

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
15 November 2007 (15.11.2007)

PCT

(10) International Publication Number
WO 2007/130300 A2

(51) International Patent Classification:
B01L 9/00 (2006.01)

(21) International Application Number:
PCT/US2007/010046

(22) International Filing Date: 26 April 2007 (26.04.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/797,534 4 May 2006 (04.05.2006) US
60/813,476 14 June 2006 (14.06.2006) US
11/703,494 7 February 2007 (07.02.2007) US

AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, 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, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(71) Applicant (*for all designated States except US*): **THE BODE TECHNOLOGY GROUP, INC.** [US/US]; 10430 Furnace Rd., Suite 107, Lorton, VA 22079 (US).

(72) Inventor; and

(75) Inventor/Applicant (*for US only*): **SANGHA, Jangbir S.** [US/US]; 6508 W. 125th Place, Overland Park, KS 66209 (US).

(74) Agent: **STITT, Richard P.**; 120 West 12th Street, Kansas City, MO 64105 (US).

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM,

Declarations under Rule 4.17:

- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

- *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SPECIMEN TRAY

(57) Abstract: A holder for a plurality of biological specimen collection devices having collection absorbents extending therefrom is provided, the holder operating to organize and identify the collection devices and operating to position the collection devices for extraction of sample portions from each of the collection absorbents of the multiple collection devices while positioning a sample punch absorbent cleaning strip adjacent the collection absorbent of each device to allow cleaning of the sample punch between each use.



WO 2007/130300 A2

5

SPECIMEN TRAY**Cross-Reference to Related Application**

This application claims priority under 35 U.S.C. 119(e) and 37
10 C.F.R. 1.78(a)(4) based upon copending U. S. Provisional Application,
Serial No. 60/797,534 for SPECIMEN TRAY, filed May 4, 2006 and U. S.
Provisional Application, Serial No. 60/813,476 for SPECIMEN TRAY, filed
June 14, 2006, and which are incorporated herein by reference.

15

Field of the Invention

The field of the present invention relates generally to specimen
devices for collecting, storing, transporting and testing biological
specimens. In particular, the present invention provides a tray for holding
a plurality of biological specimen collection devices that facilitates the
20 efficient organization, identification, sampling and testing of the biological
samples.

Background of the Invention

Collecting and testing biological specimens is conducted on daily
25 basis in laboratories throughout the world. Examples of biological
specimen testing includes DNA analysis, substance testing, uranalysis,
serum/blood testing and genetic analysis. Prior to the introduction of
automated mechanical technology, biological specimens were collected
and tested manually. With the advent of automated mechanical
30 technology, however, testing of biological samples has become more rapid
and reliable.

One example of this automated technology involves the use of
micro well plates or micro titer plates. The typical micro well plate is
configured to have eight rows, each row having twelve wells (or 96 wells in
35 the plate). Recently developed micro well plates have as many as 384
wells in the plate. Biological specimens first are collected in various ways
including using an absorbent that retains the biological specimen in an
efficient manner. The biological specimens are then transferred into the

5 wells of a micro well plate or "plate" for subsequent analysis. One way to transfer the biological specimen to the plate is through a "punch" method. Typically, a device will punch an area of the absorbent containing the biological specimen into a particular well (A1, A2, A3, A12)(Fig. 5) of a micro well plate. This process is repeated for each of the wells of the
10 plate. Although the plates allow for the rapid analysis of a multitude of biological specimens, the process of transferring specimens to the wells of the plates is time consuming and prone to cross contamination and misidentification of the specimens inserted into the wells. For example, cross contamination may occur if the "punch" device used to remove a
15 portion of the absorbent to be analyzed in the well is not cleaned prior to punching of a subsequent absorbent containing a different biological specimen. Also, with the use of large groups of specimens as may be found in the 96 well plates, there exists a higher chance of incorrectly labeling or identifying one of the 96 biological specimens placed into the
20 wells of the plate. Finally, because of the sheer quantity of samples of biological specimens generated with the use of micro well plate assays, there is a vital need to organize, store and transport biological specimens contained on the absorbents of a specimen collector.

25 **Summary of the Invention**

The present invention facilitates the collection, storage, identification, sampling and testing of biological specimens contained on an absorbent. The specimen collector with absorbent is placed on the designated location on the specimen tray. The specimen tray organizes
30 the specimen collectors in a side by side fashion so that an automated process of testing the biological specimens may proceed in a rapid, convenient and accurate way. Also, the present invention provides several ways in which cross contamination of biological specimens may be prevented both in storing the devices and in sampling and testing the
35 biological specimens. A further advantage of the present invention is that each device containing a biological sample is easily identified because of a unique code that is associated with the device. Yet another advantage

5 of the present invention is the storage and transport of several devices in a convenient, organized and easily identifiable manner.

The above benefits and objectives are accomplished by a device which provides, in one embodiment, a specimen tray for retaining and holding in a spaced array a plurality of specimen collectors. An individual
10 specimen collector comprises a handle having an absorbent extending from one end of the handle. The specimen tray is configured to align the absorbents of a plurality of specimen collectors adjacent a portion of a cleaning absorbent paper mounted on the specimen tray. In general the cleaning absorbent is mounted on the area of the specimen tray holding
15 the absorbent ends of the specimen collectors. When a punch is used to take samples of the absorbent, the punch may be cleaned by punching the cleaning absorbent paper prior to moving on to the next absorbent to be punched.

