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— 包括国际检索报告。

(54) **Title:** IMMUNE CHROMATOGRAPHIC STRIP DISC FOR MULTIPLE ANALYSIS AND DETECTING METHOD BY USING IT

(54) **发明名称:** 一种免疫层析多重检测试纸盘及使用其进行检测的方法

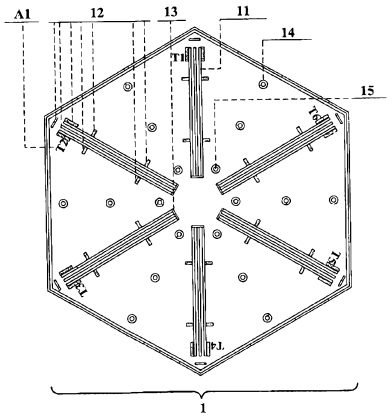

图 2 / Fig. 2

(57) **Abstract:** An immune chromatographic strip disc for multiple analysis comprises: a base of disc, a lid engaged to the base, and a drainage plate disposed between test strips on the base and the lid of disc. An application opening is formed in the lid of strip disc, is opposite to the drainage plate, and communicates with a drainage groove formed by a plurality of drainage channels placed on underside of the lid. Supports of test strips are positioned on the base corresponding to the position and number of the plurality of drainage channels on lid. The edge of the drainage plate overlaps the sample pad of the test strip adjacent to the application opening, wherein the test strip is placed on the support of test strip. The present invention also provides a multiple immune chromatographic method by using the strip disc, through which multiple analytes in a sample can be detected simultaneously in an assay.

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(57) 摘要：

一种免疫层析多重检测试纸盘，包括一试纸盘底壳、一可与试纸盘底壳盖合的试纸盘上盖、以及一置于试纸盘底壳上的试纸条与试纸盘上盖之间的引流片，所述试纸盘上盖设加样孔，且加样孔正对引流片，所述加样孔连通一设于上盖内面由多个引流通道组成的引流槽，所述底壳设与上盖的多个引流通道位置和数量对应的试纸条承载台，且所述引流片边缘搭接于所述试纸条承载台上所承载的试纸条靠近加样孔一端的样品垫上。本发明还提供一种利用所述试纸盘进行免疫层析多重检测的方法，可实现对一份样品进行一次试验操作而完成多种目标被检物的同时检测。

AN IMMUNOCHROMATOGRAPHIC TEST STRIP PLATE FOR MULTIPLE DETECTIONS AND METHOD

Technical Field

The present invention belongs to the field of immunologic diagnosis technique, and relates to an immunochromatographic technique for multiple detections. The present invention provides an immunochromatographic test strip plate and an immunochromatographic method for multiple detections by the test strip plate. This makes it possible that test results, whether various analytes exist or not, can be gained by detecting one sample only once.

Background of the Invention

Immunochromatography is a kind of comparatively mature technique for on-site rapid detection. Traditional immunochromatographic test strip 4 is shown in Figure 1. The strip comprises the following components: analytical membrane (mainly nitrocellulose membrane) 101, conjugate pad (mainly glass fiber) 102, sample pad 103 (mainly glass fiber or absorbent paper) and absorbent pad (mainly absorbent paper) 104. The above components are fixed on the sticky substrate 105 with proper overlapping sequence. The overlap of the above components ensures continuity of liquid flow on the strip. When performing the detection, a sample is added to sample pad 103, then enters the conjugate pad 102 through penetration and siphon to redissolve marker-biomolecular conjugates therein. Under the siphon effect of absorbent pad 104, the sample and conjugates leave the conjugate pad 102, enter into the membrane 101 and flow toward the absorbent pad 104 inside the membrane 101. In the processing, specific immunologic reactions will occur between conjugates, target analytes, test line 106 and control line 107 to generate indicative signals. Markers which are commonly used to generate indicative signals include colloid gold, fluorescein, dye, etc. However, any kind of immunochromatographic strip has to follow the detecting mode of one-to-one, namely, only one analyte can be detected in one assay for one sample. This kind of detecting mode is complicated and

time-consuming when it's used for screening various target analytes in suspected samples.

Summary of the Invention

According to one aspect of the present invention there is provided an immunochromatographic test strip plate for multiple detections comprising: a base on which the strips are disposed; a upper cover engaged with the base; and a drainage piece disposed between the strips and the upper cover, wherein a sample-adding opening is disposed in said upper cover directly opposite the drainage piece, said sample-adding opening connects with a drainage groove formed by a plurality of drainage channels formed on an underside of the upper cover, several strip stages are disposed on the base opposite to the drainage channels according to their location and number, and the edge of the drainage piece overlaps sample pads disposed adjacent to one end of the sample-adding opening, and wherein the drainage channel comprises two upper fringes and a lower fringe, all drainage channels connect sequentially and an inner side of the two upper fringes occlude an edge of each stage and extend directly to an upper side of the base.

Preferred embodiments of the invention may also provide an immunochromatographic method for multiple detections using the test strip plate of the present invention, which may make it possible for a detecting mode of one-to-many, namely, various target analytes to be detected in one assay for one sample simultaneously.

Preferred embodiments provide an immunochromatographic test strip plate, which comprises: a base, a upper cover which can engage with the base, a drainage piece disposed between the strips on the base and cover. In the cover, there is a sample-adding opening which is just opposited to the drainage piece. The sample-adding opening connects with a drainage groove formed by many drainage channels. On the base, there are several strip stages corresponding to drainage channels in an underside of the cover with their location and number. The edge of drainage piece laps on sample pads adjacent to the ends near sample-adding opening of strips on the strip stages.

According to preferred embodiments, the shape of said plate for multiple detections may be one of a group including: circle, square, rectangle, diamond, regular polygon and the sample-adding opening is located at the geometric center of one of the above shapes. Several strip stages of the base are arranged in central symmetry or axial symmetry.

Several sets of fixing stoppers may be disposed along the edge of every stage in

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immunochromatographic plate, and numbering regions are located on each stage near the edge of the plate base.

The strip stage may consist of three protuberances, and the end adjacent to the symmetric center or axis is sealed by equal-height stoppers.

Several sets of pressure pieces may be disposed on underside of the upper cover at interval place where the channel of the drainage groove extends outwards. The channel of the drainage groove may extend outwards, a result-observing window, an endpoint-indicating window and fixing rivets may also be disposed on underside of the upper cover in interval sequence.

Several rows of female rivets may be disposed in the base of the plate and male rivets are correspondingly disposed on underside of the cover.

According to preferred embodiments, the drainage channel comprises two upper fringes and a lower fringe, and all drainage channels connect sequentially. The inner side of the two upper fringes occlude with the edge of the stage and extend directly to upside of the base. The relationship between height of the lower fringe (h2) and height of the upper fringe (hl) is expressed as follows:

h2=h1-(height of stage + thickness of sticky substrate of strip + thickness of sample pad of strip).

The shape of said immunochromatographic test strip plate for multiple detections may be one of a group including: circle, diamond and regular polygon, the sample-adding opening may be disposed at the geometric center and several strip stages on the base would be arranged in central symmetry.

Moreover, the shape of above said strip plate may be one of a group including: square and rectangle, the sample-adding opening may be disposed at the symmetric axis and several strip stages on the base would be arranged in axial symmetry.

According to above said immunochromatographic test strip plate for multiple detections, the numbers on the outer side of the lid may correspond to those on the base of the disc. In addition, the ID window for marking the serial number of the samples, user holding indication and inserting direction indication may also be provided.

According to another aspect of the invention there is provided a immunochromatographic method for multiple detections using a immunochromatographic test strip plate of the above described type comprising a qualitative detection, comprises

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the following steps:

Step 1: Assembling the test strip plate by placing different types of strips on the corresponding stage;

Step 2: Adding a liquid sample through the sample-adding opening and judging the test endpoint through the endpoint-indicating window;

Step 3: Observing and recording results of the different strips through the result-observing windows; and

Step 4: Comparing the test results with a standard in order to judge the occurrence of certain immunologic reactions and determine existence of certain analytes.

According to another aspect of the invention there is provided a immunochromatographic method for multiple detection using a immunochromatographic test strip plate of the above described type comprising a quantitative detection, comprises the following steps:

Step 1: Assembling the test strip plate by placing different types of strips on the corresponding stage;

Step 2: Adding a liquid sample through the sample-adding opening and judging the test endpoint through the endpoint indicating window;

Step 3: Inserting the plate into a detector according to the user holding indication and the inserting direction indication on an outside of the upper cover;

Step 4: Using the detector to analyze one strip quantitatively through the result-observing window, the test result of the strip being displayed by the apparatus;

Step 5: Rotating or moving the plate to the next strip and using the detector again to perform another quantitative analysis;

Step 6: Repeating step 5) until all strips on the plate are analyzed; and

Step 7: Determining existence of certain analyte and its concentration.

Preferred embodiments of the invention relate to establishing an immunochromatographic detecting mode for multiple detections by designing a specific immunochromatographic test strip plate, so that various immunochromatographic reactions can occur symmetrically and synchronously in multiple strips for one sample.

