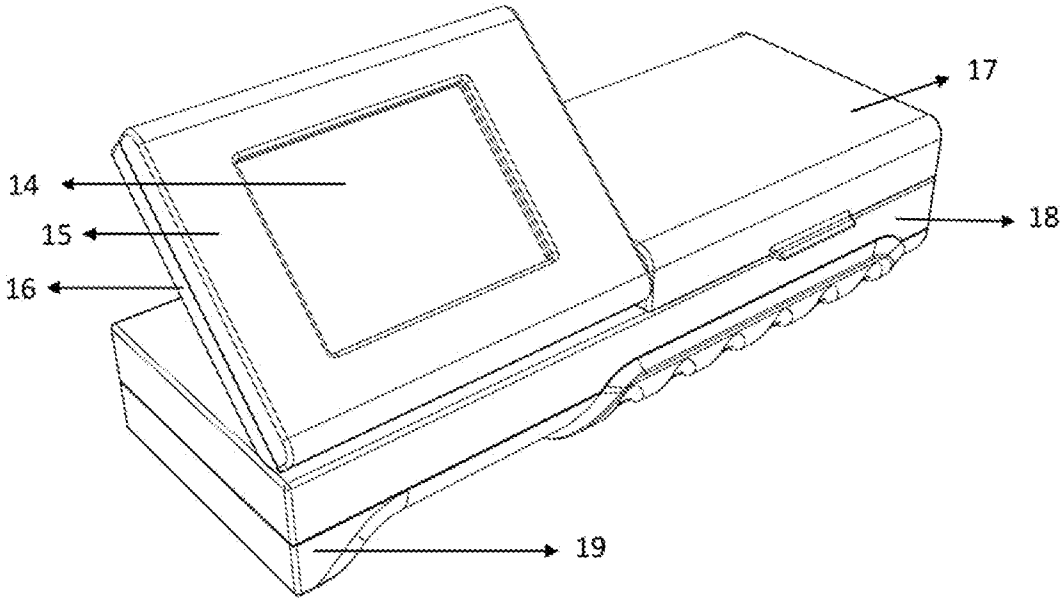


FIGURE 4

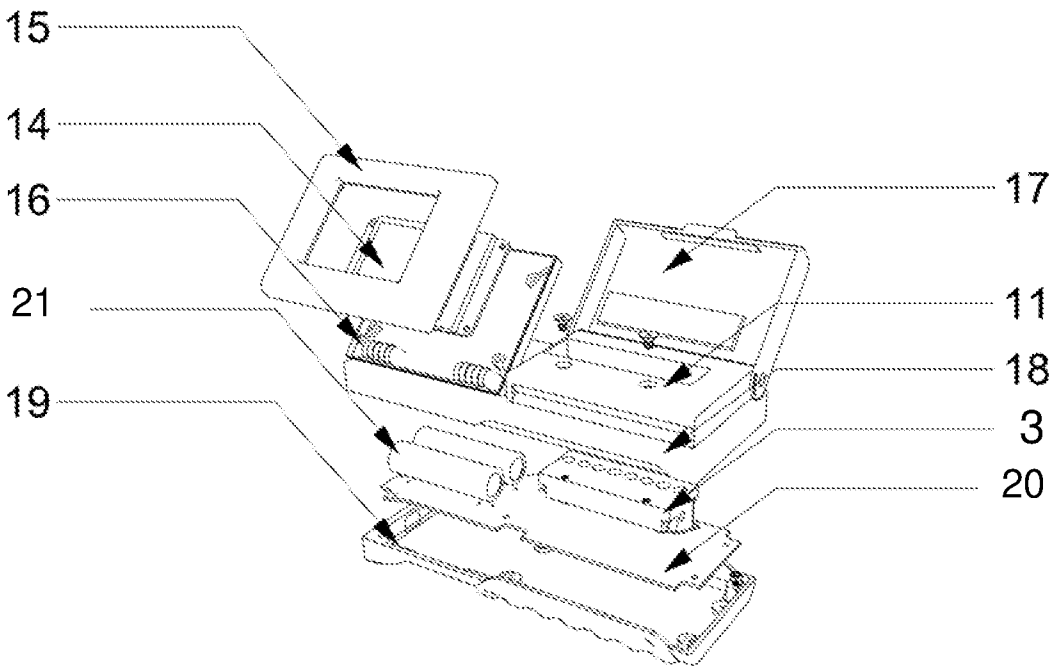