In another embodiment, a different benefit is accomplished by use
20 of unique identifying codes associated with an individual specimen collector. One example of such a unique identifying code is a barcode. In another embodiment, a plurality of specimen trays containing specimen collectors with absorbents are stacked on top of each other and stored in a second container. The configuration and separation of the specimen trays
25 prevents cross contamination of biological specimens contained on the absorbents of the specimen collectors.

The foregoing and other objects are intended to be illustrative and are not meant in a limiting sense. Many possible embodiments of the invention may be made and will be readily evident upon a study of the
30 following specification and accompanying drawings comprising a part thereof. Various features and subcombinations of invention may be employed without reference to other features and subcombinations. Other objects and advantages of this invention will become apparent from the following description taken in connection with the accompanying drawings,
35 wherein is set forth by way of illustration and example, an embodiment of this invention.

5

Description of the Drawings

Preferred embodiments of the invention, illustrative of the best modes in which the applicant has contemplated applying the principles, are set forth in the following description and are shown in the drawings and are particularly and distinctly pointed out and set forth in the appended claims.

Fig. 1 is a top plan view of a first embodiment showing a plurality of specimen collectors with absorbents retained in side by side array in the tray holder slots numbered 1 thru 12 this first embodiment allowing the filling one row of a micro well tray and showing a cleaning absorbent paper strip across one edge of the specimen tray;

Fig. 2 is a top plan view of a second embodiment that shows a specimen collector tray that is similar to that of Fig. 1, but having a reduced number of specimen collectors therein and suitable for use with a micro well plate by filling the columns of eight wells across the plate;

Fig. 3 is a front and left side perspective view of multiple specimen trays configured in a stacked arrangement to maintain the collector absorbents in spaced array to avoid contact and cross-contamination during storage of the collector absorbents;

Fig. 4 is a front and left side perspective view of a plurality of sets of multiple specimen trays in stacked arrangement that have been placed in a storage container for archival purposes and/or shipping;

Fig. 5 is a front and left side perspective view of a micro well plate of the type having 96 wells.

Fig. 6 is a top and right side perspective view of an embodiment showing shoulders **45a,b** which support the absorbent as it is retained within the tray and showing the projecting feet **30** which allow a first tray to

5 stackably register with indents **32** (Fig. 7) of a second tray for archival storage of the collectors; and

Fig. 7 is a bottom and right side perspective view of the embodiment of Fig. 6 showing indents **32** which register with projecting feet **30** (Fig. 6) of an adjacent tray to allow stackable registration of trays for archival storage of the collectors fitted therein.

Detailed Description

15 Referring to Fig. 1, an embodiment is shown which comprises a tray holder **10** for holding and storing biological specimen collectors **12c – 12l** within collector receivers **15c - 12l** and with collectors **12a** and **12b** not shown in collector receivers **15a** and **15b**. The specimen collectors comprise an absorbent **14** attached to a handle **16**, and each is
20 individually and uniquely identified by a bar code **18** on handle **16**. The specimen collectors also may be provided with a slidable cover **17** mounted on handle **16** that allows the absorbent **14** to be covered for protection and uncovered for sample gathering or analysis after collection. Specimen collectors **12** are typically used in biological testing and forensic applications. A biological sample is placed onto absorbent **14** of specimen collector **12**, and the specimen collector **12** generally is shipped to a
25 testing laboratory for analysis of the biological specimen placed on absorbent **14**. Such tests are conducted using various chemistry analyzers and other mechanical devices which operate in a highly efficient manner. One of the principal delays in accomplishing such specimen testing is the punching out of a sample portion from absorbent **14** and the placement of the punched out specimen portion into a well of a micro well plate as is shown in Fig. 5. Typically, such micro well plates come in various sizes, such as the configuration of 96 wells comprised of twelve
30 wells across and eight such rows. A micro well plate having 96 wells is shown in Fig. 5.

Still referring to Fig. 1, device **10** allows for rapid arrangement of hundreds of specimen collectors **12** into a fixed side-by-side arrangement

5 within tray **10**. A void **13** is provided at a location in tray **10** that is immediately underneath the location of absorbent **14** when a collector **12** having absorbent **14** extending therefrom is inserted into one of collector receivers **15a - 15l**. As will be described hereinafter, void **13** allows a portion, or sample, punched out of absorbent **14** to fall into a well of a
10 micro well plate **50** (Fig. 5). A cleaning absorbent paper **20** is provided closely positioned adjacent absorbent **14** and which can be used to clean a sample punch out device between the making of punches into absorbents **14**. Through the use of specimen tray **10**, a large volume of specimen collectors may be rapidly arranged into multiple trays **10** by a
15 relatively unskilled individual and inserted into a sample punching machine. The sample punching machine can robotically extract one or more punches from each absorbent **14** of specimen collectors **12a - 12l** positioned within tray **10** and intermittently clean the punch head on cleaning absorbent paper **20**. Cleaning is accomplished by punching
20 cleaning absorbent paper **20** one or more times between the punching of the various absorbents **14**. The portions punched from cleaning absorbent paper **20** are allowed to fall through cleaning void **21** (Fig. 6) and be discarded. This then allows a very high punch rate to be obtained and a very high rate of processing of hundreds of specimen collectors **12a - 12l**
25 while maintaining accuracy of delivery of the punched out portion of absorbent **14** into a well of a micro well plate.

