

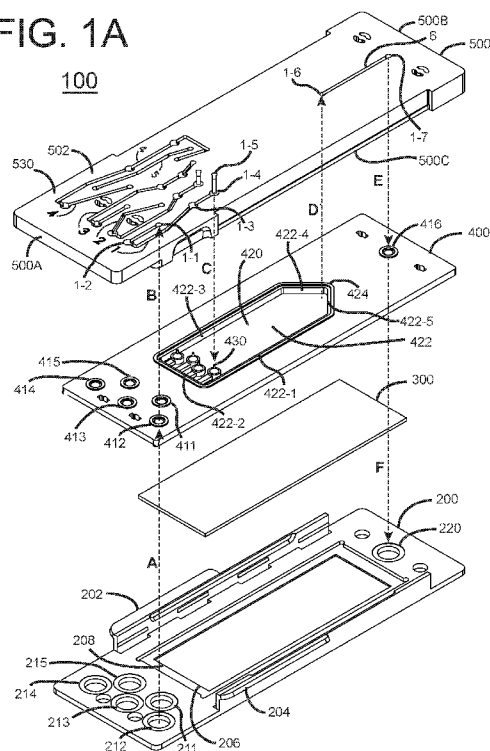


- (51) International Patent Classification:
B01L 3/00 (2006.01) *G01N 33/48* (2006.01)
- (21) International Application Number:
PCT/US2016/023852
- (22) International Filing Date:
23 March 2016 (23.03.2016)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
14/666,301 23 March 2015 (23.03.2015) US
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- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK,

[Continued on next page]

(54) Title: SELF-CONTAINED SLIDE RECEPTACLE FOR PATIENT SPECIMENS

FIG. 1A



(57) Abstract: A self-contained sample processing cartridge, is disclosed. The sample processing cartridge includes a first member that includes a receiver to receive a sample specimen slide. The cartridge may also include a second member that closes on the first member to form a chamber inside the cartridge. The sample specimen slide forms a surface of the chamber. Placing the slide in the cartridge effectively completes the chamber of the cartridge. In one embodiment, the receiver of the first member includes an open region adjacent which the specimen slide is received. The second member includes a plurality of fluid inputs and at least one fluid output. The plurality of fluid inputs couples to the chamber by a plurality of channels respectively therebetween. In one embodiment, at least one of the plurality of channels may include a reagent reservoir and at least one of the plurality of channels includes a dissolvable blocking reservoir.



SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:**Declarations under Rule 4.17:**

— *of inventorship (Rule 4.17(iv))*

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

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

SELF-CONTAINED SLIDE RECEPTACLE FOR PATIENT SPECIMENS

BACKGROUND

[0001] The disclosures herein relate generally to patient specimen testing, and more specifically to apparatus for more efficiently testing patient specimens. The testing of patient specimens requires a great deal of precision and accuracy, which necessarily consume a large amount of time in conventional patient specimen testing protocols. It is desirable to maintain this precision and accuracy while processing patient specimen more efficiently.

BRIEF SUMMARY

[0002] In one embodiment, a self-contained sample processing cartridge, is disclosed. The sample processing cartridge includes a first cartridge portion including a receiver that receives a specimen slide. The sample processing cartridge further includes a second cartridge portion that closes on the first cartridge portion to form a chamber interior to the cartridge, wherein the specimen slide forms a surface of the chamber. In one embodiment, the specimen slide forms one wall of the chamber to effectively complete the chamber. In one embodiment, the receiver of the first cartridge portion includes an open region adjacent which the specimen slide is received. In one embodiment, the second cartridge portion includes a plurality of fluid inputs and at least one fluid output. The plurality of fluid inputs couples to the chamber by a plurality of channels respectively therebetween. In one embodiment, at least one of the plurality of channels includes a reagent reservoir. In one embodiment, at least one of the plurality of channels includes a blocking reservoir.

BRIEF DESCRIPTION OF THE DRAWINGS

[0003] The appended drawings illustrate only exemplary embodiments of the invention and therefore do not limit its scope because the inventive concepts lend themselves to other equally effective embodiments.

[0004] Fig. 1A is an exploded view of one embodiment of the disclosed sample processing cartridge

[0005] Fig. 1B is a top perspective view of one embodiment of the disclosed sample processing cartridge.

[0006] Fig. 1C is a plan view of one end of the disclosed sample processing cartridge.

[0007] Fig. 1D is a plan view of an opposite end of the disclosed sample processing cartridge.

[0008] Fig. 1E is a plan view of one side of the disclosed sample processing cartridge.

[0009] Fig. 1F is a plan view an opposite side of the disclosed sample processing cartridge.

[0010] Fig. 1G is a top plan view of one embodiment of the disclosed sample processing cartridge.

[0011] Fig. 1H is a bottom view of one embodiment of the disclosed sample processing cartridge showing a specimen slide forming one surface of the chamber thereof.

[0012] Fig. 1I is a top perspective view of one embodiment of the disclosed sample processing cartridge showing a hinge connecting the different portions of the cartridge together.

DETAILED DESCRIPTION

[0013] In one embodiment, a self-contained sample processing cartridge is disclosed. The cartridge includes a lower member with a slide receiver that receives a slide with a sample thereon. The cartridge also includes an upper member configured such that when the upper member is closed upon the lower member, a chamber is formed between the upper member and the lower member. The slide being situated within the sample processing cartridge effectively completes the cartridge chamber and provides one of the major surfaces of the cartridge chamber. The sample processing cartridge includes multiple fluid inputs and at least one fluid output. In one embodiment, the upper member of the cartridge includes multiple fluid channels. One or more of the fluid channels include reservoirs, such as reagent reservoirs and fluid blocking reservoirs, as explained in more detail below. In one embodiment, the user is provided with a complete cartridge assembly except for the glass slide on which the specimen is placed. The reservoirs in the channels of the cartridge assembly are preloaded with reagents required for the particular testing protocol corresponding to the sample on the glass slide of the cartridge. Such reagents may include antibodies, DNA/RNA oligonucleotides and enzymes. When the user places the glass slide in the lower member and closes the upper member, the glass slide forms one of the interior walls of the sealed chamber.