Compared with the prior art, preferred embodiments of the invention have the following technique advantages:

Compared with traditional one-to-one immuno-detecting mode, preferred

embodiments of the invention establish an immunochromatographic detecting mode for multiple detections by designing a specific immunochromatographic test strip plate so that the existence of various target analytes can be determined in one assay for one sample. Thus, a detection mode of one-to-many is achieved. In the prior art, although the mode of performing multiple detections with several kinds of the strips was mentioned briefly, it does not ultimately resolve the problems that exist necessarily during the combined detection, such as uneven distribution of the liquid sample, non-uniform immunochromatography reaction and liquid sample loss caused by overflow, etc. It makes the combined detection can not be actually achieved. Preferred embodiments of the present invention may directly resolve the above problems by means of the special arrangement of the strips, the usage of the drainage piece and the design of the drainage groove on the upper cover of the plate. With these advantages, the synchronous detections which are uniform and prompt can be carried out successfully.

Description of the Drawings

Figure 1: a graph showing the structure of the strip.

Figure 2: a graph showing the base of the plate.

Figure 3A: a graph showing the underside of the upper cover of the plate.

Figure 3B: a graph showing the structure of the drainage channel in underside of the upper cover of the plate.

Figure 4: a graph showing the outer side of the upper cover of the plate.

Figure 5: a graph showing the assembling process of the plate.

Figure 6: a graph showing the base of the centrally symmetric 10 strips-assembled plate.

Figure 7A: a graph showing the underside of the centrally symmetric 10 strips-assembled plate cover.

Figure 7B: a graph showing the structure of the drainage channel in underside of the centrally symmetric 10 strips-assembled plate cover.

Figure 8: a graph showing the outer side of the centrally symmetric 10 strips-assembled plate cover.

Figure 9: a graph showing the assembling process of the centrally symmetric 10 strips-assembled plate.

Figure 10: a graph showing the base of the axially symmetric 10 strips-assembled plate.

Figure 11A: a graph showing the underside of the upper cover of the axially symmetric 10 strips-assembled disc.

Figure 11B: a graph showing the structure of the drainage channel on the underside of the upper cover of the axially symmetric 10 strips-assembled disc.

Figure 12: a graph showing the outer side of the upper cover of the axially symmetric 10 strips-assembled plate.

Figure 13: a graph showing the assembling process of the axially symmetric 10 strips-assembled plate.

Detailed Description of Preferred Embodiments

The Test strip plate comprises four components: a base 1 (see Figure 2, Figure 6, Figure 10), a upper cover 2 (see Figure 3A/3B and Figure 4, Figure 7A/7B and Figure 8, Figure 11A/11B and Figure 12), drainage piece 3 (see Figure 5, Figure 9, Figure 13) and test strips 4 (see Figure 1). Said base 1 and upper cover 2 are fitted to engage for use. Said drainage piece 3 are disposed between the upper cover 2 and the test strips carried on the base 1.

The base 1 contains several strip stages 11 which are arranged in central symmetry (see Figure 2, Figure 6) or axial symmetry (see Figure 10). Several sets of fixing stoppers 12 and equal-height stoppers 13 are disposed along the edge of every stage 11. Numbering region A1 is provided on each stage near the edge of the base 1. Several rows of female rivets 14 are disposed in the base of the disc.

As shown in Figure 2, said strip stage 11 comprises three protuberances, and its end adjacent to the symmetric center or axis is sealed by equal-height stopper 13 to

prevent overflow of the liquid sample. Said fixing stopper 12 is configured around the strip stage 11. Said strip stage 11 is combined with the fixing stoppers 12 for carrying and fixing strips, thereby keeping them in central symmetry or axial symmetry as consistent with strip stages 11, with sample pads of test strips gathering at the symmetric center or axis. Said numbering region A1 is provided near the edge of each strip stage 11 for indicating the different types of strips carried on the strip stage 11. Said several rows of female rivets 14 are used to engage with the upper cover 2, wherein the group of female rivets 14 adjacent to the symmetric center or symmetry axis innermostly can also be used as fixed rivets 15 for fixing the drainage piece 3.

See Figure 3 and Figure 4, the upper cover 2 comprises both underside and upside of the upper cover, and consists of the following components: drainage groove 21, several sets of pressure pieces 22, 23, 24, fixing rivets 25, several rows of male rivets 26, sample-adding opening 27, result-observing window 28, endpoint-indicating window 29, numerical code B1, ID window B2, holding indication B3 and inserting direction indication B4. Drainage groove 21, pressure pieces 22,23,24, fixing rivets 25 , male rivets 26 are disposed on underside of the upper cover. Sample-adding opening 26, result-observing window 27 and endpoint-indicating window 28 penetrate through the upper cover 2 from underside to upside. Numerical code B1, ID window B2, holding indication B3 and inserting direction indication B4 are only disposed on upside of the upper cover.

Said drainage groove 21 is formed by integrating the drainage channels 20 corresponding to each strip. As shown in Figure 3B, said drainage channel 20 comprises two upper fringes 201 and one lower fringe 202. The inner sides of said upper fringe 201 occlude with the edge of the stage 11 and extend directly to the upside of the base 1. The relationship between height h2 of said lower fringe 202 and height of the upper fringe h1 is expressed as follows: h2=h1-(height of stage + thickness of sticky substrate of strip + thickness of sample pad of strip). The lower fringe 202 chucks the sample pad 103 tightly. Said upper fringes 201 and lower fringes 202, together with the stage 11, equal-height stoppers 13, the strips 4, the

drainage piece 3, upside of the base 1 and underside of the lid of disc 2, define a closed sample pool and the drainage channels corresponding to each strip.

Said three pressure pieces 22,23,24 correspond to the overlapping areas of absorbent pad 104 and analytic membrane 101, conjugate pad 102 and analytic membrane 101, as well as sample pad 103 and the conjugate pad 102 (see Figure 1) in turn, which ensures the continuity of the liquid flow in the strip. The said fixing rivet 25 can penetrate into the absorbent pad 104 of the strip for further stabilizing the strip to prevent it from moving. Said male rivets 26 can interlock with the female rivets 14 on the base 1, which further engage and fix upper cover 2 and base 1. Said sample-adding opening 27 is disposed at the center of cover 2 and is opposite to the drainage piece 3 after the base and cover are engaged together. In the process of detection, the liquid sample is added to the drainage piece 3 through the sample-adding opening 27. Said result-observing window 28 and endpoint-indicating window 29 are arranged in line and are disposed corresponding to the stage 11 of the base 1, wherein the result-observing window 28 is disposed in the middle of the line and opposite to the analytic membrane 101 of the test strip after the base and cover are engaged together. After the assay is completed, the result can be evaluated based on the analytic membrane 101 through the result-observing window 28. Terminal-indicating window 29 is disposed on the portion of the line adjacent to the edge of the upper cover 2 and opposite to the absorbent pad 104 of the strip after the base and upper cover are engaged together. The immunochromatography process can be monitored through endpoint-indicating window during the detection.

Said numerical code B1 on the upper cover, corresponding to the numerical code A1 on the base 1 one to one, is used for indicating different types of the strip. Said ID window B2 can be used for marking the serial number of the detected sample. Said holding indication B3 and inserting direction indication B4 can indicate the direction of inserting the plate into the detector for quantitative detection.

As shown in the Figure 5, the drainage piece 3 is a kind of membrane with large bed volume and uniform microscopic structure. The material of membrane can be glassfiber, filter paper, non-woven fabrics, or etc. The drainage piece 3 is opposite to

the drainage groove 21 during assembling, so it can contact the sample pads 103 of each strip and partly overlap the sample pads 103.

The above components are assembled to form the plate.

The assembling process shown in Figure 5 comprises three steps: placing the test strip, placing the drainage piece and installing the upper cover. Firstly, the specific strips are placed on the specific stage 11 according to the numerical code A1 on the base. The arrangement mode of the stages 11 and the orientating function of the fixing stoppers 12 make the strips gathering in central symmetry or axial symmetry with the sample pads. Then, drainage piece 3 is placed with female rivets 14 on the innermost portion of the base 1 as the fixing rivet 15. The drainage piece 3 overlaps with the sample pads of all strips partly. The large bed volume of the draining piece 3 can prevent the overflow of the liquid sample. Furthermore, the uniform microscopic structure of the drainage piece ensures the uniformity of the sample distribution to each strip. At last, the female rivets 14 in the base 1 interlock with the male rivets 26 on the upper cover 2 to integrate the strip plate in union. In the assembled plate, the sample-adding opening 27, the result-observing windows 28 and the endpoint-indicating windows 29 of the upper cover opposite the drainage piece 3 fixed on the base 1, analytic membranes 101 and absorbent pads 104 of each strip, respectively. Furthermore, the three pressure pieces 22,23,24 opposite the overlapping area of the absorbent pad 104 of each strip and the analytic membrane 101, the overlapping area of the conjugate pad 102 and the analytic membrane 101, as well as the overlapping area of the sample pad 103 and the conjugate pad 102, which ensures the continuity of each chromatographic channels. In order to prevent the overflow of the liquid sample and ensure the uniformity of the chromatographic reaction in each strip, the unique drainage groove 21 is designed on underside of the upper cover 2, including the drainage channels 20 corresponding to each strip. The inner sides of the upper fringes 201 on both sides of the drainage channel 20 occlude with the edge of the stage 11 and extend directly to upside of the base 1. The lower fringe 202 on the middle of the drainage channel 20 chunks the sample pad tightly. In addition, the face-centered end of the stage 11 is sealed by the equal-height stopper 13. Following

the buckling and closing of the base and upper cover of plate, the stage 11, equal-height stoppers 13, the strips 4, the drainage piece 3, the drainage groove 21 and upside of the base 1 and underside of the upper cover 2 define a closed sample pool and drainage channels corresponding to each strip, thereby effectively preventing sample loss and ensuring the synchronism and uniformity of absorption of the sample by each strip simultaneously.

