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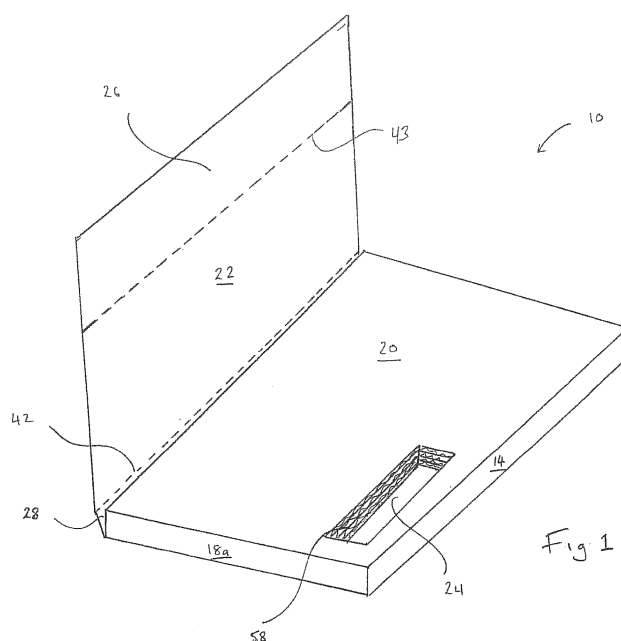
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**GB 2154982 A** **WO 2008/146010 A1**  
**WO 2003/022199 A1** **WO 2002/045647 A2**  
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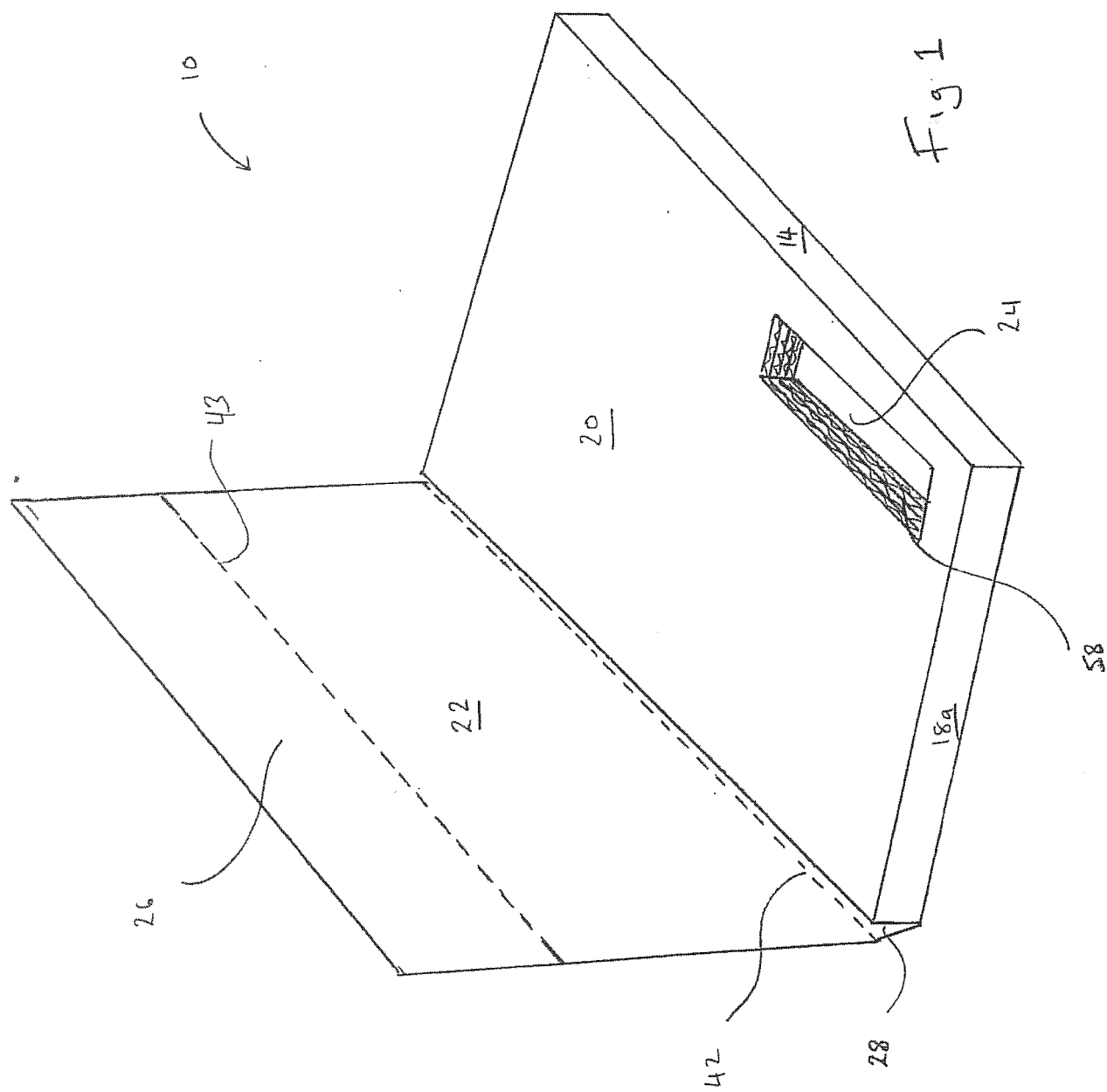
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Other: **WPI and EPODOC**