[0014] Fig 1A is an exploded view of one embodiment of the disclosed sample processing cartridge 100. Cartridge 100 includes lower member 200, glass slide 300, gasket 400 and upper member 500. Lower member 200 may be fabricated from polycarbonate, polypropylene or other plastic material. Opposed sides of lower member 200 include wing-like tabs 202 and 204 that facilitate the user grasping the cartridge 100 for ease of opening the cartridge. Lower member 200 includes an aperture, i.e. an open region, 206 adjacent a recessed retaining ledge 208. Recessed retaining ledge 208 acts as a receiver that receives and retains glass slide 300 and its sample, i.e. specimen, when the user

places glass slide 300 in lower member 200. Glass slide 300 forms one of the sides of the cartridge chamber that is discussed below.

[0015] Lower member 200 includes fluid inputs 211, 212, 213, 214 and 215 to which different fluids such as chemical reagents may be supplied when cartridge 100 is fully assembled with glass slide 300 therein. Lower member 200 also includes a fluid output 220 through which all fluids from the chamber within cartridge 100 exit when testing such as staining of the sample (not shown) on the slide 300 within the cartridge is complete.

[0016] Cartridge 100 includes gasket 400 that may be fabricated from rubber or similar elastomeric material that provides sealing properties. Gasket 400 includes gasket holes 411, 412, 413, 414 and 415 that mate with fluid inputs 211, 212, 213, 214 and 215, respectively, of lower member 200. Gasket 400 further includes an open region 420 that defines the dimensions of chamber 422. Gasket 400 includes five walls 422-1, 422-2, 422-3, 422-4 and 422-5 that provide the vertical dimension of chamber 422 as depicted in Fig. 1A. Glass slide 300 provides the bottom surface of chamber 422 when the cartridge 100 is completely assembled and closed.

[0017] The output end 424 of chamber 422 is V-shaped to promote better flow of reagents through chamber 422 toward the output of the cartridge. Gasket 400 includes a plurality of check valves such as valve 430 that seat in the corresponding holes such as hole 1–4 that extend to the lower or interior major surface 500C of upper member 500. The plurality of check valves such as valve 430 prevent or limit the undesired backflow of reagents from chamber 422 back toward the fluid inputs 211-215 of cartridge 100.

[0018] Cartridge 100 includes 5 fluid channels designated 1, 2, 3, 4 and 5. It is noted that channel 5 snakes around fluid channel 4 in Fig. 1A. Fluid channel 5 does not include a check valve into the chamber because in one embodiment fluid channel 5 does not contain any cartridge reagent reservoirs. Fluid channel

5 may exclusive supply off-cartridge bulk reagents from tubes/containers plugged into a separate test instrument.

[0019] Cartridge 100 also includes upper member 500 that exhibits four fluid channels that are formed extending into the major surface 502 thereof. These four fluid channels are input channels that are designated 1, 2, 3 and 4 adjacent input end 500A. Upper member 500 also includes an output fluid channel 6 adjacent output end 500B. The lower or interior major surface 500C of upper member 500 provides the top surface, i.e. roof, of chamber 422 when cartridge 100 is completely assembled and closed. In one embodiment, a sealing layer 530 is situated at major surface 502 to seal the fluid channels, input holes, output holes, and reservoirs thereof within cartridge 100. In Fig. 1A, sealing layer 530 is transparent to allow viewing of the contents of the fluid channels. Sealing layer 530 may be fabricated from a thin layer of clear plastic tape material that adheres to major surface 502. In another embodiment, sealing layer 530 is not transparent and may include a label identifying the reagents packaged in the cartridge and the protocol to be used for that particular cartridge. Sealing layer 530 may also have a barcode label identifying the cartridge reagents, purpose, protocol, and manufacturing information.

[0020] A representative fluid flow through a fully assembled closed cartridge 100 containing a sample specimen is now discussed. The fully assembled closed cartridge 100 is placed in one of multiple bays in a test instrument that is discussed in more detail below. While cartridge 100 stores multiple low-volume reagents on board the cartridge itself for a particular test protocol, the test instrument provides higher volume reagents as needed for the particular test. The test instrument acts as a source of higher volume reagents that is external to the cartridge itself. These higher volume reagents may include general reagents and buffers, water, alcohol, and application(s) specific wash reagents and specimen processing reagents. The higher volume reagents are supplied via dedicated reagent port/channel on the cartridge. In actual practice, higher

volume reagents pass through reagent fluid channel 4, namely the channel that snakes around channel 4.

[0021] For example, if a particular test protocol requires a higher volume of reagent, the test instrument provides the required reagent to a representative fluid input 212 of lower member 200. While Fig. 1A is an exploded view of cartridge 100 that shows vertical dashed lines with arrows to indicate fluid flow from the input side to the output side of cartridge 100, it should be understood that before testing commences, cartridge 100 is fully assembled with glass slide 300 therein to form a sandwich-like structure such as depicted in the assembled cartridge 100 of Fig. 1B. Returning to Fig. 1A, the reagent provided to fluid input 212 flows upward through gasket hole 412, as indicated by arrow A. After passing through gasket hole 412, the reagent passes through hole 1-1 of upper member 500, as indicated by arrow B. The reagent continues flowing and flows along channel 1. In actual practice, higher volume reagents pass through reagent fluid channel 4, namely the channel that snakes around channel 4.

[0022] Port 1-1 is a port for incoming lyophilized reagent rehydration water/buffer. Protocol specific Lyophilized reagent (antibodies, DNA/RNA oligonucleotides or enzymes) can be located in position 1-2, and/or 1-3, and/or 1-4. In one embodiment, lyophilized reagent can be located in 1-2 and lyophilized "blank" buffer (without reagents antibodies or DNA/RNA or enzyme) "blocking pellet?" can be "packed" in 1-3, and/or 1-4. In another embodiment, lyophilized reagent can be located within the channel structure (not in reservoir) between the reservoirs and lyophilized "blank" buffer can be "packed" in 1-2 and/or 1-3 and/or 1-4. The lyophilized "blank" buffer acts as chemically dissolvable valves protecting the lyophilized reagents from chamber back-flow or vapors from within the bay manifold or chamber. Packing of the lyophilized blank buffer makes the channel air tight and traps any vapor or moisture entering the channel thus protecting the lyophilized reagent from premature rehydration or vapor contamination prior to its use. When a channel is opened for flow, the

rehydration water or buffer flows through that channel rehydrating the lyophilized “blank” buffer and lyophilized reagent and dispensing into the chamber. Each channel 1-4 can contain a unique lyophilized reagent or same. The normally closed check valves within the chamber sealing 1-4 channels also isolate the channels from chamber. When rehydration water or buffer flows through the channel, it rehydrates all lyophilized reagents in its path and pushes the check valve open into the chamber. The purpose of check valves and dissolvable channel block is same as preventing back flow from chamber into the channel and acting as vapor barrier to protect the lyophilized reagent located within that channel path/reservoirs. It is possible to have an embodiment where check valves are not designed in and only blocking lyophilized pellet is utilized as check valves to prevent back flow from chamber into a channel.