In summary, the plate has the following three technical features:

1. The arrangement of strips in central symmetry or axial symmetry ensures the uniformity of absorption of the sample by each strip;
2. The drainage piece partly overlapping with the sample pad of each strip has a large bed volume to prevent the overflow of the liquid sample. Furthermore, the uniform microscopic structure of the drainage piece ensures the uniformity of the sample distribution;
3. The drainage groove on underside of the upper cover and the base define a closed space for reaction and drainage, and it ensures the uniformity of the reaction in each strip and prevents the overflow of the liquid sample simultaneously.

Shape of above said test strip plate may be one of the group including: circle, square, rectangle, diamond, regular polygon and any other geometrical shapes. Said plate can carry N strips, wherein N is natural number. Therefore, the plate of the invention may have various modifications. Preferred embodiments of the present invention will be described by way of the specific examples, but it not intended to be limited to the following examples.

The detecting method can be used for the qualitative detection, comprising the following steps:

1. Assembling the test strip plate by placing different types of the strips on the stage with different numbers.

2: Adding the liquid sample through the sample-adding opening and judging the test endpoint through the endpoint-indicating window.

3: Observing and recording the results of the different strips through the result-observing window.

4: Comparing the test results with the standard in order to judge occurrence of certain immunologic reaction and determine existence of certain analytes.

The detecting method can also be used for the quantitative detection, comprising the following steps:

1: Assembling the test strip plate by placing different types of the strips on the stage with different numbers.

2: Adding the liquid sample through the sample-adding opening and judging the test endpoint through endpoint-indicating window.

3: Inserting the plate into detector according to the user holding indication and the inserting direction indication on outside of the upper cover of plate.

4: Powering on the detector to analyze one strip quantitatively through result-observing window. Test result of the strip is displayed by the apparatus.

5: Rotating or movieng the plate to the next numbered strip and powering on the detector again to perform another quantitative analysis.

6: Repeating the step 5 until all strips of the plate are analyzed.

7: Determine existence of certain analyte and its concentration.

Example 1: The centrally symmetric 6 strips-assembled plate.

Figures 2-5 show the structure and the assembling process of the central symmetric 6 strips-assembled plate. The plate according to this example , which is designed to carry six strips, has a shape of hexagon with its geometric center as symmetric center. All sample pads 103 of the strips point to the symmetric center. The details for the plate according to this example have been described as discussed above with reference to Figures, and its description will be omitted.

Example 2: The centrally symmetric 10 strips-assembled plate.

Figures 6-9 are referenced based on above description. The centrally symmetric 10 strips-assembled plate according to this example consists of base 1 (Figure 6), upper cover 2 (Figures 7 and 8), drainage piece 3 and strips 4 (Figure 9). The base 1 includes 10 stages 11, 10 sets of fixing stoppers 12, 10 equal-height stoppers 13, 10

sets of pressure pieces 22,23,24, and 10 rows of female rivets 14, 10 numerical codes A1. The upper cover 2 include drainage groove 21 consisting of 10 drainage channels 20, 10 sets of the pressure pieces 22,23,24, 10 sets of fixing rivets 25, 10 rows of male rivets 26, sample-adding opening 27, 10 result-observing windows 28, 10 teminal-indicating windows 29, 10 numerical codes B1, ID window B2, holding indication B3 and inserting direction indication B4.

The assembling process (Figure 9) comprises the following steps: placing the strips 4, placing the draining piece 3 and installing the upper cover 2. The assembled plate can achieve the uniform reaction of 10 kinds of immunochromatography strips through some special designs. The stages 11 are arranged in central symmetry, and fit with the fixing stoppers 12 and the fixing rivets 25 on the upper cover to make 10 strips arranging in central symmetry gathering toward the center with the sample pads 103. Therefore, with such spatial structure, the uniform immunochromatographic reaction on the various strips 4 can be achieved. The female rivets 14 in innermost portion of the base 1 fit with the male rivets 26 on the upper cover to engage the plate, and they can also be used as fixing rivets 15 to fix the draining piece 3 and make it partly overlap with the sample pad 103 of each strip 4. Consequently, with large bed volume and uniform internal structure, the drainage piece 3 prevent the overflow of the liquid sample and ensure the even distribution of the sample to each strip, resulting in the uniform reaction in different strips. The base 1 and the upper cover 2 of the plate engage together to make the pressure pieces 22,23,24 on underside of the upper cover 2 press on the overlapping areas of the absorbent pad 104 and the analytic membrane 101, the conjugate pad 102 and the analytic membrane 101, as well as the sample pad 103 and the conjugate pad 102. It ensures the continuity of immunochromatographic reaction in the strips. The drainage groove 21 on underside of the upper cover 2 is formed by integrated ten draining channels 20 corresponding to each strip 4. Each drainage channel 20 includes two upper fringes 201 and one lower fringe 202. The inner sides of two upper fringes 201 occlude with the edge of the stage 11 and extend directly to the upside of the base 1. The relationship between height of lower fringe h2 and height of upper fringe h1 is as follows:

h2=h1-(height of stage + thickness of sticky substrate of strip + thickness of sample pad of strip).

The relationship ensures that the upper fringes 201 occlude with the edge of the stage 11 and chuck to the underside of the base 1, and at the same time, the lower fringe 202 chucks to the sample pad 103 tightly. In addition, the face-centered end of stage 11 is sealed by the equal-height stopper 13. Therefore, following the engagement of the base and upper cover of plate, the stage 11, equal-height stoppers 13, the strips 4, the drainage piece 3, the draining groove 21 and the upside of the base 1 and underside of the upper cover 2 define a closed sample pool and immunochromatographic channel, which can ensure that the sample can be distributed to each strip uniformly while preventing loss of the sample due to overflow. During the detection by the assembled plate, the liquid sample is dropped to the drainage piece 3 through the sample-adding opening 27 and then the immune-reaction begins. The process of the immunochromatographic reaction can be monitored through terminal-indicating window 29 opposite the absorbent pad 104 during the detection and the final result can be read through result-observing window 28 opposite the analytic membrane. For the strips that can be analyzed quantitatively by the detector, the holding indication B3 and inserting direction indication B4 on the plate can indicate the direction of the plate inserted in detector.

At last, a synchronous and uniform immunochromatographic reaction can occur on 10 kinds of strips by using the centrally symmetric 10 strips-assembled plate and the final results for interpretation can be shown visually.

Example 3: The axially symmetric 10 strips-assembled disc.

Figures 10-13 are referenced based on above description.. The axially symmetric 10 strips-assembled plate according to this example has a shape of rectangle, and 10 strips are arranged along the axis symmetrically with 5 strips on each side, which makes sample pads 13 of the strips adjacent to the axis. Specifically, the axially symmetric 10 strips-assembled disc consists of base 1 (Figure 10), upper cover 2 (Figures 11 and 12), drainage piece 3 and strips 4 (Figure 13). The base 1 includes

stage 31, fixing stoppers 32, equal-height stoppers 33, female rivets 34, male rivets 35, and numerical codes C1. The upper cover 2 include drainage groove 41, pressure pieces 42,43,44, fixing rivets 45, male rivets 46, sample-adding opening 47, result-observing window 48, endpoint-indicating window 49, numerical codes D1, ID window D2, holding indication D3, inserting direction indication D4.

The assembling procedure (Figure 13) includes the following steps: placing the strip 4, placing the drainage piece 3, installing the upper cover 2. The assembled plate can achieve the uniform immunochromatographic reaction of 10 kinds of strips through some special designs. The stages 31 are arranged in axial symmetry, and fit with the fixing stoppers 32 and the fixing rivets 45 on the upper cover to make 10 strips arranging in axial symmetry gathering toward the symmetric axis with the sample pad. Therefore, with such spatial structure, the uniform immunochromatographic reaction on the various strips can be achieved. The female rivets 34 in the base fit with the male rivets 46 on the upper cover to engage the plate, and two female rivets 34 disposed on the symmetric axis and four male rivets 35 can also be used as fixing rivets 36 to fix the drainage piece 3 and make it partly overlap the sample pad 103 of each strip. Consequently, with large bed volume and uniform internal structure, the drainage piece 3 prevent the overflow of the liquid sample and ensure the even distribution of the sample to each strip, resulting in the uniform reaction on the different strips. The base 1 and the upper cover 2 of plate engage together to make the pressure pieces 42,43,44 on underside of upper cover press on the overlapping areas of the absorbent pad 104 and the analytic membrane 101, the conjugate pad 102 and the analytic membrane 101, as well as the sample pad 103 and the conjugate pad 102, which ensures the continuity of immunochromatographic reaction in the strips. The draining groove 41 on underside of the upper cover consists of integrated ten draining channels 40 corresponding to each strip. Each drainage channel 40 includes two upper fringes 401 and one lower fringe 402. Every two drainage channels 40 disposed on the same side of axis are linked by the connection board 403, while two drainage channels 40 disposed on the different side of axis are linked by the connection board 404. The inner sides of two upper fringes occlude with

the edge of the stage 31 and extend directly to the underside of the base. The relationship between height of lower fringe h2 and height of upper fringe h1 is as follows:

h2=h1-(height of stage + thickness of sticky substrate of strip + thickness of sample pad of strip).