(54) Title of the Invention: **Container for Transporting a Biological Sample**  
Abstract Title: **A container for transporting a biological sample**

(57) A fluid impermeable container 10 for transporting a biological sample, the container comprising folded sheet material 58 which is fluid impermeable, the folded sheet material defining a base (fig 2;12), enclosing side walls 18a, 14, an upper wall 20 and a container closing member 22 wherein the upper wall 20 is configured to define an opening to a recess 24 for receiving a receptacle containing a biological sample to be transported and the recess is sealingly enclosed by the container closing member when the container is in a closed configuration. Ideally, the folded sheet material may comprise a fluid impermeable laminate coating. The container closing member 22 may comprise an adhesive which is exposed by releasing a backing strip. The container is ideally used for transporting a sample held within a receptacle via the mail or postal service. The container may further comprise an absorbent material inside the recess and perforations or tear tabs for accessing the recess after the closure member has been sealed.



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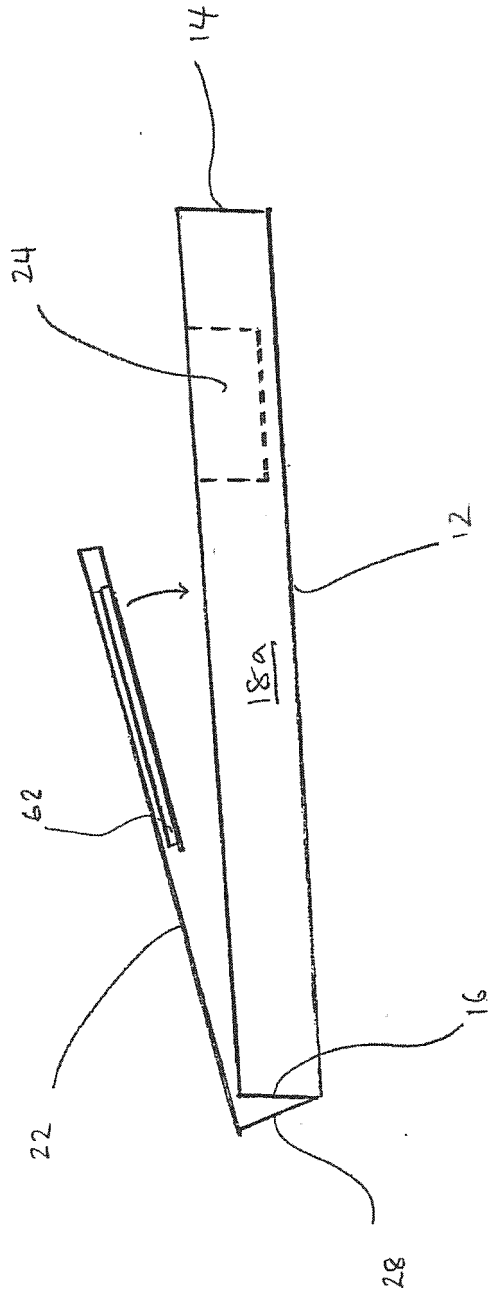
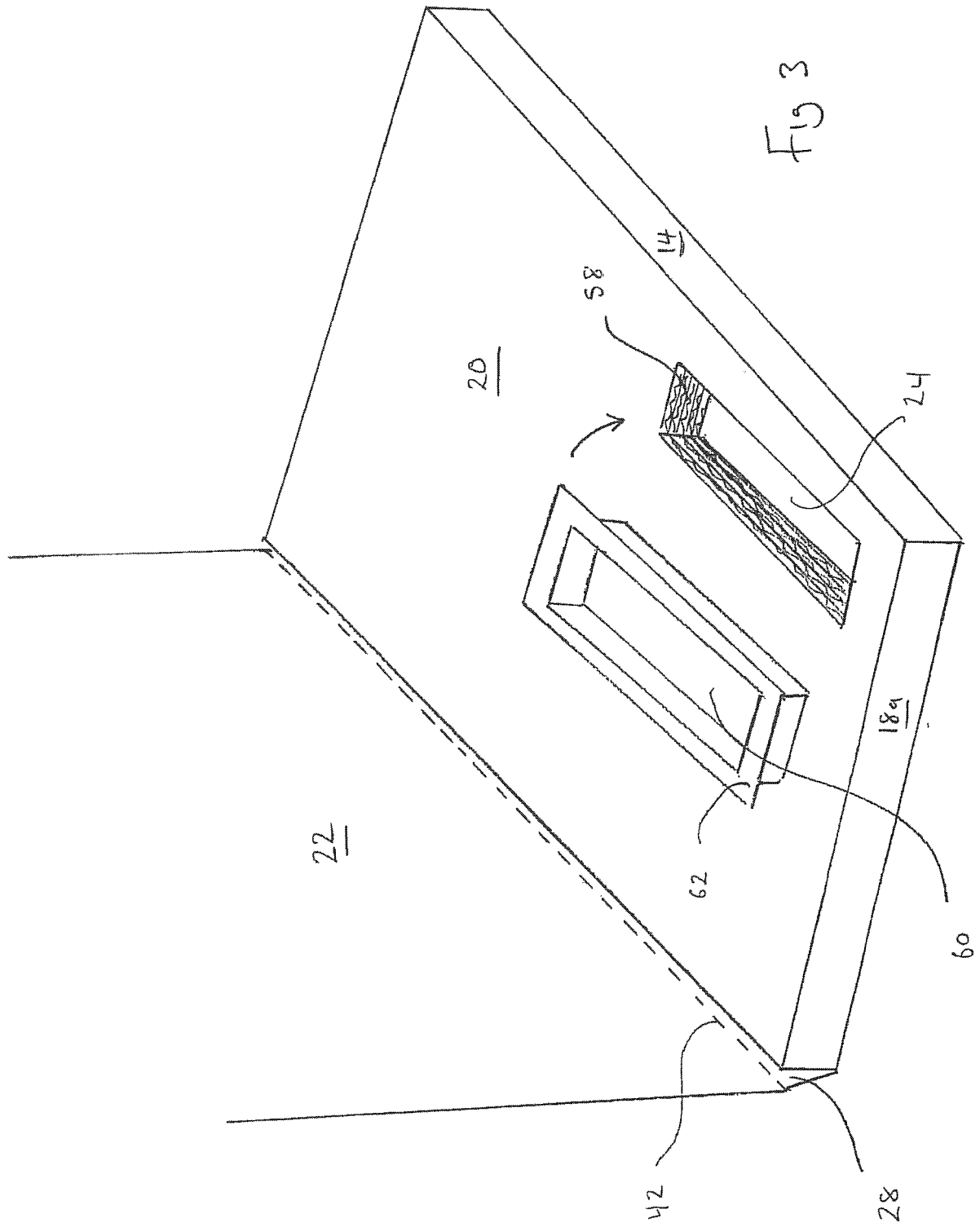