FIGURE 5

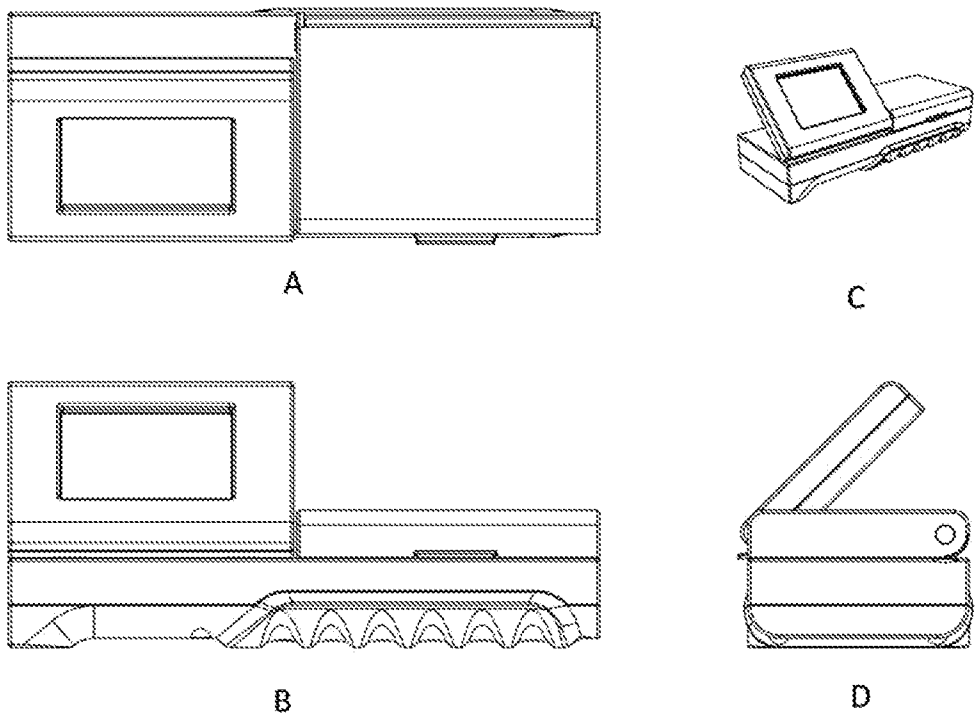


FIGURE 6