The relationship ensures that upper fringes 401 occlude with the stage 31 and chuck to the underside of the base 1, and at the same time, the lower fringe 402 chucks to the sample pad 103 tightly. In addition, the face-axis end of stage 31 is sealed by the equal-height stopper 33. Therefore, following the engagement of the base and upper cover of plate, the stage 31, equal-height stoppers 33, the strips 4, the drainage piece 3, the drainage groove 41 and the upside of the base 1 and underside of the upper cover 2 define a whole closed sample pool and immunochromatographic channel, which can ensure that the sample can be distributed to each strip uniformly while preventing loss of the sample due to overflow. During the detection by the assembled plate, the liquid sample is dropped to the drainage piece 3 through the sample-sdding opening 47 and then the immune-reaction begins.

The process of the immunochromatographic reaction can be monitored through endpoint-indicating window 49 opposite the absorbent pad 103 during the detection and the final result can be read through result-observing window 48 opposite the analytic membrane. For the strips that can be analyzed quantitatively by the detector, the holding indication D3 and the inserting direction indication D4 on the plate can indicate the direction of the plate inserted in detector.

At last, a synchronous and uniform immunochromatographic reaction can occur on 10 kinds of strips by using the axially symmetric 10 strips-assembled plate. The final results for interpretation can be shown visually.

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The invention has been described by way of non-limiting example only and many modifications and variations may be made thereto without departing from the spirit and scope of the invention.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

The reference in this specification to any prior publication (or information derived from it), or to any matter which is known, is not, and should not be taken as an acknowledgment or admission or any form of suggestion that that prior publication (or information derived from it) or known matter forms part of the common general knowledge in the field of endeavour to which this specification relates.

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CLAIMS

1. An immunochromatographic test strip plate for multiple detections comprising:

a base on which the strips are disposed;

a upper cover engaged with the base; and

a drainage piece disposed between the strips and the upper cover,

wherein a sample-adding opening is disposed in said upper cover directly opposite the drainage piece, said sample-adding opening connects with a drainage groove formed by a plurality of drainage channels formed on an underside of the upper cover, several strip stages are disposed on the base opposite to the drainage channels according to their location and number, and the edge of the drainage piece overlaps sample pads disposed adjacent to one end of the sample-adding opening, and

wherein the drainage channel comprises two upper fringes and a lower fringe, all drainage channels connect sequentially and an inner side of the two upper fringes occlude an edge of each stage and extend directly to an upper side of the base.

2. The immunochromatographic test strip plate for multiple detections according to claim 1, wherein the shape of said test strip plate is a geometric shape of the group including: circle, square, rectangle, diamond and regular polygon, the sample-adding opening is disposed at the geometric center of one of the said shapes, and the strip stages on the base are arranged in central symmetry or axial symmetry.

3. The immunochromatographic test strip plate for multiple detections according to claim 1 or 2, wherein several sets of fixing stoppers are disposed along the edge of every strip stage, and numbering regions are provided on each stage at the place near the edge of the base.

4. The immunochromatographic test strip plate for multiple detections according

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to any one of claims 1 to 3, wherein the strip stage comprises three protuberances, and an end adjacent to the symmetric center or axis is sealed by equal-height stoppers.

5. The immunochromatographic test strip plate for multiple detections according to any one of claims 1 to 4, wherein several sets of pressure pieces are disposed on an underside of the upper cover at interval positions where the channel of the drainage groove extends outwards, and a result-observing window, an endpoint-indicating window and fixing rivets are disposed on underside of the upper cover in interval sequence.

6. The immunochromatographic test strip plate for multiple detections according to any one of claims 1 to 4, further comprising several rows of female rivets disposed in the base and corresponding to male rivets disposed on an underside of the upper cover.

7. The immunochromatographic test strip plate for multiple detections according to claim 5, wherein several rows of female rivets in the base correspond to male rivets on underside of the upper cover.

8. The immunochromatographic test strip plate for multiple detections according to any one of claims 1 to 4, wherein numbers disposed on an upper side of the upper cover correspond to those on the base, and a ID window used for marking the serial number of detected samples, a user holding indication and a inserting direction indication are disposed on an upper side of the upper cover.

9. The immunochromatographic test strip plate for multiple detections according to claim 5 or claim 7, wherein numbers disposed on an upper side of the upper cover correspond to those on the base, and a ID window used for marking the serial number

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of detected samples, a user holding indication and a inserting direction indication are disposed on an upper side of the upper cover.

10. The immunochromatographic test strip plate for multiple detections according to any one of claims 1 to 4, wherein the relationship between the height of lower fringe h2 and the height of upper fringe hl of the drainage channel is expressed as follows:

h2=h1-(height of stage+thickness of sticky substrate of strip+thickness of sample pad of strip)

11. The immunochromatographic test strip plate for multiple detections according to any one of claims 5, 7 or 9, wherein the relationship between the height of lower fringe h2 and the height of upper fringe hl of the drainage channel is expressed as follows:

h2=h1-(height of stage+thickness of sticky substrate of strip+thickness of sample pad of strip)

12. An immunochromatographic method for multiple detections using a immunochromatographic test strip plate according to any one of claims 7, 9 or 11, comprising a qualitative detection comprising the following steps:

1) Assembling the test strip plate by placing different types of strips on the corresponding stage;

2) Adding a liquid sample through the sample-adding opening and judging the test endpoint through the endpoint-indicating window;

3) Observing and recording results of the different strips through the result-observing windows; and

4) Comparing the test results with a standard in order to judge the occurrence of certain immunologic reactions and determine existence of certain analytes.

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13. An immunochromatographic method for multiple detections using a immunochromatographic test strip plate according to claim 9 or claim 11, comprising a quantitative detection comprising the following steps:

1) Assembling the test strip plate by placing different types of strips on the corresponding stage;

2) Adding a liquid sample through the sample-adding opening and judging the test endpoint through the endpoint indicating window;

3) Inserting the plate into a detector according to the user holding indication and the inserting direction indication on an outside of the upper cover;

4) Using the detector to analyze one strip quantitatively through the result-observing window, the test result of the strip being displayed by the apparatus;

5) Rotating or moving the plate to the next strip and using the detector again to perform another quantitative analysis;

6) Repeating step 5) until all strips on the plate are analyzed; and

7) Determining existence of certain analyte and its concentration.

14. An immunochromatic test strip plate for multiple detections substantially as hereinbefore described with reference to the drawings and/or Examples.

15. An immunochromatographic method for multiple detections substantially as hereinbefore described with reference to the drawings and/or Examples.