Fig 2



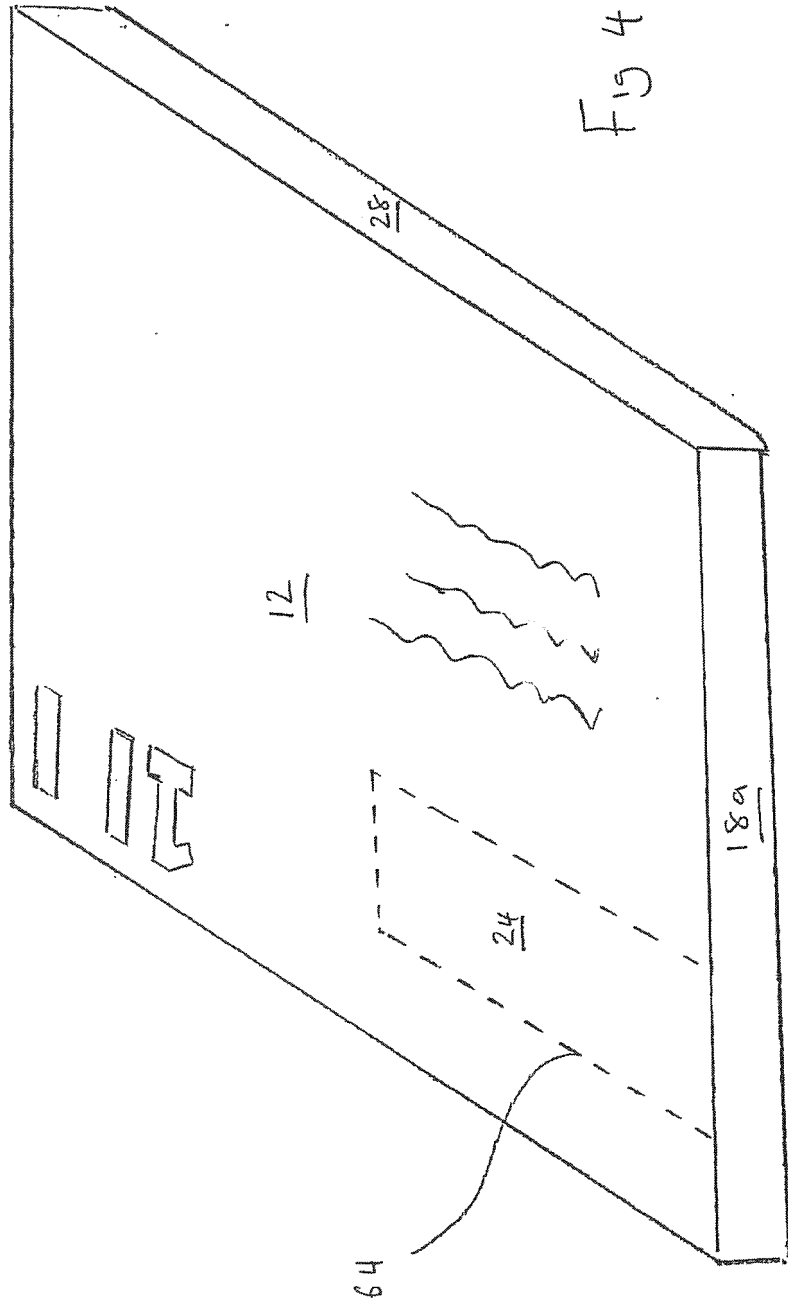