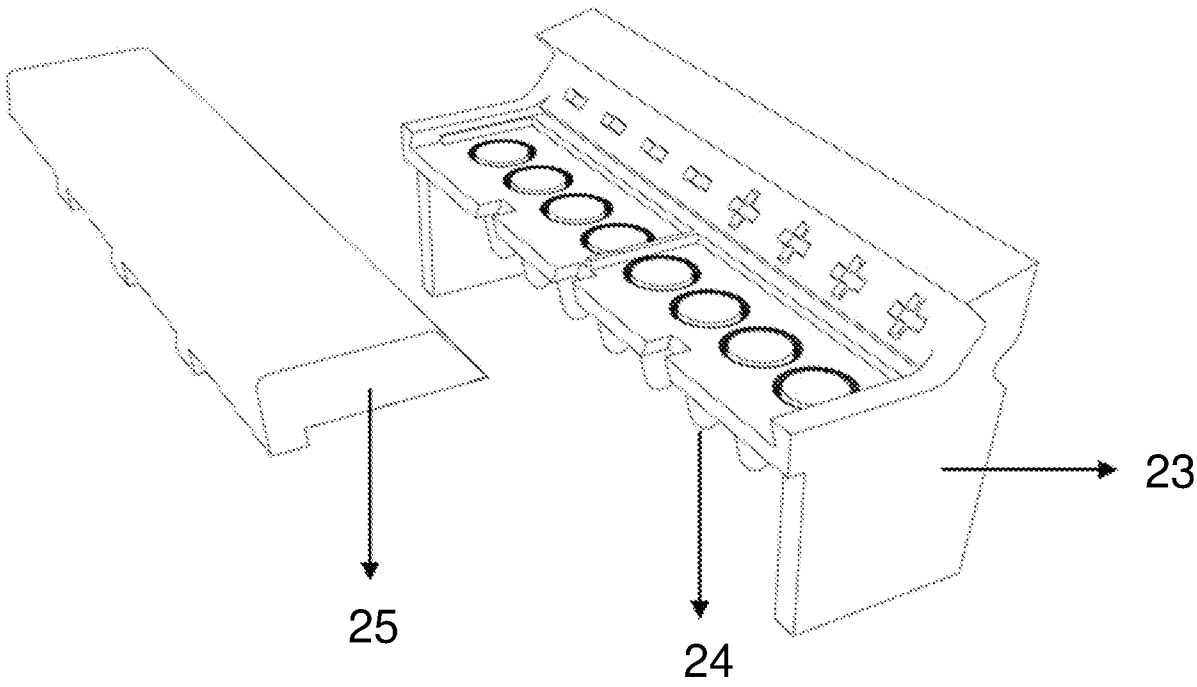


FIGURE 7

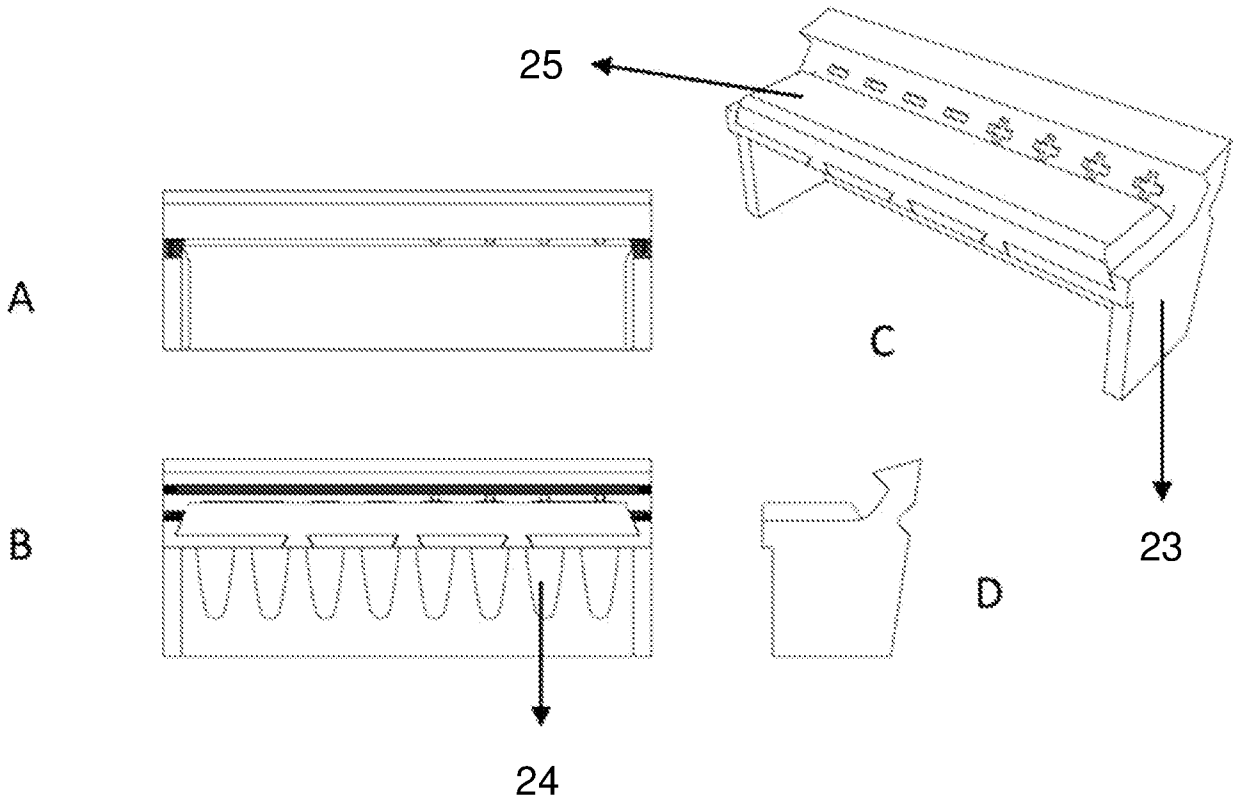


FIGURE 8