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Drawings

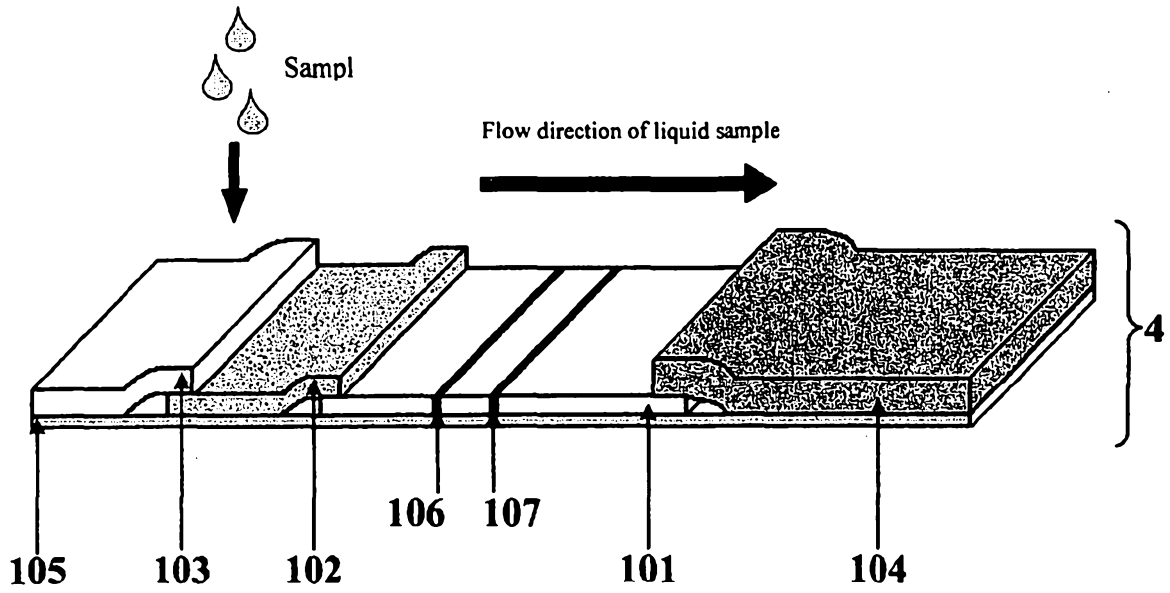

Figure 1

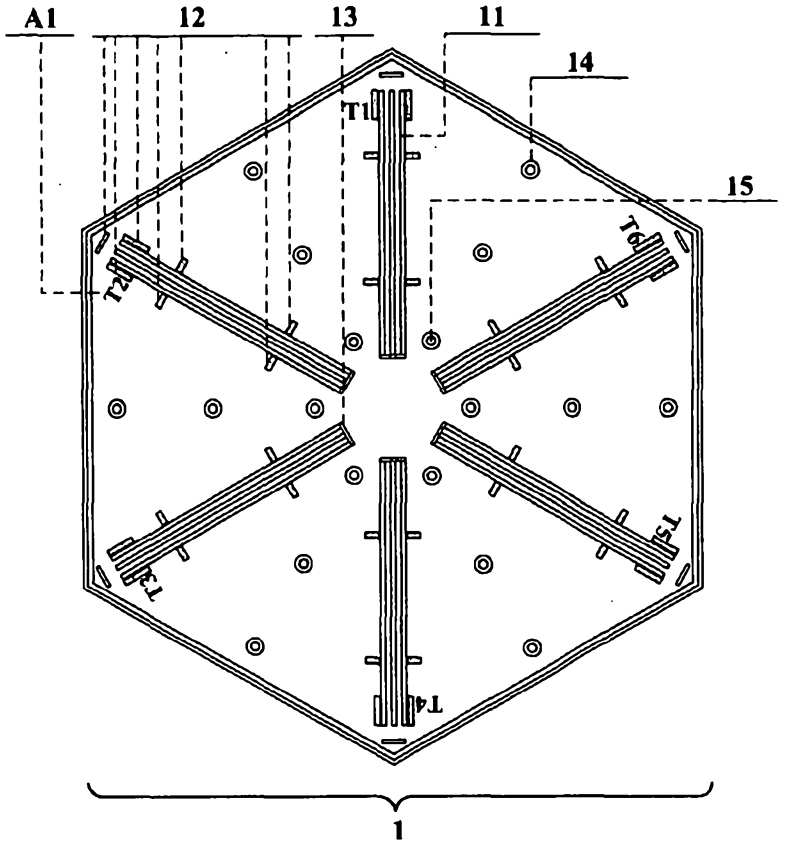

Figure 2

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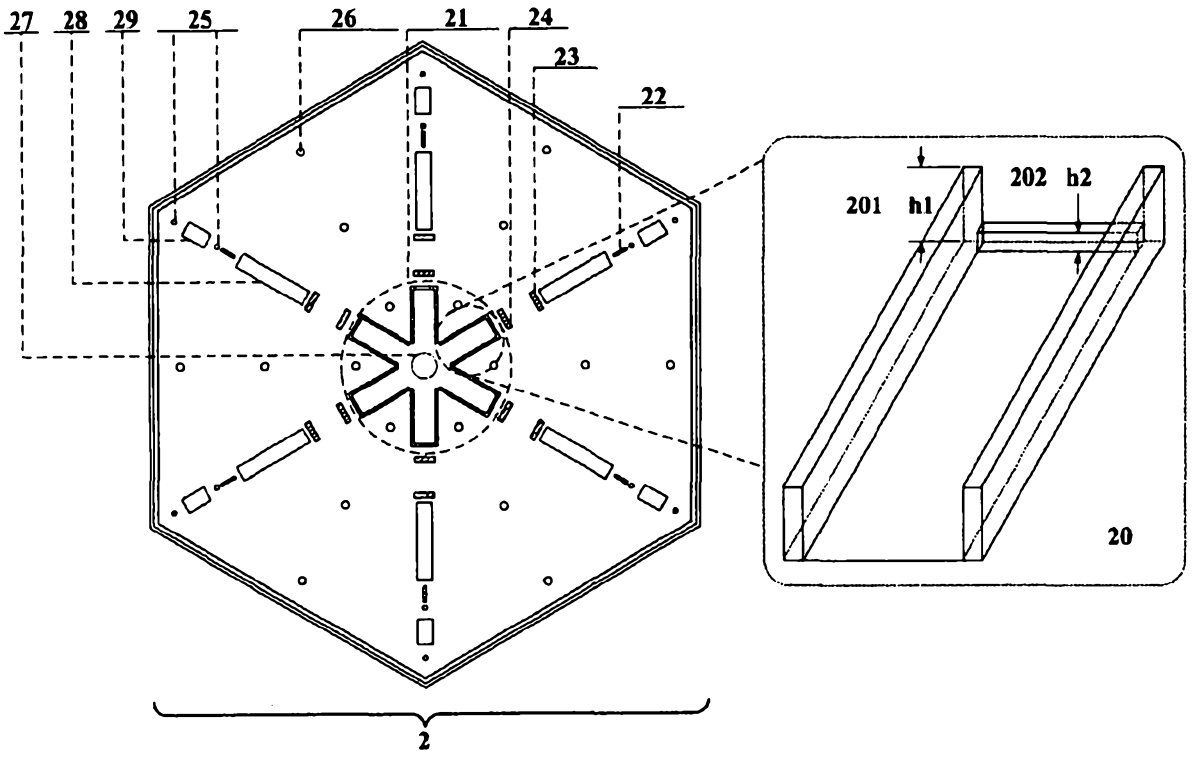

Figure 3A **Figure 3B**

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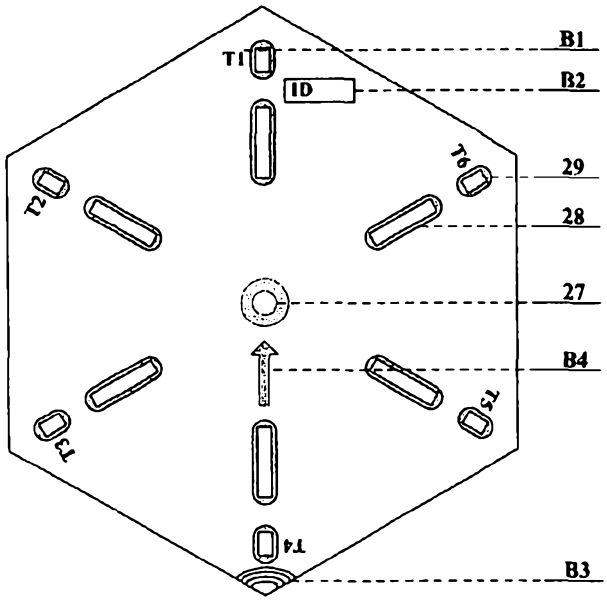

Figure 4

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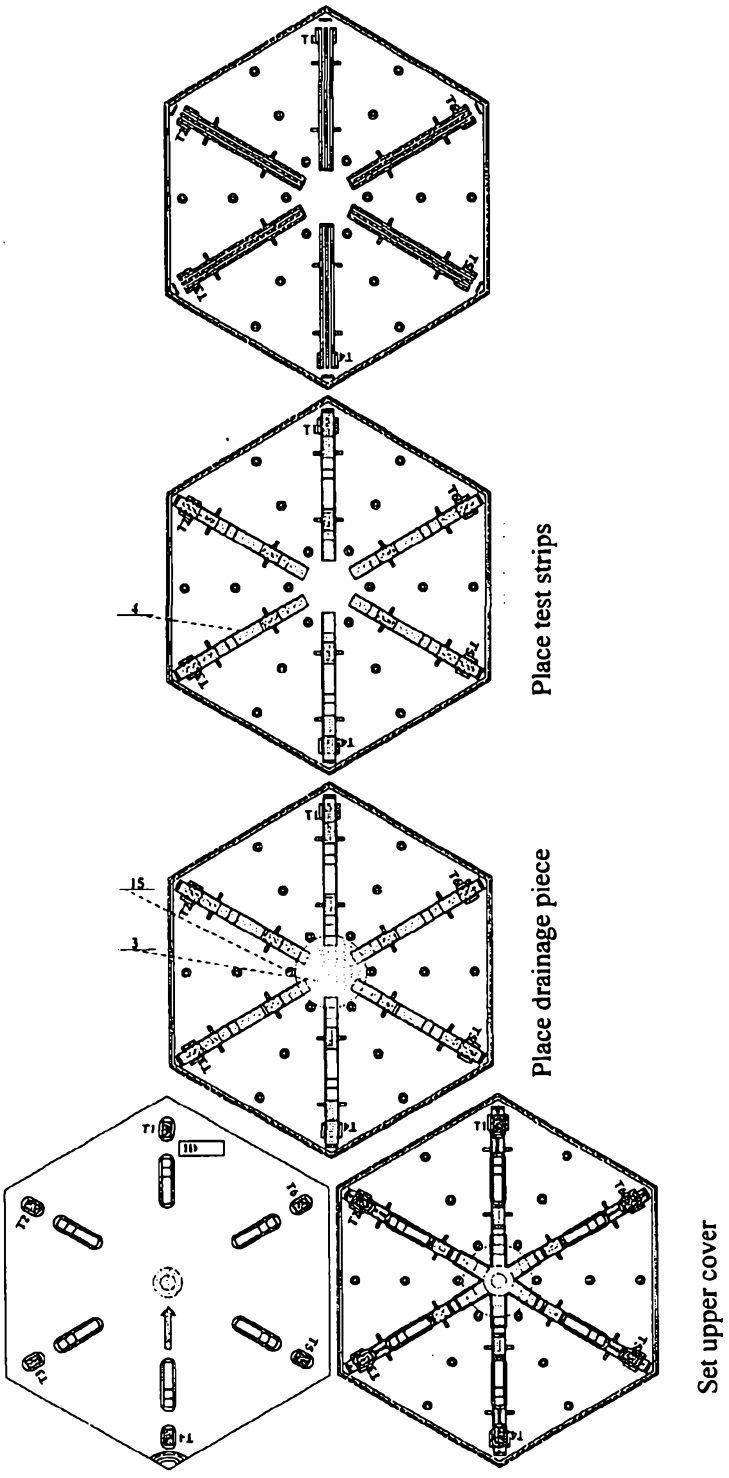