In operation, a laboratory worker receives a plurality of specimen collectors **12**, each of which is separately enclosed in a shipping container. The technician removes each specimen collector **12** from its shipping
30 container and places each collector **12** into a collection receiver **15a - 15l** as is indicated by the position number **22** (e.g., 1, 2, 3 12) shown in Fig. 1. Each specimen collector **12** is retained within a particular collection receiver **15a - 15l** of tray **10** by frictional fit against tabs **24**. This allows the technician to press fit each specimen collector **12** into a collection
35 receiver **15a - 15l** of tray **10** with the specimen collectors being retained in collection receiver **15** by frictional fit against tabs **24**. Once the technician has arranged the proper number of specimen collectors **12a - 12l** into the

5 collection receivers **15a - 15l** of tray **10** (in this case, **12** collectors can be fitted into tray **10** of Fig. 1) the tray is then inserted into the punch device.

During the punching operation, the punch device (not shown) positions tray **10** underneath the punch device so absorbent **14** of specimen collector **12a** (not shown) which is residing in position 1 (**22**, Fig. 1) is positioned under the punch head. The punch device also aligns the appropriate well **40A1** (Fig. 5) of a micro well plate **50** (Fig. 5) beneath tray **10** (Fig. 1) so well **40A1** is directly beneath absorbent **14a** of position 1 (**22**) of tray **10** to allow the punched out sample **42** (Fig. 5) from absorbent **14a** to fall into the well **40A1** of micro well plate **50** therebelow. Once the absorbent sample has been punched from absorbent **14a**, the punch then retracts and punches one or more times through cleaning absorbent paper **20**, and specifically, in the portion of cleaning absorbent paper **20** located in front of position 2 of tray **10**. A strip of cleaning absorbent paper **20** is located adjacent the top edge of the tray **10**. This allows for cleaning of the punch head prior to extracting a new sample from the successive specimen collector **12b** that resides within position 2 of tray **10**. The previously described procedure is repeated such that a specimen is punched from each absorbent **14a - 14l** of the specimen collectors **12a - 12l** that have been inserted into positions 1-12 of tray **10**.

25 Referring now to Fig. 5, once this procedure is repeated for the entire number of specimen collectors **12a - 12l** that have been inserted into tray **10** each of wells **40A1 - 40A12** of micro well plate **50** will have received one of punched samples **42a - 42l** (only punched samples **42a**, **42b** and **42c** are shown in Fig. 5) thereby filling one row of micro well plate **50**. At this point the punch device will automatically advance to the next tray **10** and re-align the wells of plate **50** to position a first absorbent **14a** of second tray **10** over the first well **40B1** of the second row of wells in plate **50** to continue filling plate **50**.

35 Referring now to Fig. 2, an alternate embodiment is shown having eight specimen collectors **12a-12h** arranged therein for use with a micro titer tray but with the punched samples from the absorbents being directed into the wells according to column order (See, Fig. 5, e.g. A1, B1, C1, . . .

5 .H1). This alternate embodiment can be operated upon in the manner previously described for the embodiment of Fig. 1.

Referring to Fig. 3, multiple specimen trays **10** are shown stacked for convenience of storage. The spacing of stacked trays **10** by feet **30** (Fig. 6) maintains a spaced array of collector absorbents **14** to provide
10 separation between absorbents **14**. This spaced array avoids cross contamination of the specimens on specimen collectors **12**.

Referring to Fig. 4, the utility of specimen trays **10** may be seen in the ability to stack, store and ship large numbers of specimen collectors **12** and again without the potential for cross contamination of absorbents **14**
15 as absorbents **14** are maintained and spaced apart arrangement.

Referring now to Fig. 5, a typical micro well plate **50** is shown of the 96 well configuration produced by twelve columns and eight rows of wells. Punched samples **42a**, **42b** and **42c** are shown respectively within wells **40A1**, **40A2** and **40A3**, each sample residing within a well of the first row, or Row A, of the plate **50**.
20

Referring now to Figs. 6 and 7 a support structure for absorbent **14** of collector **12** is shown extending from the sidewalls adjacent void **13** of tray **10**. Also the interrelationship between feet **30** (Fig. 6) and indents **32** (Fig. 7) will be described. Each void **13** of tray **10** may be provided with
25 shoulders **45a, b** which extend into void **13** from either side of tray **10**. Shoulders **45a, b** serve to support absorbent **14** as it resides within void **13**. Shoulders **45a, b** also provide a structure to resist the bending or drooping of absorbent **14** downwardly where it could contact other surfaces or other collectors and thereby become cross-contaminated by
30 such extraneous contact with other surfaces. Shoulders **45a, b** further provide support to absorbent **14** during the punching process by acting to resist the force of the punch device against absorbent **14** thereby retaining absorbent **14** in proper position and away from contact with extraneous surfaces. In Figs. 6 and 7, feet **30** are shown (Fig. 6) and indents **32** are
35 shown (Fig. 7). In the embodiment of Figs. 6 and 7 feet **30** and indents **32** are opposite faces of the same structure and therefore present alignable, or registerable, structures which serve to allow the stacking of trays **10** into groups (Fig. 3) having the absorbents **14** spaced apart from one another

5 to avoid cross-contamination. In this manner multiple trays **10** having multiple collectors **12** can be stacked together for archival storage of the collectors fitted therein. Also shown in Figs. 6 and 7 are standoffs **33** which serve to space a first tray **10** from a second tray **10** stacked onto the first tray **10**.

10 In the foregoing description, certain terms have been used for brevity, clearness and understanding; but no unnecessary limitations are to be implied therefrom beyond the requirements of the prior art, because such terms are used for descriptive purposes and are intended to be broadly construed. Moreover, the description and illustration of the
15 inventions is by way of example, and the scope of the inventions is not limited to the exact details shown or described.