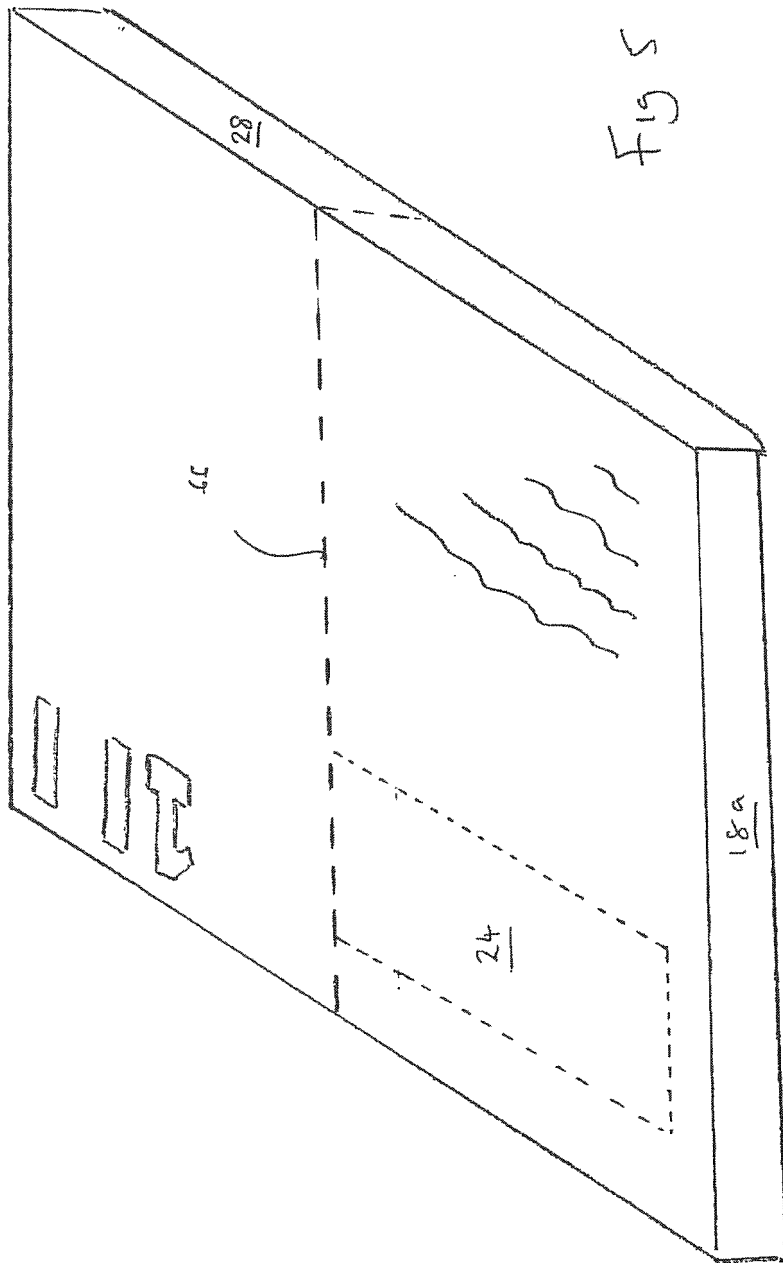