[0023] A representative fluid channel 1 extends between hole 1-1 and hole 1-5, as shown. The reagent fluid flows from hole 1-1 along channel 1, by reservoir 1-2, by reservoir 1-3, by reservoir 1-4, to exit hole 1-5.

[0024] After flowing through fluid channel 1, the reagent exits hole 1-5. The reagent flows downward in the direction of gravity and pressure as indicated by arrow C. Prior to fluid flowing through channel 1, check valve 430 is closed, i.e. check valve 430 rests in a corresponding hole such as 1-4 or 1-5 to prevent backflow of fluids in chamber 422 toward the fluid inputs of cartridge 100. However, once fluid from fluid input 212 passes through channel 1 and reaches valve 430, valve 430 flexibly opens downward in the direction of gravity under the pressure of fluid flow from the input which is under pressure supplied by a pump in the test instrument described below. The reagent provided to input 212 thus reaches chamber 422 and the sample (not shown) on glass slide 400. After passing through chamber 422, the reagent and other fluids in chamber 422 will pass from V-shaped chamber end 422 up to hole 1-6 as indicated by arrow D. The fluids then travel along liquid channel 6 to hole 1-7. From hole 1-7, the fluids travel through gasket output hole 416 as indicated by arrow E. The fluids then

travel from gasket whole 416 to fluid output hole 220 in lower member 220, as indicated by arrow F, at which point the fluids are exhausted from cartridge 100 for collection and proper disposal. Once the fluids are drained from the cartridge, the cartridge may be opened and the user removes the slide removed from the cartridge. The specimen on the slide may then be studied under a microscope. Such viewing under a microscope is post-processing, i.e. post-staining or post treatment by the liquid chemicals that were in chamber 422.

[0025] Fig. 1B is a top perspective view of the assembled cartridge 100 with the glass specimen slide 300 installed inside. Like numbers indicate like elements when comparing cartridge 100 of Fig. 1B with cartridge 100 of Fig. 1A. Fig. 1B shows that upper member 500 includes an indentation 505 adjacent wing-like tab 204 of lower member 200. Indentation 505 cooperates with wing-like tab 204 to make it easier for the user to grasp cartridge 100. Upper member 500 also includes another indentation 510 (not shown in this view) adjacent wing-like tab 202 on the opposed side of upper member 500 for the same purpose. In one embodiment, upper member 500 includes a ledge adjacent end 500A that overhangs lower member 200 below.

[0026] Fig. 1C is a front side plan view of cartridge 100 including upper member 500 and lower member 200, and showing wing-like table 202 and 204. Fig. 1C is viewed facing upper member end 500A. Fig. 1D is a rear side plan view of cartridge 500 including upper member 500 and lower member 200, and showing wing-like table 202 and 204. Fig. 1D is viewed facing upper member end 500B.

[0027] Fig. 1E is a right side plan view of cartridge 500 including upper member 500 and lower member 200, and showing wing-like tab 204. Fig. 1E is viewed facing tab 204. Fig. 1F is a left side plan view of cartridge 500 including upper member 500 and lower member 200, and showing wing-like tab 202. Fig. 1F is viewed facing tab 202.

[0028] Fig. 1G is a top plan view of cartridge 100 showing the upper member 500 of cartridge 100. When comparing the view of Fig. 1G with cartridge 100 of Fig. 1B, like numbers indicate like elements.

[0029] Fig. 1H shows a bottom plan view of cartridge 100. The view of Fig. 1H shows upper member 500, lower member 200, multiple fluid inputs such as fluid input 212. Upper member 500 includes a roof 515 with a fluid channel 520 therein. Fluid channel 520 includes a channel opening 525 that fluidically couples to one of the remaining fluid inputs of upper member 500 other than fluidic input 212. In this way a fluid such as a reagent or water is supplied to chamber 422 in a quantity and/or concentration appropriate for a particular test protocol. Chamber output end 424 is V-shaped and corresponds to the V-shape of the gasket 400 end adjacent an output hole 530 in roof 515 of upper member 500. Output hole 530 fluidically couples to fluid output 220 of lower member 200 via fluid channel 6 which is visible in Fig. 1B.

[0030] Fig. 1I is a perspective view of an alternative embodiment cartridge, namely cartridge 100' that is configured similarly to cartridge 100 of Fig. 1B, except that cartridge 100' includes a hinge 605 that connects upper member 500 to lower member 200 at the output end of the cartridge. In one embodiment, hinge 605 is a living hinge that is integrally formed of the same polycarbonate, plastic, or similar material that forms upper member 500 and lower member 200.

[0031] In one embodiment, cartridge 100 may include multiple interior alignment pins and corresponding holes that assist in aligning, mating and closing upper member 502 to lower member 200.

[0032] The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. As used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in

this specification, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components, and/or groups thereof.

[0033] The corresponding structures, materials, acts, and equivalents of all means or step plus function elements in the claims below are intended to include any structure, material, or act for performing the function in combination with other claimed elements as specifically claimed. The description of the present invention has been presented for purposes of illustration and description, but is not intended to be exhaustive or limited to the invention in the form disclosed. Many modifications and variations will be apparent to those of ordinary skill in the art without departing from the scope and spirit of the invention. The embodiment was chosen and described in order to best explain the principles of the invention and the practical application, and to enable others of ordinary skill in the art to understand the invention for various embodiments with various modifications as are suited to the particular use contemplated.