Certain changes may be made in embodying the above invention, and in the construction thereof, without departing from the spirit and scope of the invention. It is intended that all matter contained in the above
20 description and shown in the accompanying drawings shall be interpreted as illustrative and not meant in a limiting sense.

Having now described the features, discoveries and principles of the invention, the manner in which the device is constructed and used, the characteristics of the construction, and advantageous, new and useful
25 results obtained; the new and useful structures, devices, elements, arrangements, parts and combinations, are set forth in the appended claims.

It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention herein
30 described, and all statements of the scope of the invention which, as a matter of language, might be said to fall therebetween.

5

CLAIMS

What is claimed is:

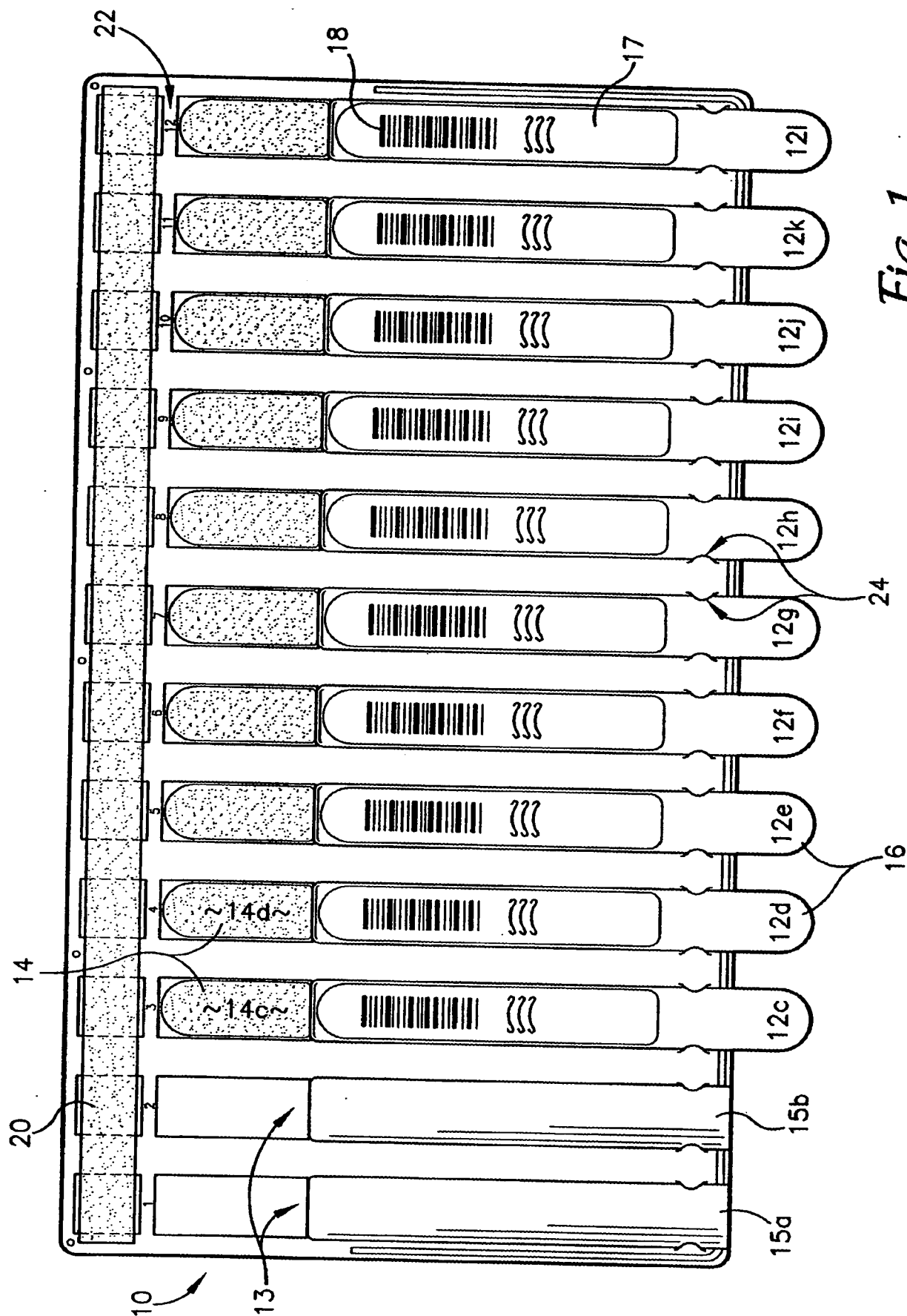
- 10 1. A holder for a specimen collection device the specimen collection device having an absorbent extending therefrom, the holder comprising: a tray having a top surface, a bottom surface, and four bounding edges, a plurality of spaced apart receivers on said tray, each receiver having first and second ends said receiver adapted for reception of the specimen collector device therein,
15 a plurality of voids in said tray said voids positioned adjacent to said receiver first ends for registration with the absorbent extending from the collection device, and
a punch cleaning strip on said tray, said cleaning strip positioned between the absorbent and one of said bounding edges of said tray.
20
2. The holder of claim 1 wherein each collection device is affixed with a unique identifying code.
- 25 3. The holder of claim 1 wherein said specimen tray further comprises twelve receivers.
4. The holder of claim 1 wherein said specimen tray further comprises eight receivers.
- 30 5. The holder of claim 1 wherein said cleaning strip comprises a horizontal strip of cleaning paper adjacent the top edge of the specimen tray.
- 35 6. The holder of claim 1 further comprising a shoulder extending about at least a portion of each of said voids to support the absorbent.