Figure 5

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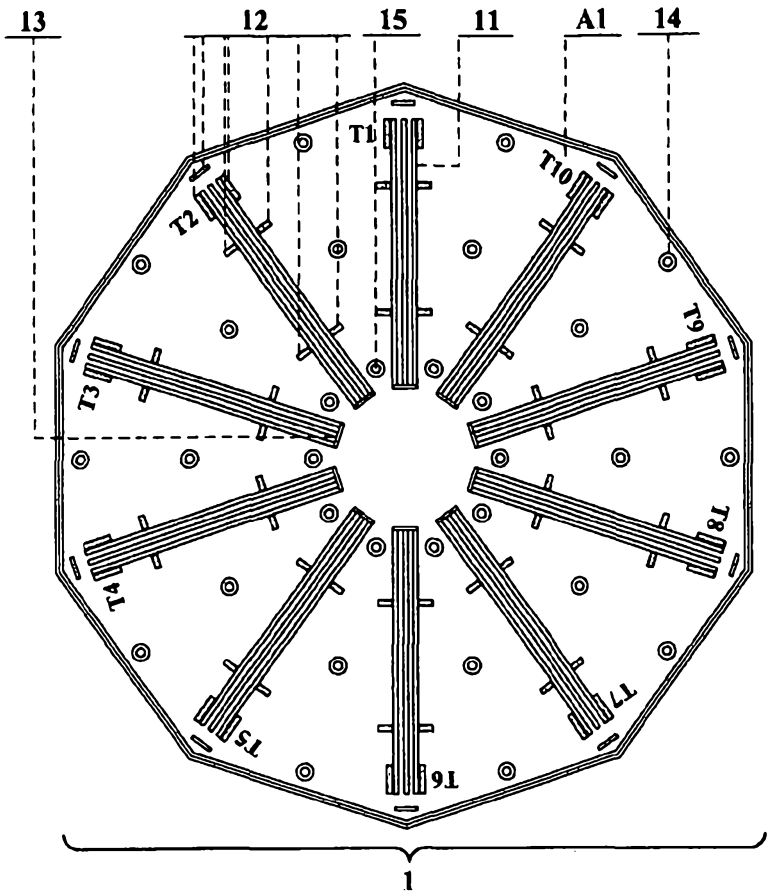

Figure 6

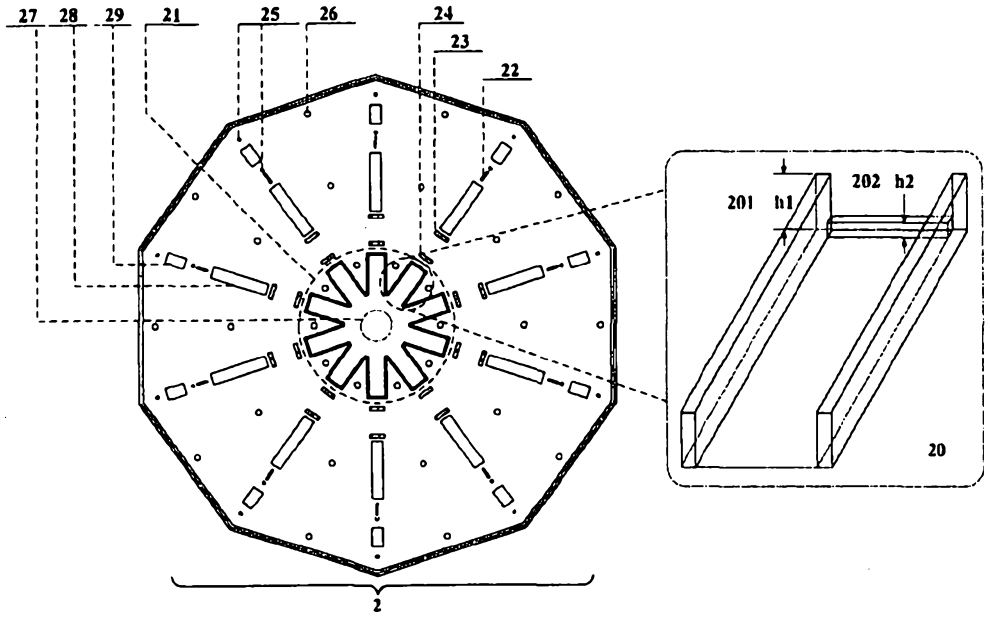

Figure 7A **Figure 7B**

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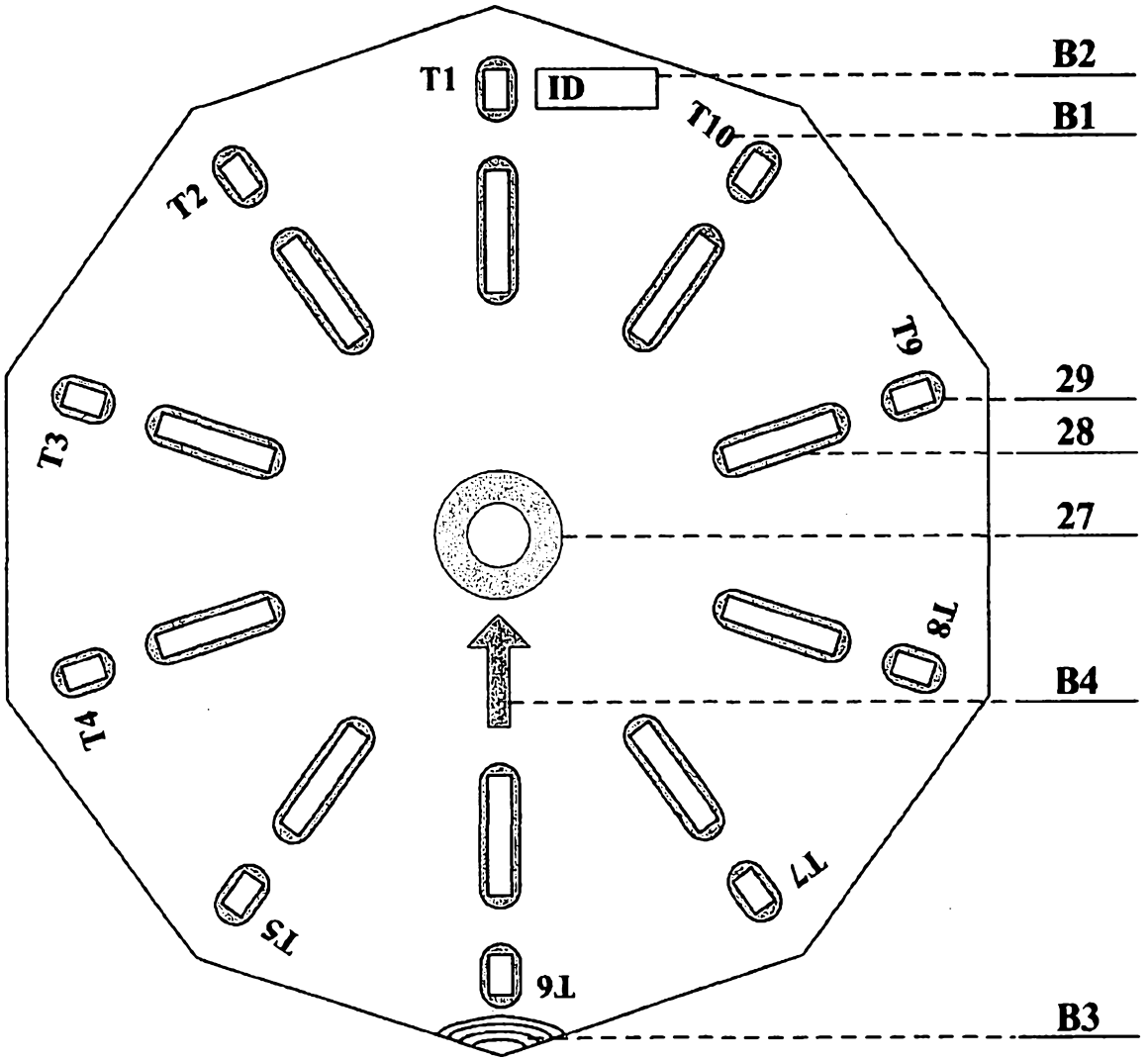