CLAIMS

What is claimed is:

1. A self-contained sample processing cartridge, comprising:
a first cartridge portion including a receiver that receives a specimen slide;
and
a second cartridge portion that closes on the first cartridge portion to form a chamber interior to the cartridge, wherein the specimen slide forms a surface of the chamber.
2. The self-contained sample processing cartridge of claim 1, wherein the receiver of the first cartridge portion includes an open region adjacent which the specimen slide is received.
3. The self-contained sample processing cartridge of claim 1, wherein the second cartridge portion includes a plurality of fluid inputs and at least one fluid output.
4. The self-contained sample processing cartridge of claim 3, wherein the plurality of fluid inputs couples to the chamber by a plurality of channels respectively therebetween.
5. The self-contained sample processing cartridge of claim 4, wherein at least one of the plurality of channels includes a reagent reservoir.
6. The self-contained sample processing cartridge of claim 4, wherein at least one of the plurality of channels includes a dissolvable blocking reservoir.

7. The self-contained sample processing cartridge of claim 4, wherein at least one of the plurality of fluid inputs is adapted to receive a reagent from a source external to the self-contained sample processing cartridge.

8. The self-contained sample processing cartridge of claim 4, further comprising a gasket seal between the first and second cartridge portions, the gasket seal including an open region including side walls that form sides of the chamber.

9. The self-contained sample processing cartridge of claim 4, further comprising respective fluid flow control check valves for the plurality of fluid channels.

10. The self-contained sample processing cartridge of claim 8, wherein the gasket seal includes respective integral fluid flow control valves for the plurality of fluid channels.

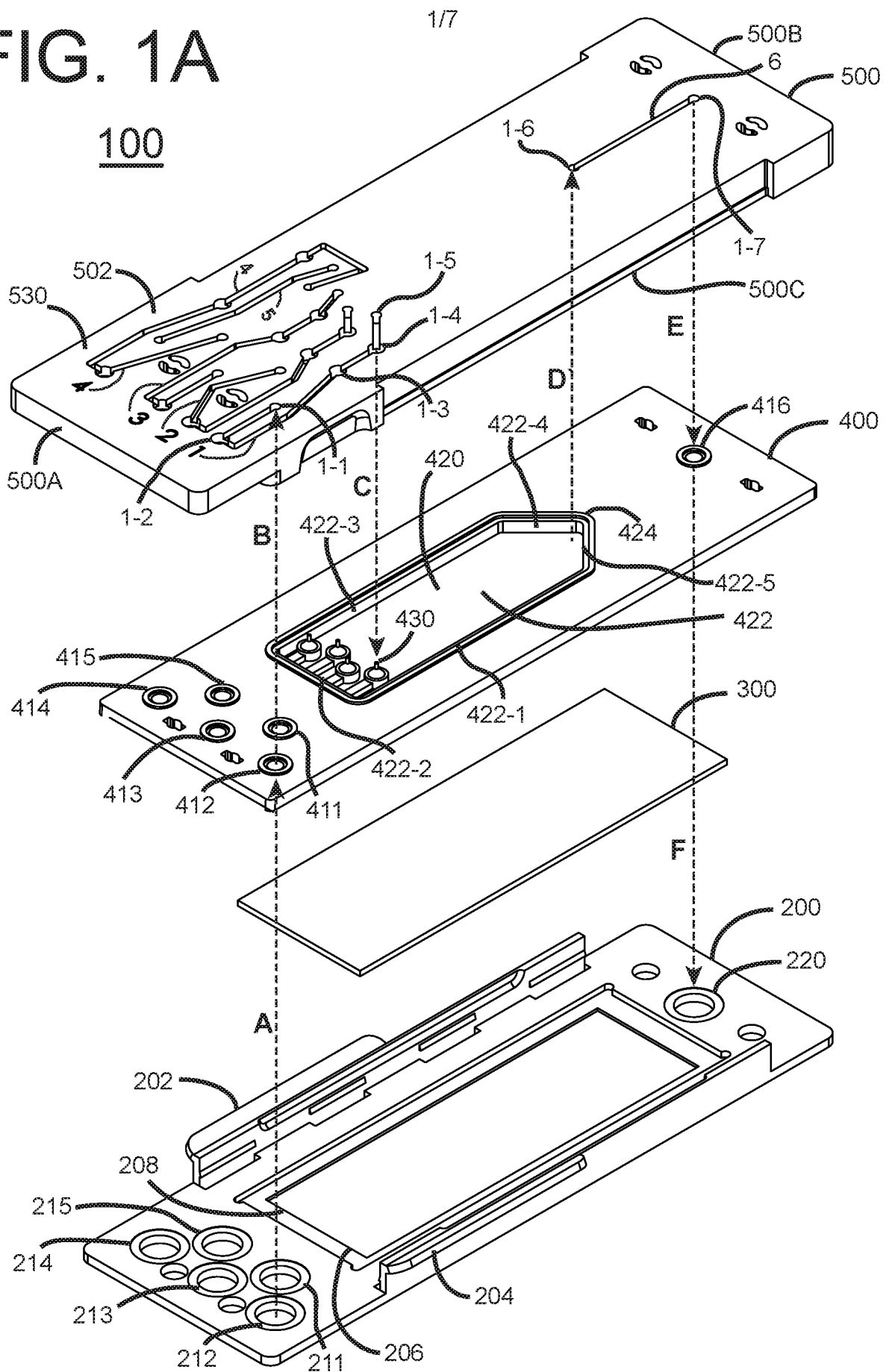
11. The self-contained sample processing cartridge of claim 4, wherein the plurality of channels of the second cartridge portion extend adjacent an exterior surface of the second cartridge portion, the self-contained sample processing cartridge further comprising a transparent layer covering the surface of the second cartridge portion, such that the interiors of the plurality of channels are visible.

12. The self-contained sample processing cartridge of claim 4, wherein the chamber includes an input end and an output end, the output end being V-shaped.

13. The self-contained sample processing cartridge of claim 8, wherein the gasket seal includes an input end and an output end, the output end of the gasket being V-shaped.

14. The self-contained sample processing cartridge of claim 4, further comprising a hinge that couples the first cartridge portion to the second cartridge portion at a common end thereof.