- 5 7. The holder of claim 1 wherein the specimen tray further comprises
opposed tabs extending into each of said receivers for frictional capture of
said collection device therebetween.
8. A specimen collector archive device the specimen collector having
10 an absorbent extending therefrom the device comprising:
a plurality of specimen trays, each specimen tray comprising:
a top surface, a bottom surface, and four bounding edges,
a plurality of spaced apart receivers on said tray, each receiver
having first and second ends said receiver adapted for
15 reception of the specimen collector device therein,
a plurality of first voids in said tray said first voids positioned
adjacent to said receiver first ends for registration with the
absorbent extending from the collection device,
a plurality of second voids in said tray said second voids positioned
20 on said tray between said first void and one of said bounding
edges of said tray,
a punch cleaning strip on said tray, said cleaning strip positioned to
cover said second voids, and
a plurality of feet extending from each of said trays for connecting
25 each of said trays of said plurality of trays in spaced apart
array to maintain separation between each of the absorbents
of said collection devices.
9. The device as claimed in claim 8 wherein said first void and said
30 second void are a single continuous void.
10. The holder of claim 8 further comprising a shoulder extending about
at least a portion of each of said first voids to support the absorbent.

- 5 11. A specimen collector and specimen collector holder comprising:
a specimen collector comprising:
a handle having a first end and a second end,
a collection absorbent extending from said first end of said handle
for collection of a biological specimen thereon, and
10 a cover slidably mounted on said handle for movement between a
first absorbent covering position and a second absorbent
exposing position,
a specimen collector holder comprising:
a tray having a top, a bottom surface, and four bounding edges,
15 a plurality of spaced apart, elongate, holder positions within said
tray, each position configured to receive and retain therein a
specimen collector device,
a plurality of voids in said tray said voids being adjacent to said
holder positions for registration with the absorbent extending
20 from said handle, and
a cleaning strip affixed to said tray, said cleaning strip positioned
between said collection absorbent and one of said bounding
edges of said tray.
- 25 12. The holder of claim 11 wherein each collection device is affixed with
a unique identifying code.
13. The holder of claim 11 wherein said specimen tray further
comprises twelve receivers.
- 30 14. The holder of claim 11 wherein said specimen tray further
comprises eight receivers.
15. The holder of claim 11 wherein said cleaning strip comprises a
35 horizontal strip of cleaning paper adjacent the top edge of the specimen
tray.

5 16. The holder of claim 11 wherein the specimen tray further comprises
opposed tabs extending into each of said receivers for frictional capture of
said collection device therebetween.

10 17. The holder of claim 11 further comprising a shoulder extending
about at least a portion of each of said voids to support the absorbent.