Figure 8

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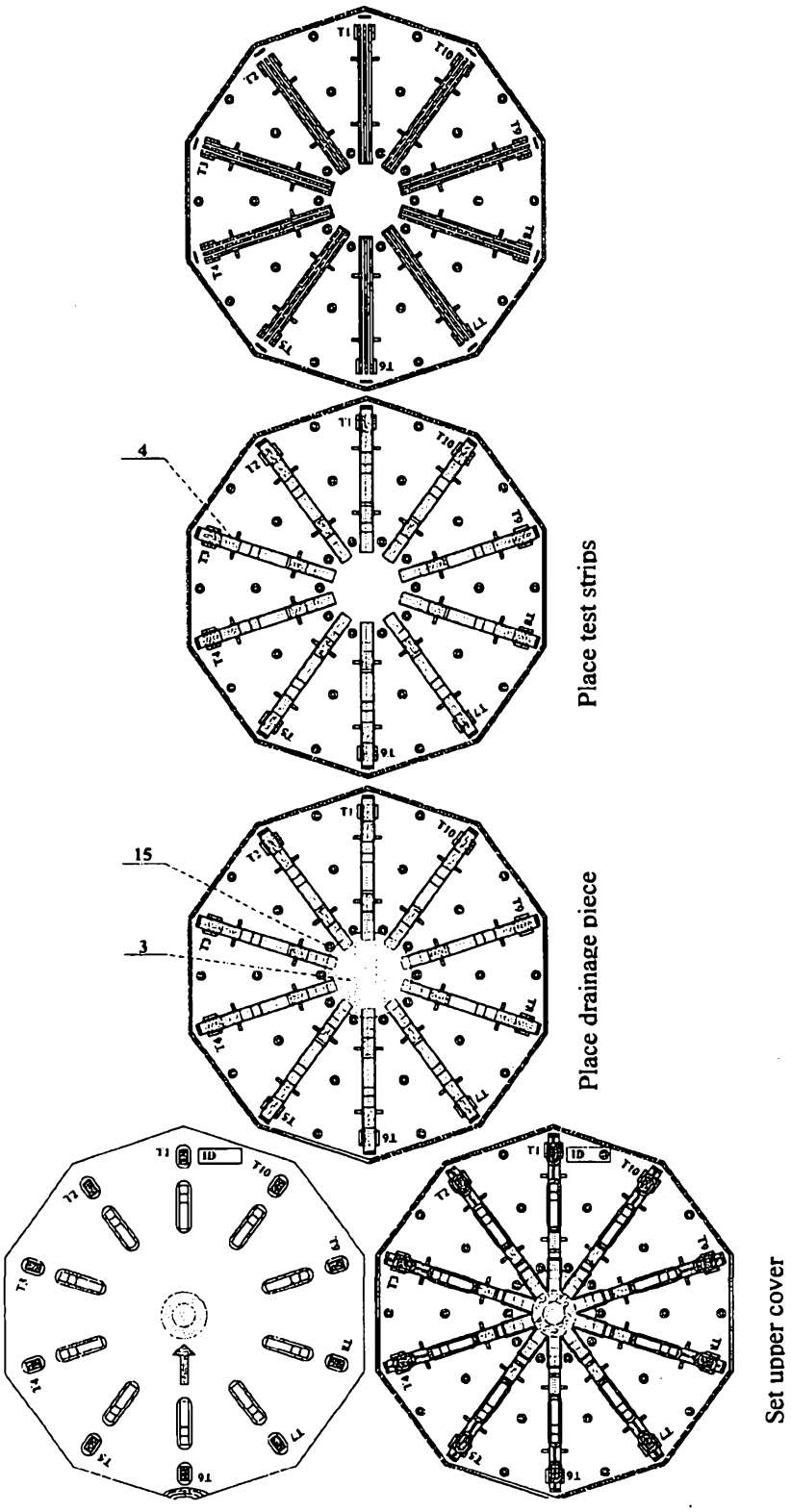