FIG. 1A



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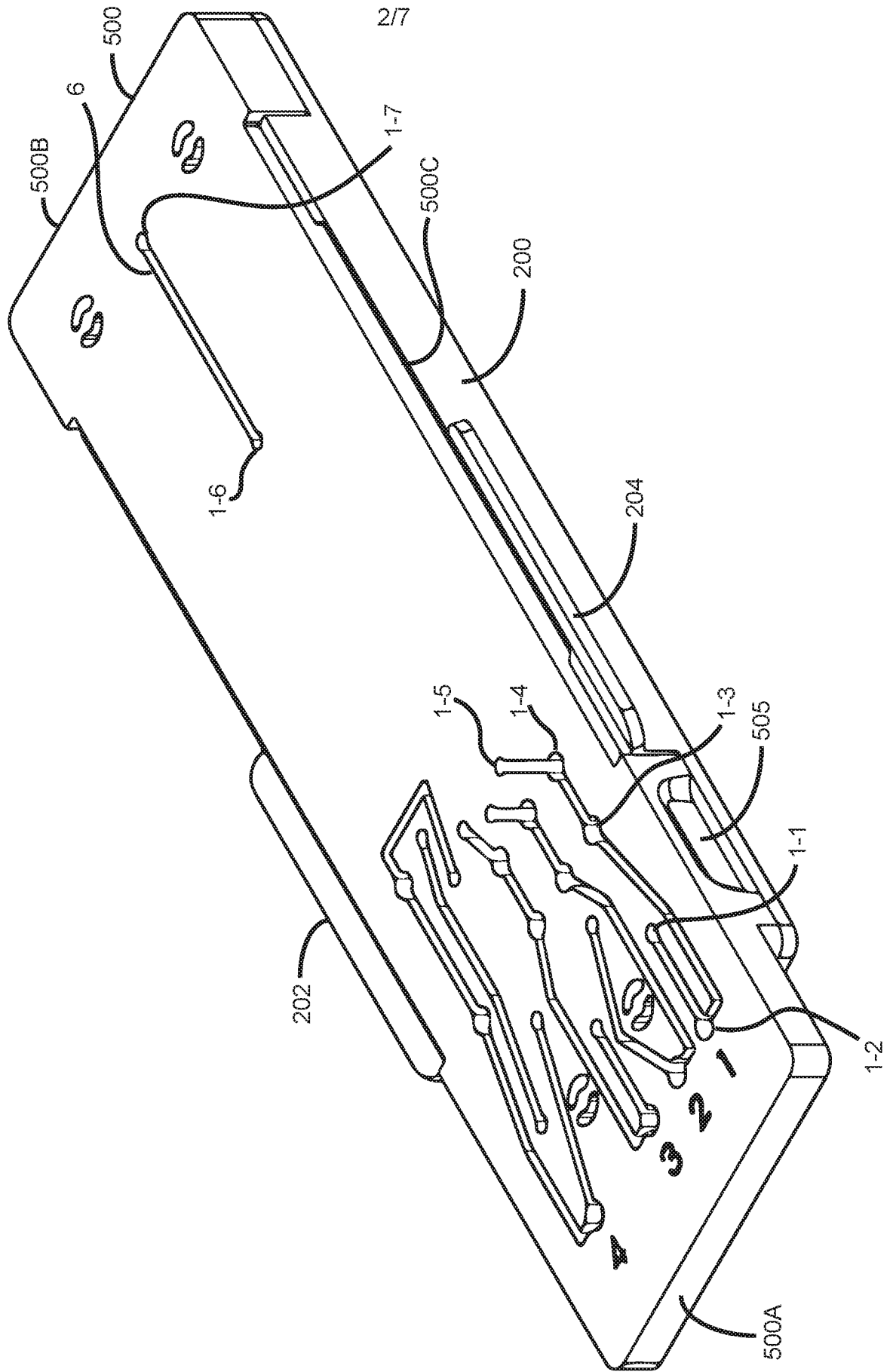