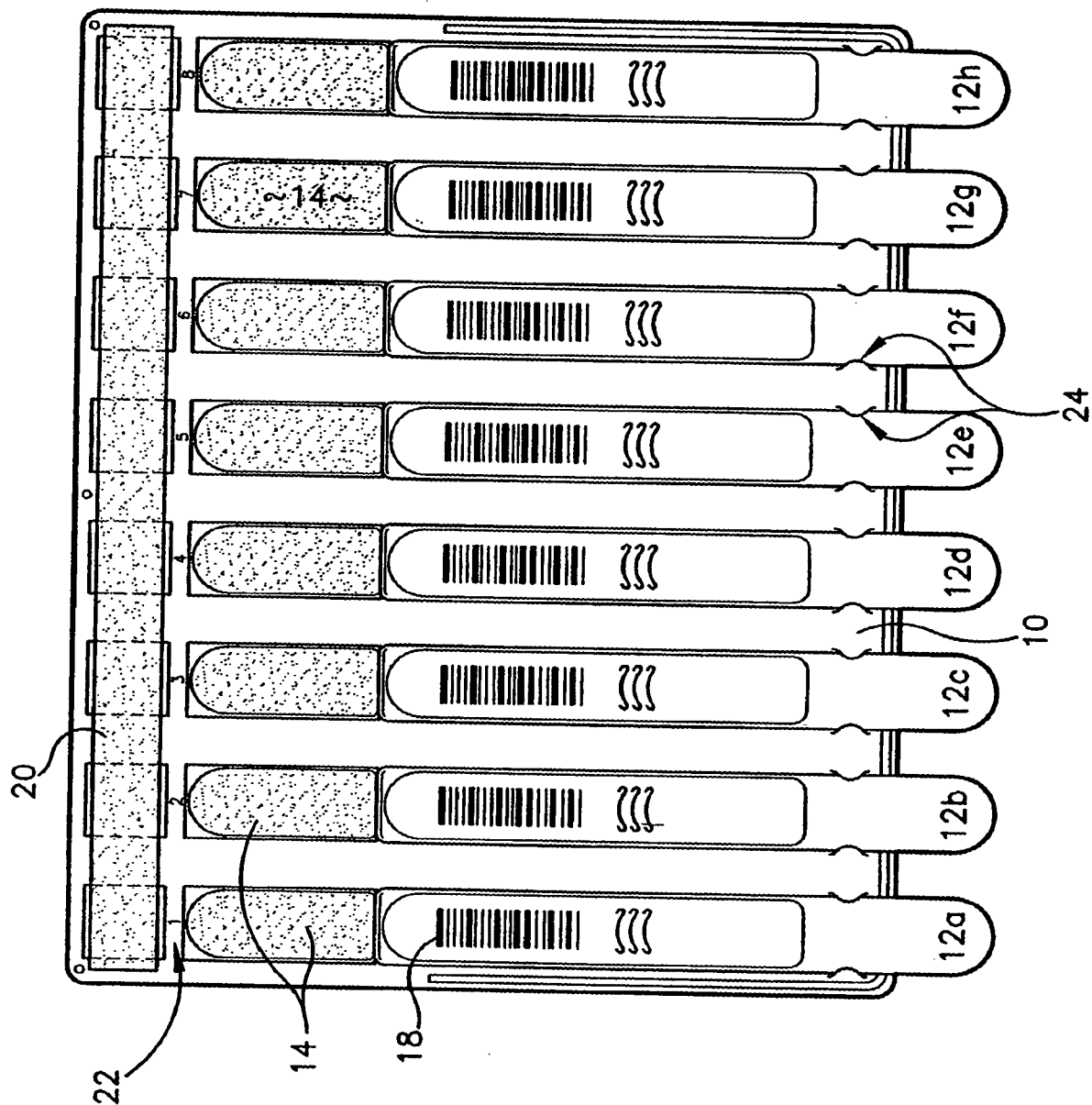
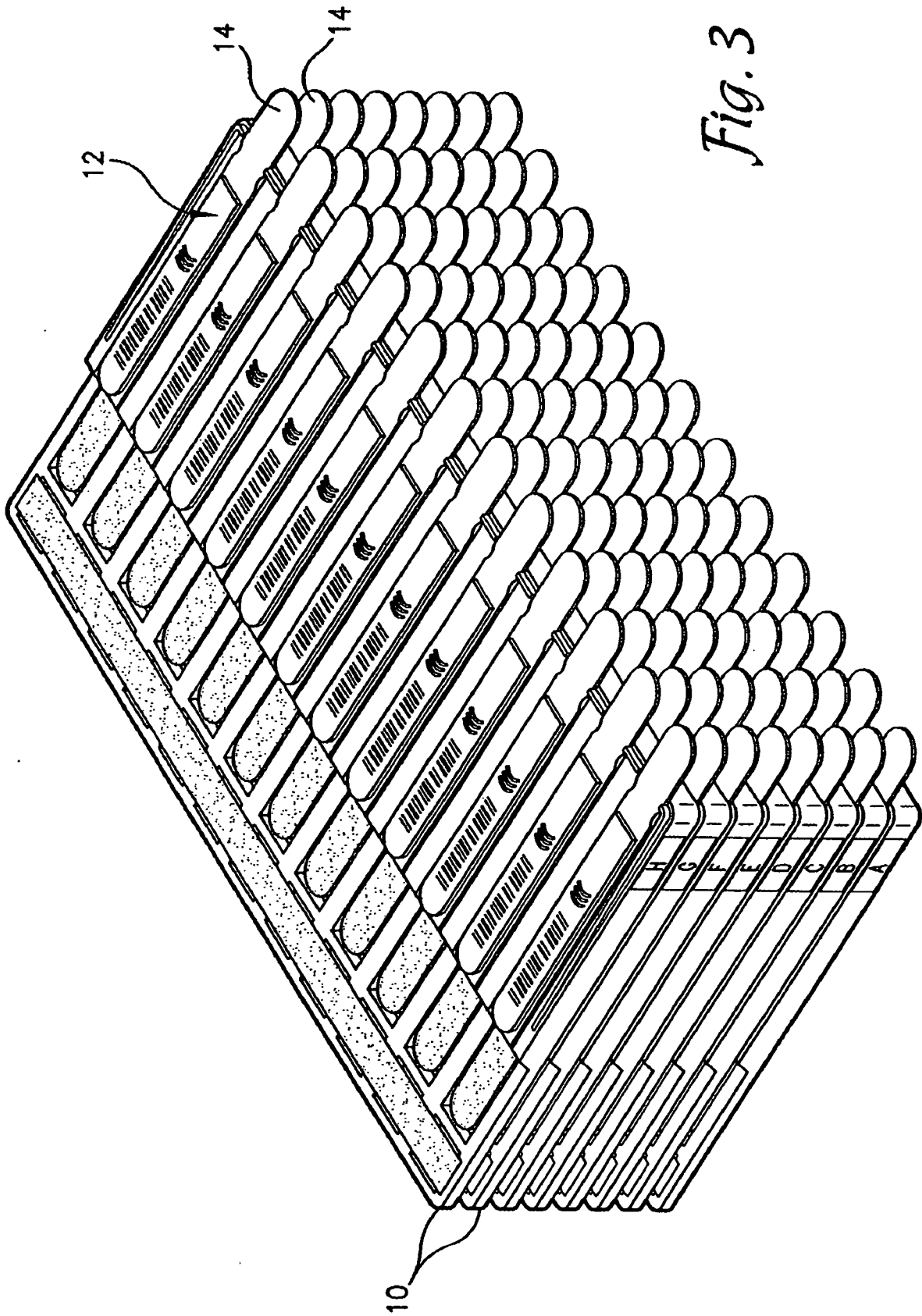