FIG 4



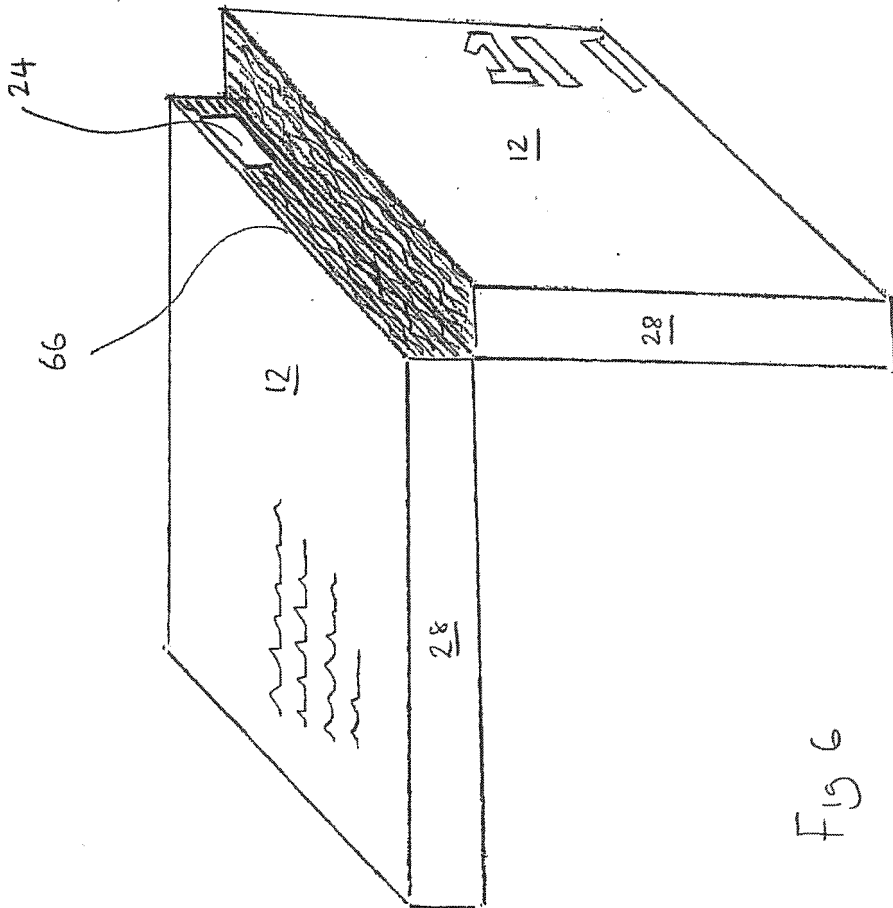


Fig 6

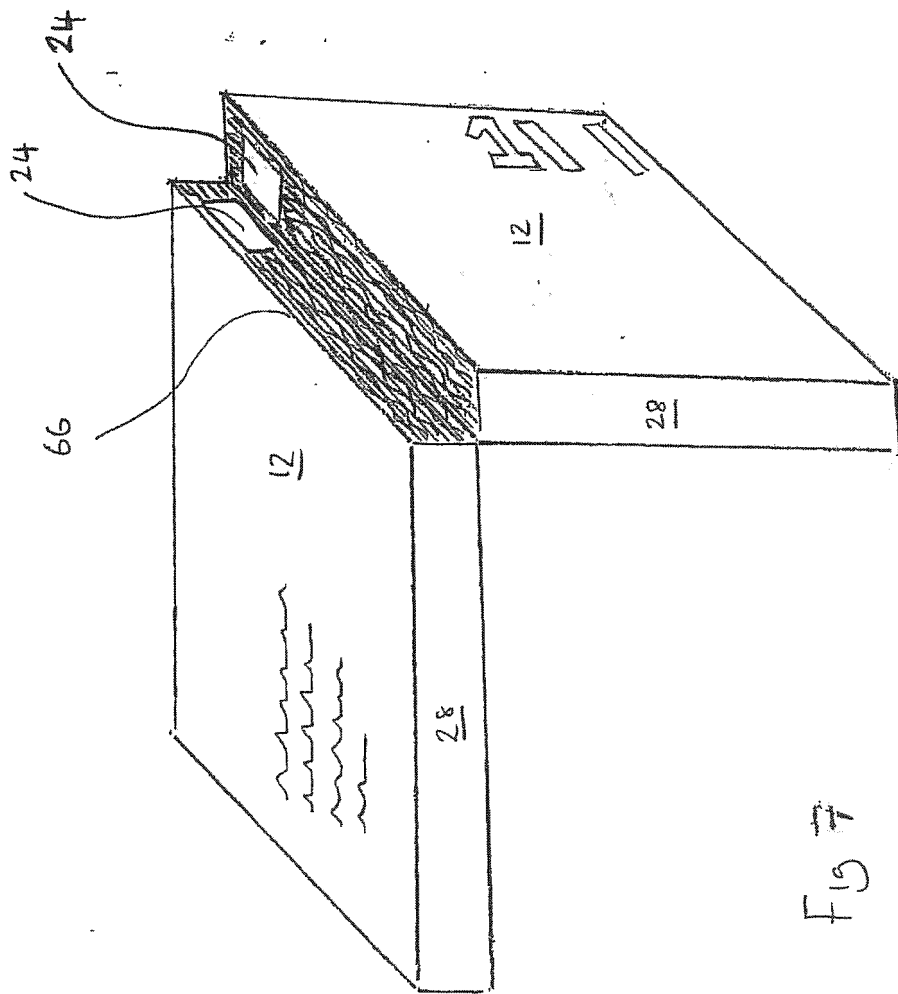


FIG 7



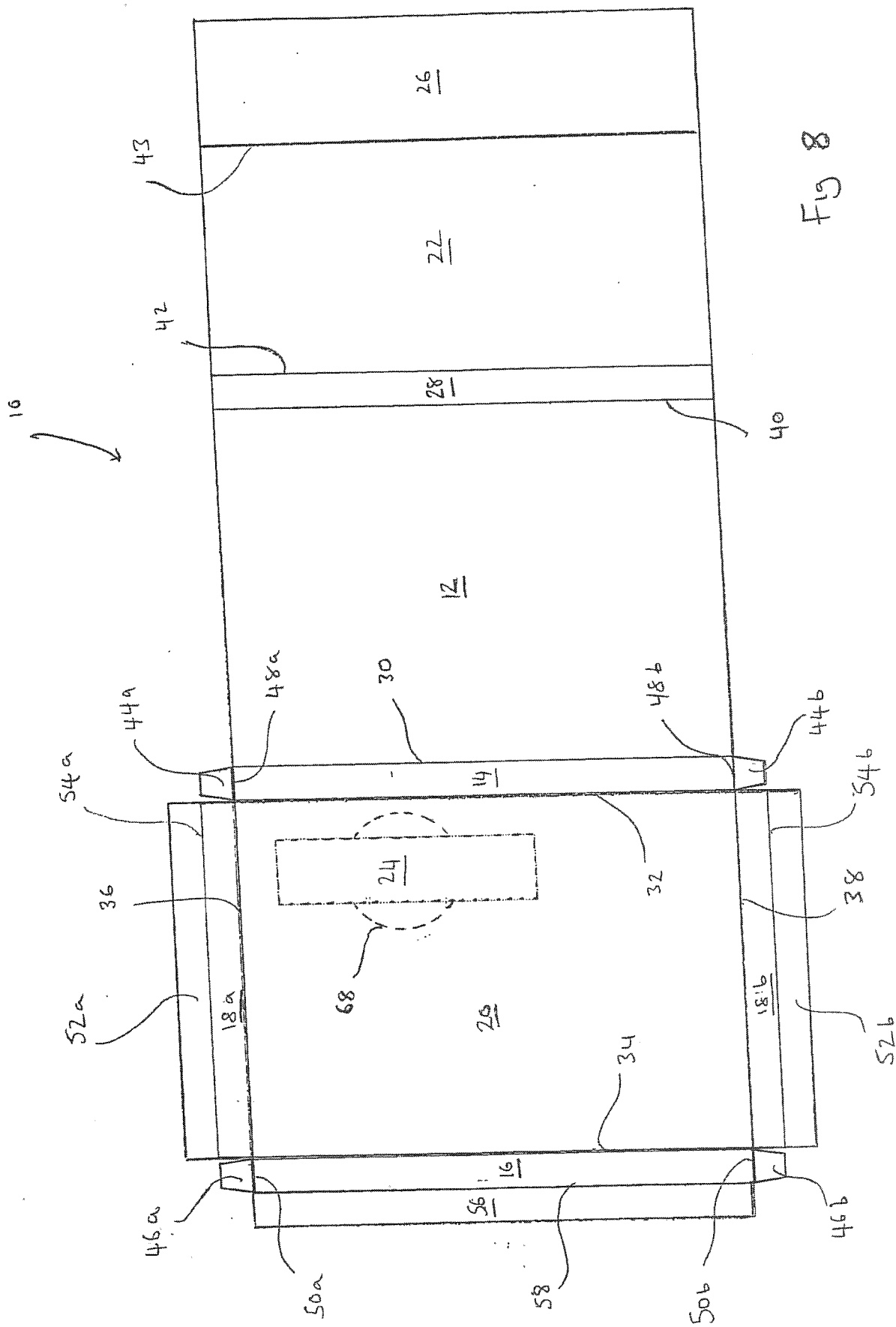


Fig 8

## CONTAINER FOR TRANSPORTING A BIOLOGICAL SAMPLE

The present invention relates to a container, and a container blank, for transporting a biological sample. The present invention also relates to a kit of parts for transporting a biological sample.

The rules and legislation governing the transportation of biological material, such as human waste, tissue, or blood samples or specimens, are becoming increasingly stringent. As a result of the health risk to humans posed by pathogens such as bacteria, viruses and fungi, which may be present in such samples, precautions must be taken to guarantee the safety of those operating in this field.

The health risk to humans posed by certain biological material can be greatly reduced by type of packaging used to store the sample during transit. Moreover, given the recent rise in self-screening initiatives, such as for bowel cancers and the like, the number of biological samples being collected at home, as well as in clinics, is rising. Such samples are invariably couriered in large quantities to medical institutes or laboratories where various analyses are conducted. It has therefore become necessary to provide effective, albeit easy to operate, packaging that complies, amongst others, with the regulations under UN3373, relating to biological substances being transported for diagnostic or investigative purposes.