FIG. 1C

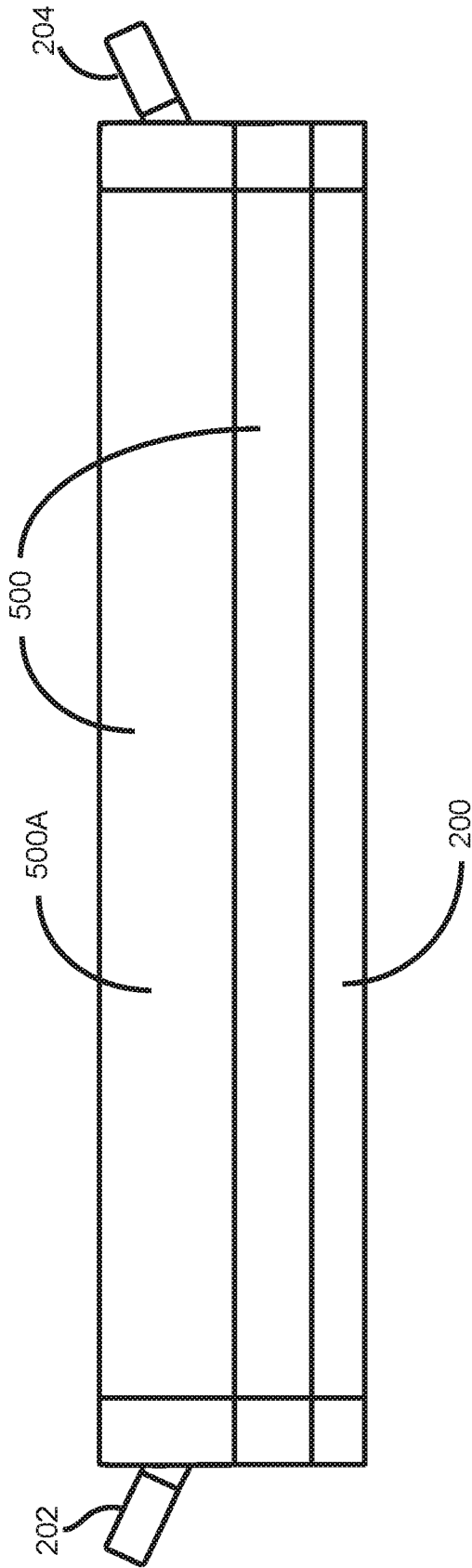


FIG. 1D

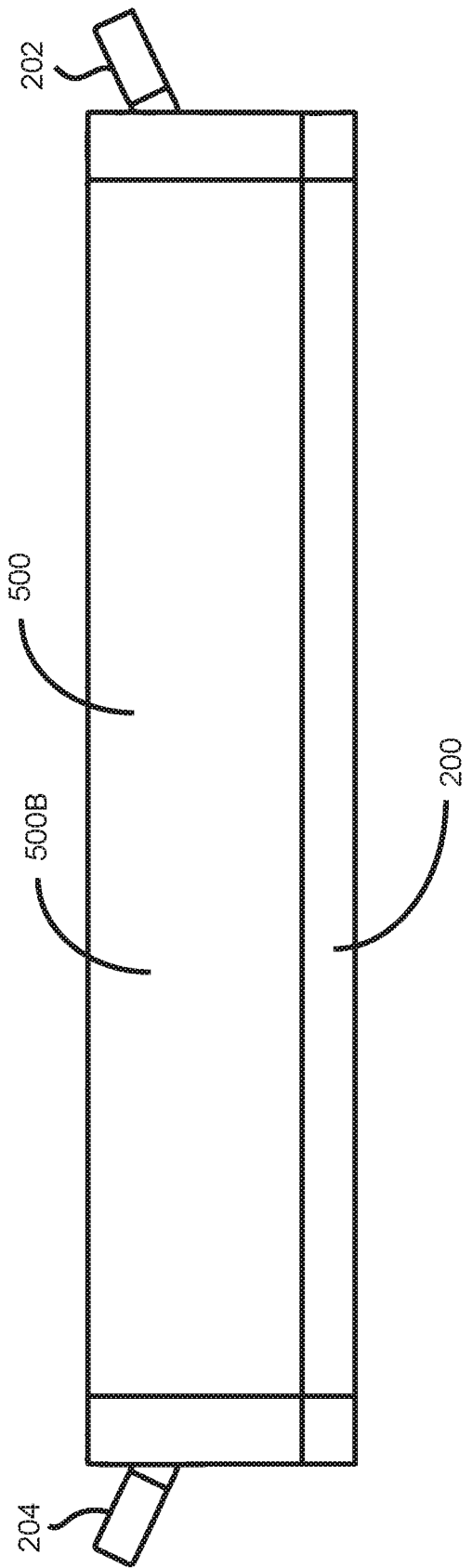


FIG. 1E

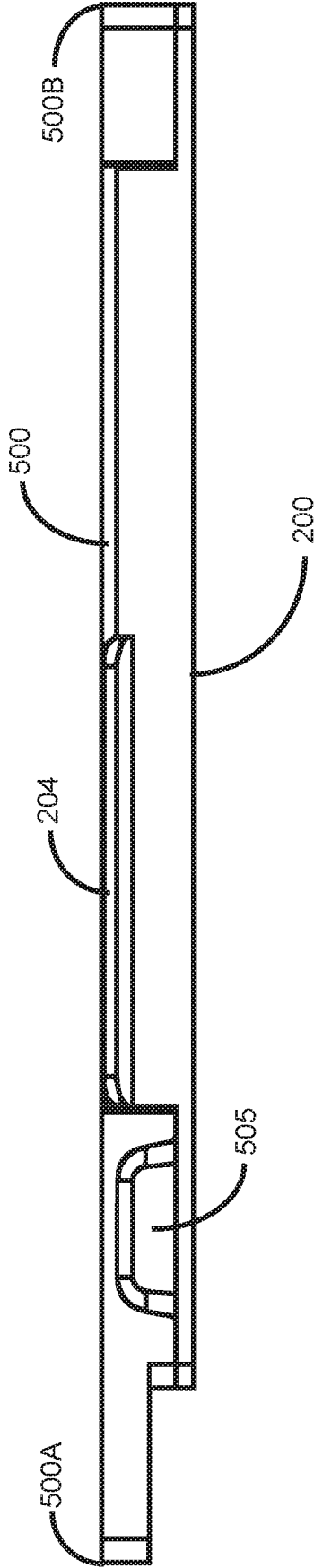
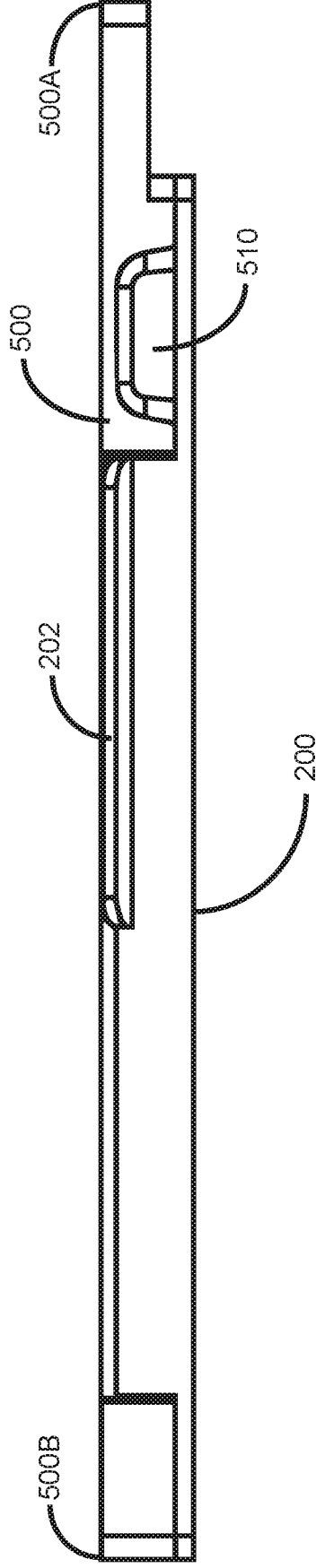
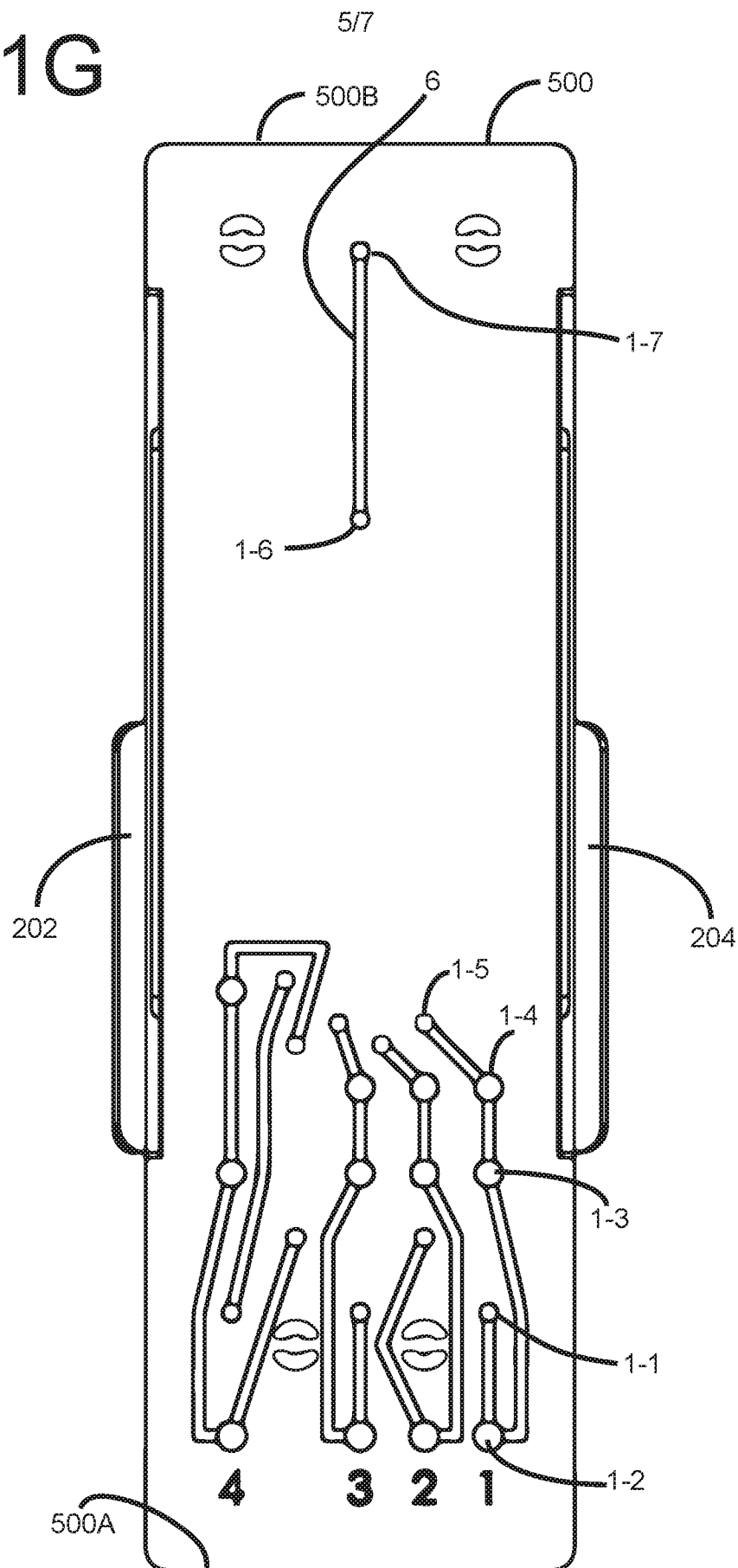