Fig. 2

Fig. 3



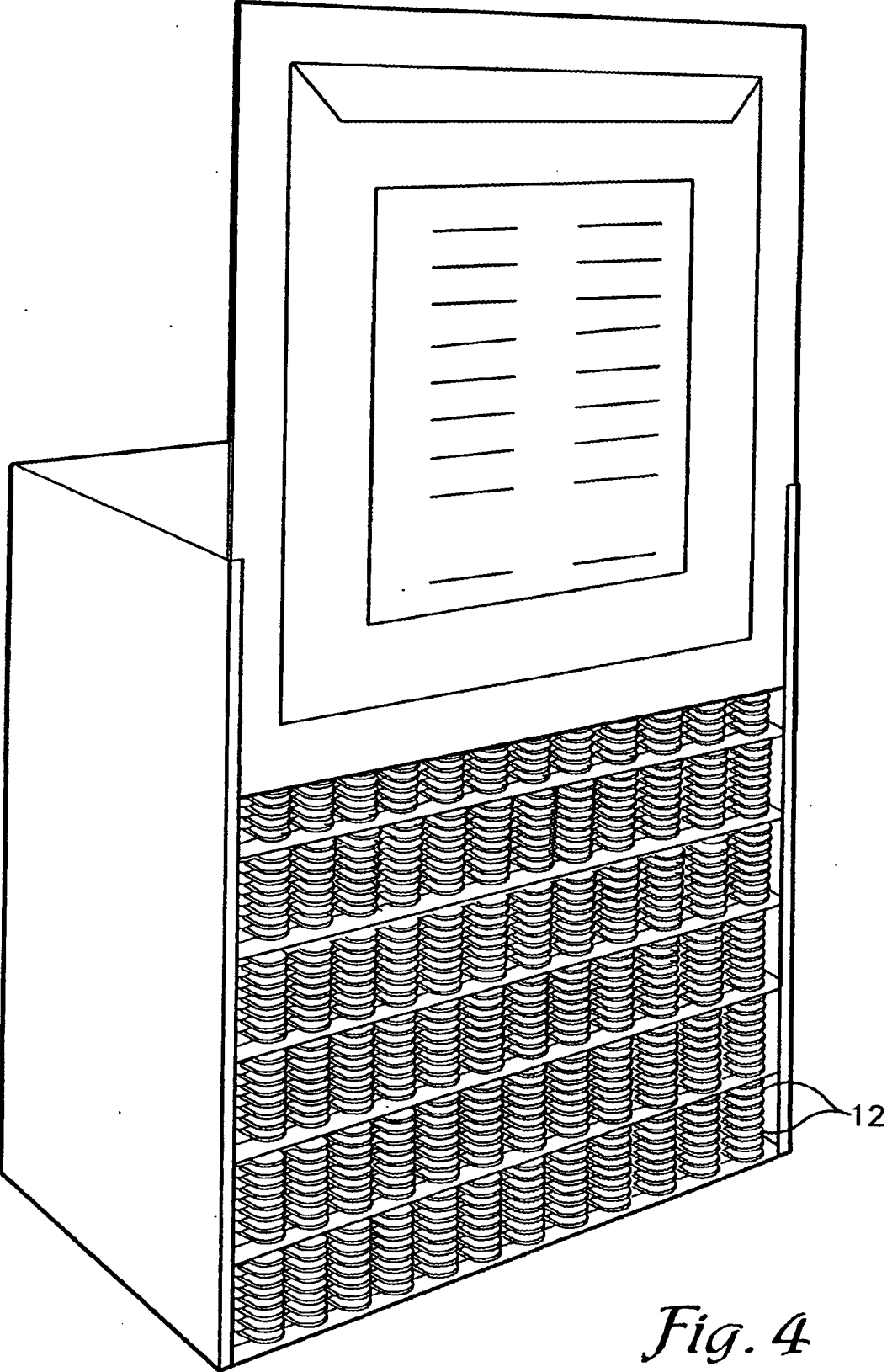
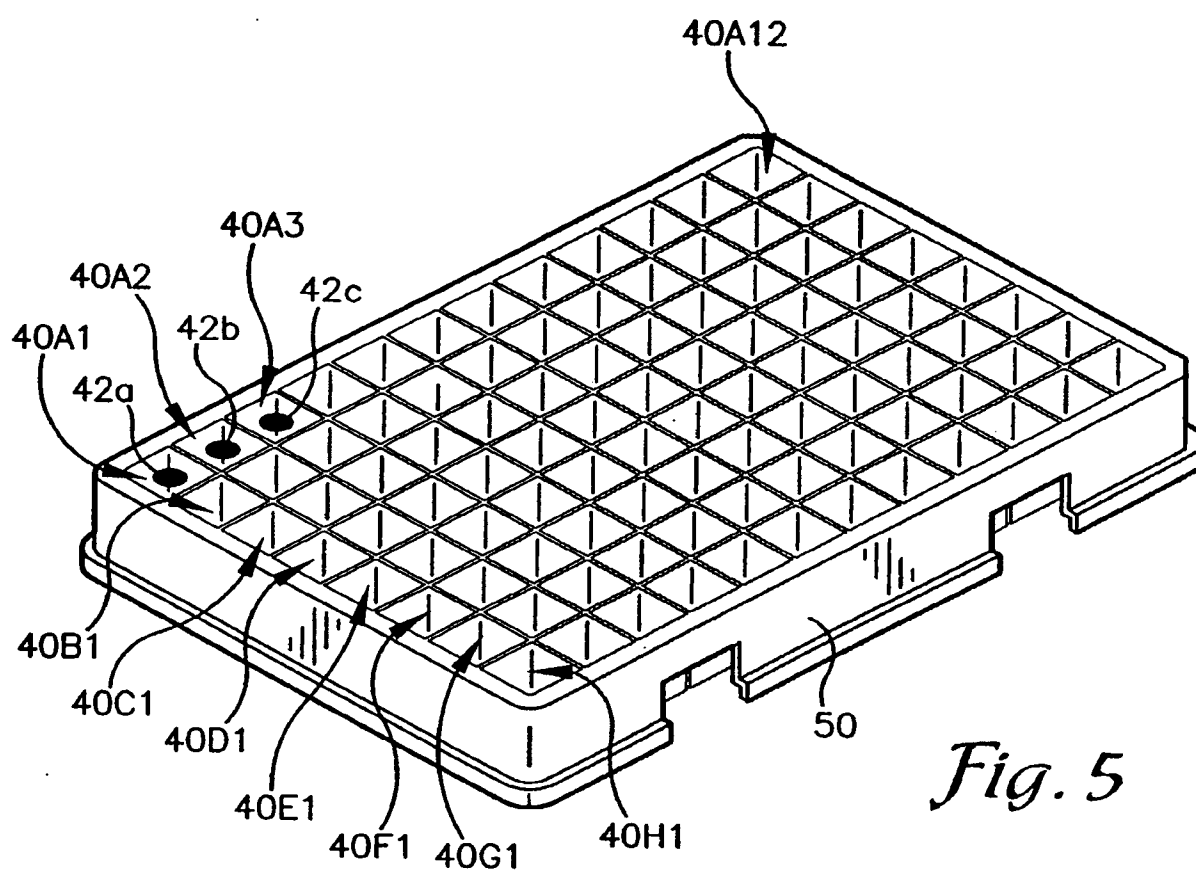