Figure of overall appearance

Figure of overall perspective

Figure9

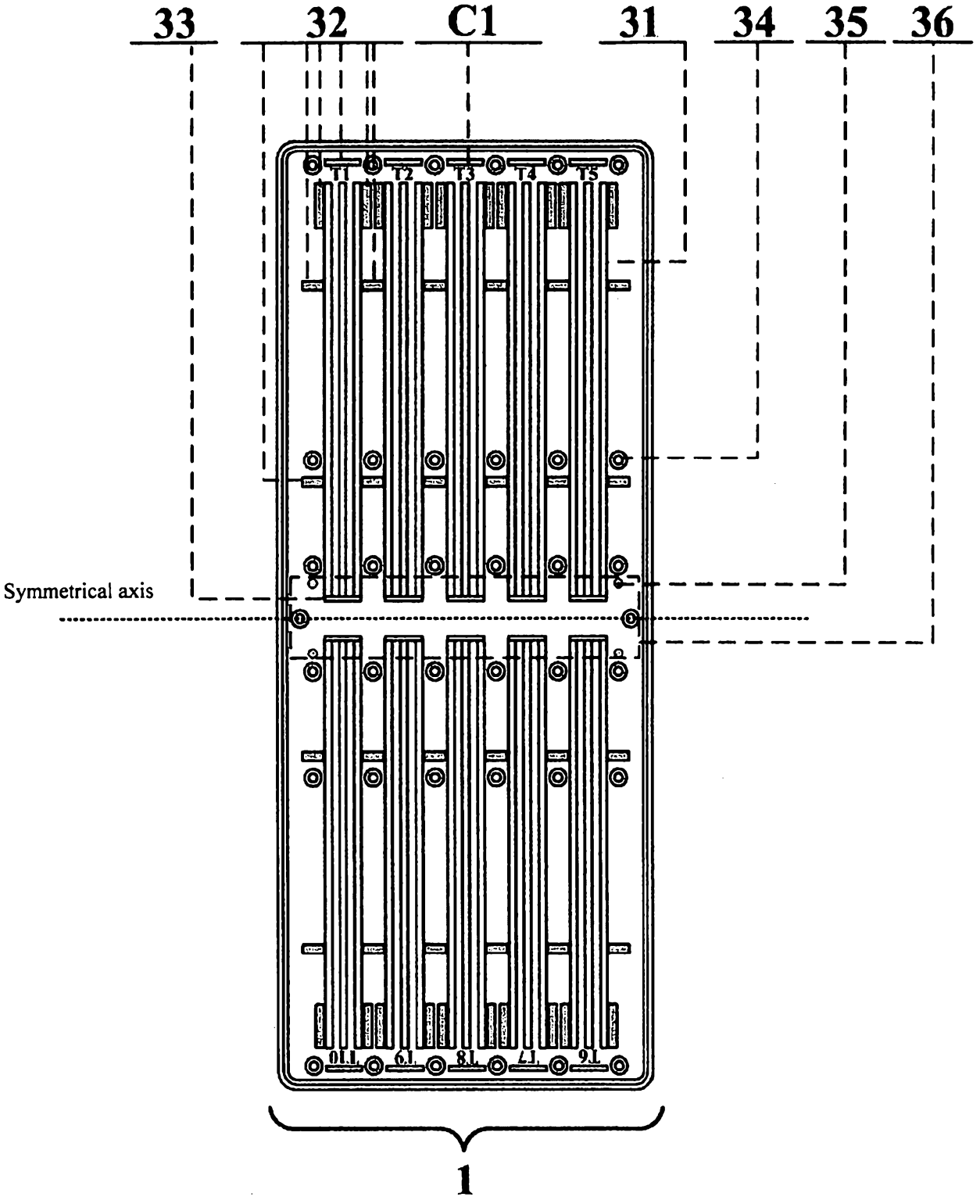

Figure 10

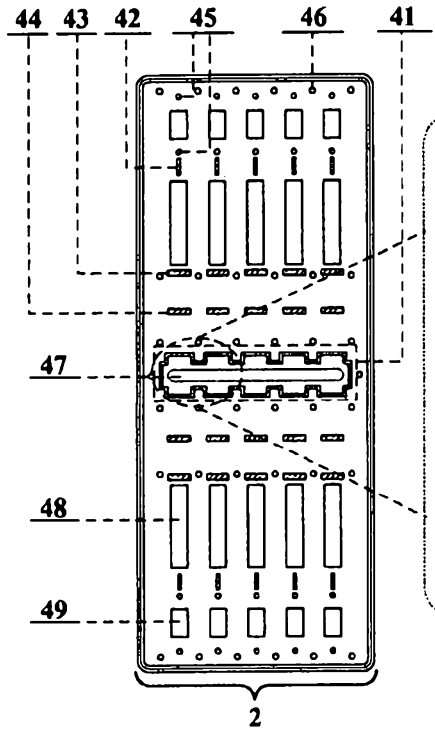

Figure 11 A

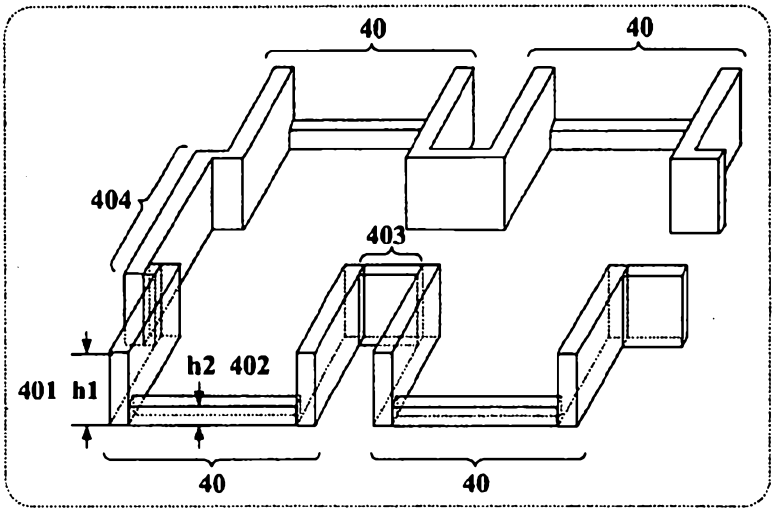

Figure 11B

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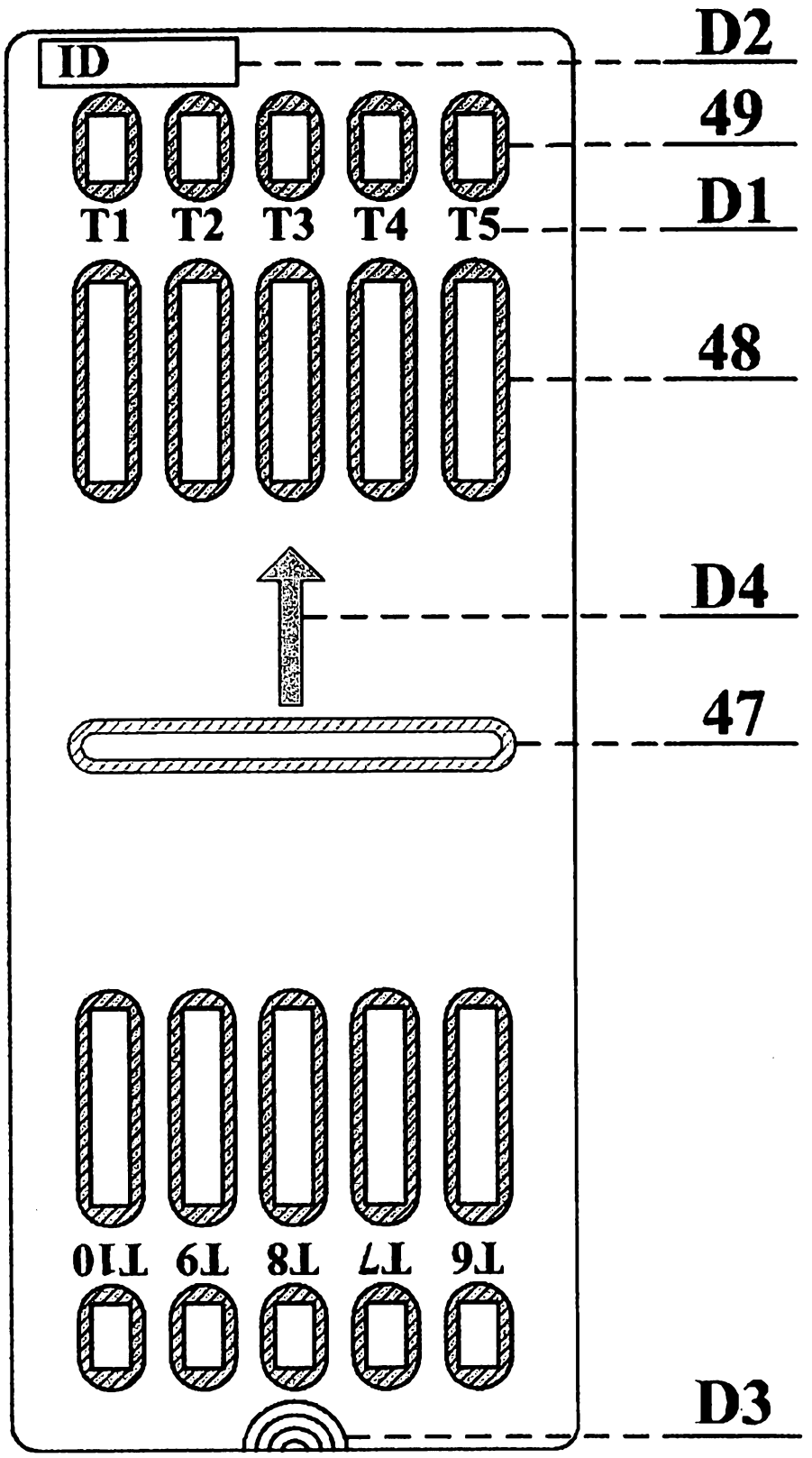

Figure 12

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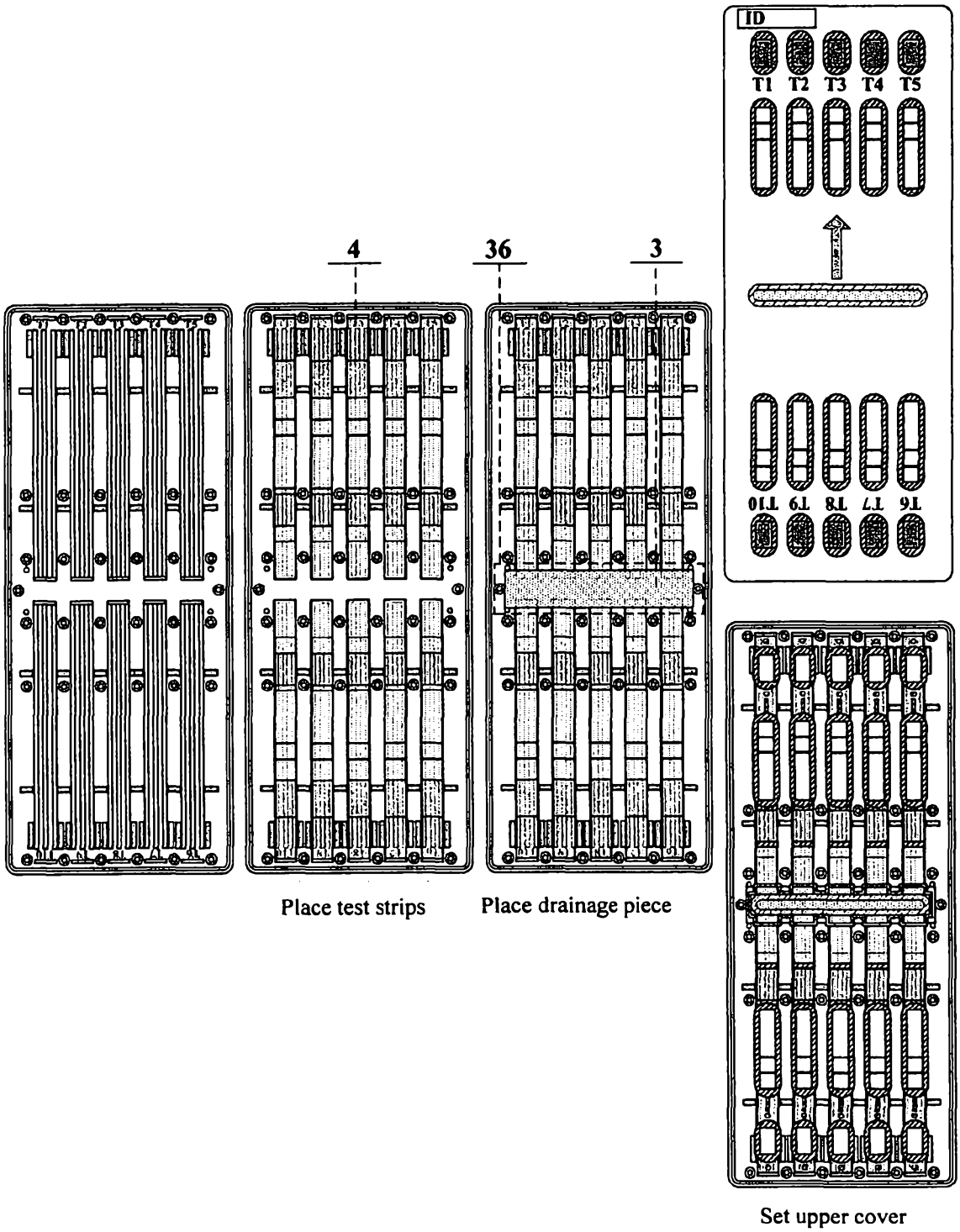

Figure 13