FIG. 1F



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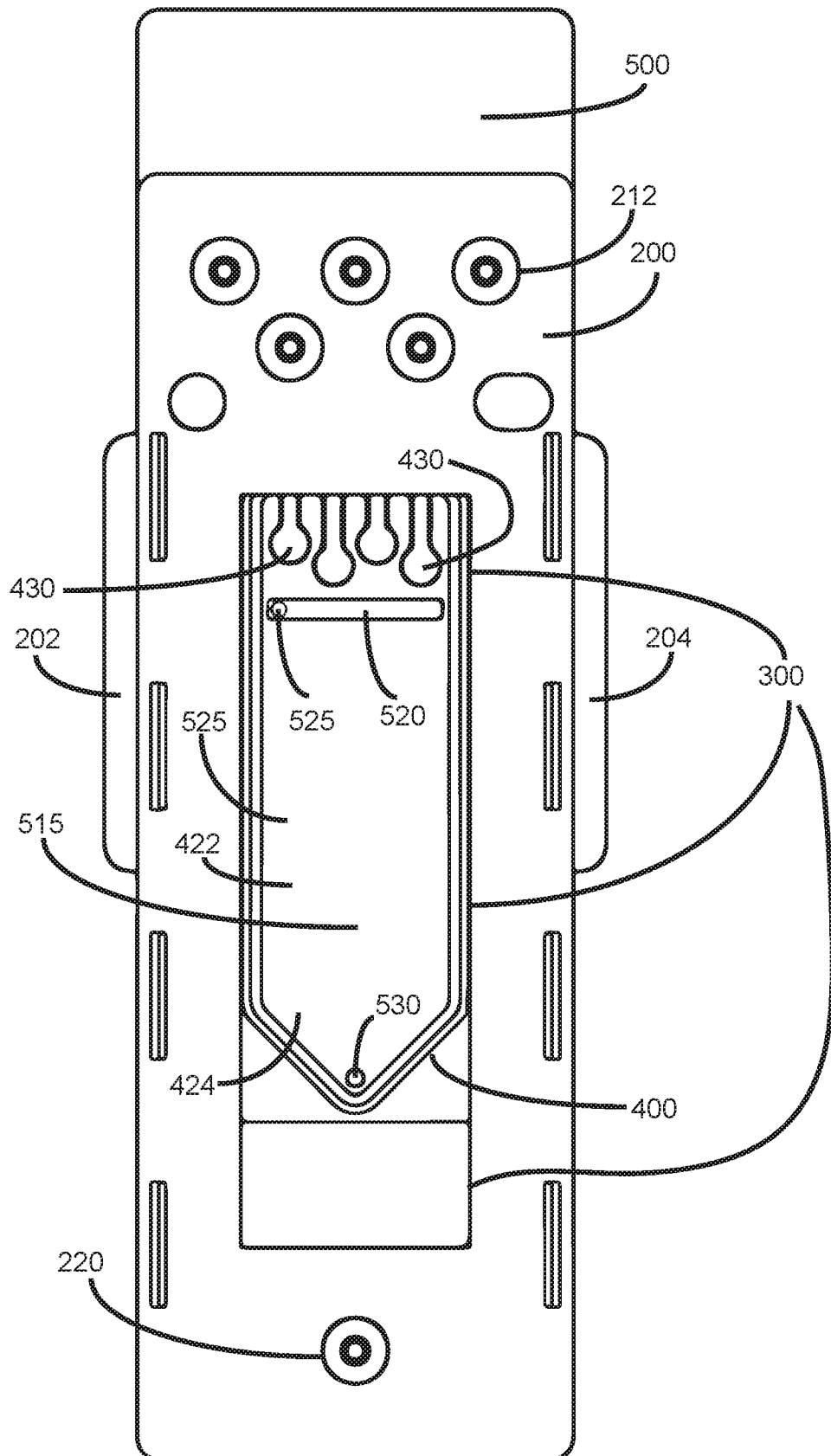
FIG. 1G