Fig. 4

*Fig. 5*

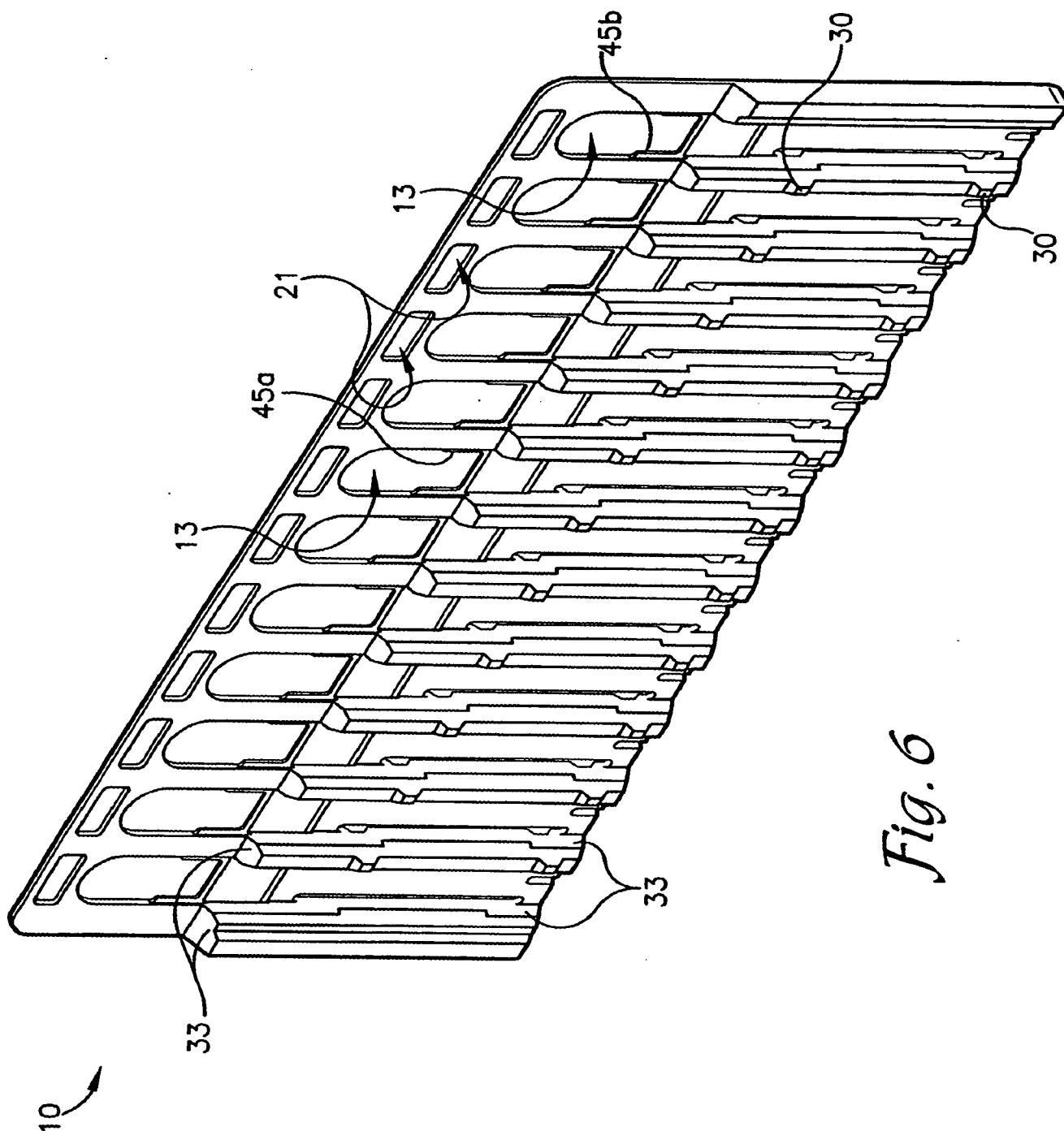


Fig. 6

Fig. 7