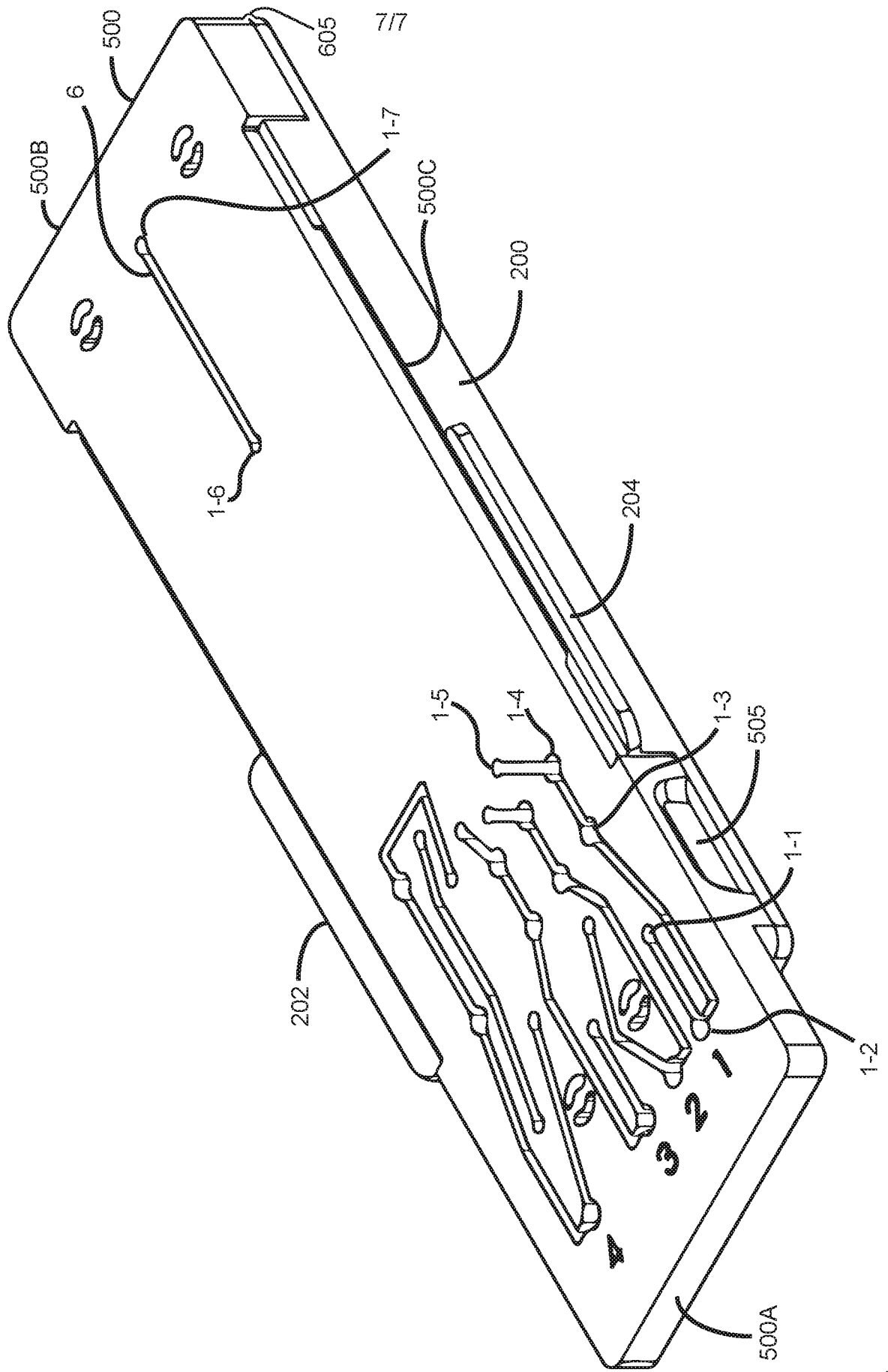
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FIG. 1H







INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/023852**A. CLASSIFICATION OF SUBJECT MATTER****B01L 3/00(2006.01)i, G01N 33/48(2006.01)i**

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)

B01L 3/00; B01L 9/00; B01L 11/00; C12M 1/00; G01N 35/08; G01N 35/00; B01F 11/02; G01N 1/10; G01N 33/48

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

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal) & Keywords: specimen slide, cartridge, receptacle, upper, lower, chamber, reservoir, channel, port, input, output

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003-0129756 A1 (THORNE, EDWARD H., IV et al.) 10 July 2003 See paragraphs [0014], [0025]; claims 1, 2, 10, 13; and figures 1-3.	1-14
A	WO 2013-106458 A2 (MICRONICS, INC.) 18 July 2013 See page 39, line 25-page 40, line 24; claim 1; and figure 14.	1-14
A	US 2006-0215155 A1 (WEBER, LUTZ) 28 September 2006 See paragraphs [0041]-[0049]; claim 1; and figures 1-3.	1-14
A	WO 03-052428 A1 (BIOMICRO SYSTEMS, INC. et al.) 26 June 2003 See claims 1, 10, 16; and figures 1, 2.	1-14
A	US 2003-0059349 A1 (HOWE, ANDRE) 27 March 2003 See paragraph [0022]; claim 1; and figures 1, 2.	1-14



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

14 July 2016 (14.07.2016)

Date of mailing of the international search report

14 July 2016 (14.07.2016)

Name and mailing address of the ISA/KR

International Application Division

Korean Intellectual Property Office

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2016/023852

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2016/023852

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