Regulations such as UN3373 impose strict requirements on the minimum features that such packaging should possess. Biological material that is known or reasonably expected to contain

harmful pathogens must be transported in packaging that includes the following key components:

- A primary receptacle, being a tube, vial or other container made of glass or rigid plastic,
- A secondary packaging encapsulating the primary receptacle and being fluid impermeable, and
- An outer packaging,

in which either of secondary or outer packaging is rigid.

Biological samples are commonly collected in vials or tubes made from glass or rigid plastic. A conventional method of packaging such samples is to place the receptacle in a sealable polythene bag, which is then itself packaged within a rigid sleeve or box. However, in self-screening studies, the multi step nature of such a packaging technique often proves over-complicated for certain people, such as the elderly, resulting in the subsequent failing of the packaging, putting those operating in this field at risk. Packaging techniques that require a multiplicity of different packages are also considerably more expensive.

Another type of packaging for use in this field is the Polymed envelope, which is made from strong vinyl material, and has a opening defined by a sealable metal zipper. The Polymed envelope is designed to be used with additional leak proof packaging. It also suffers from certain structural inadequacies, including an insufficiently rigid outer packaging. Additional packaging is therefore required for biological samples whose transportation is governed by strict regulations.

The MiniMailBox was also designed with UN3373-type regulations in mind. However, despite being conveniently sized so as to be postable through a standard letter box, the MiniMailBox is not itself leak proof, meaning that additional interior packaging is required, thereby placing an increased burden on the user to ensure that each component of the packaging is correctly and securely sealed .

Aspects of the present invention were devised with the foregoing in mind.

According to a first aspect of the present invention, there is provided a fluid impermeable container for transporting a biological sample, the container comprising folded sheet material, the folded sheet material being fluid impermeable and defining a base, enclosing side walls, an upper wall, and a container closing member, the upper wall being configured to define an opening to a recess for receiving a receptacle containing a biological sample to be transported, wherein the recess is sealingly enclosed by the container closing member when the container is in a closed configuration. The container enables a user to achieve a fluid impermeable barrier between the interior and the exterior of the container. Moreover, the container affords both fluid impermeability and durability characteristics without the need for multiple types of packaging. Consequently, the single closure packaging reduces the burden placed on the user, thereby allowing a biological sample to be packaged, either by a clinician or by a member of the public, in a simpler and more efficient manner, which complies with regulations governing the transportation of biological material, such as those imposed by UN3373.

In one embodiment of the invention, the sheet material is rigid. The container therefore provides both a fluid impermeable barrier, as well as a rigid outer packaging without the need for multiple types of packaging.

In another embodiment of the invention, the container is sized to be postable through a standard letter box. The container thereby facilitates sampling by the public in self-screening studies.

In yet another embodiment of the present invention, the folded sheet material comprises a fluid impermeable coating. Optionally, the fluid impermeable coating is provided as a laminate coating on the folded sheet material. Lamination of sheet material is an inexpensive process, and confers fluid impermeability characteristics to the resulting container.

In still another embodiment of the present invention, the folded sheet material comprises cardboard. Cardboard sheet material is easily cut and shaped, and confers strength and durability characteristics whilst being at the same time cost-effective.

In yet another embodiment of the present invention, the container closing member comprises an adhesive portion. An adhesive affords a good seal around the recess. Optionally, the adhesive portion does not extend over an area of the container closing member that overlies the opening to the recess when the container is in a closed configuration. Whilst the adhesive portion affords a good seal around the upper periphery of the recess, the area of the container closing member that overlies the opening to the recess when the container is in a closed configuration may not

comprise an adhesive. Consequently, a receptacle may not become adhered to the container closing member when the container is in use. This may be achieved by die cutting an adhesive strip. The die cutter may be shaped to correspond to the opening of the recess. Optionally, the adhesive is exposed by releasing a backing strip. The container closing member is therefore simple to operate. The adhesive and sealing characteristics of the adhesive are not compromised in the event of sample spillage.

In another embodiment of the present invention, the container further comprises one or more container reinforcing members. The one or more reinforcing member confer additional strength, rigidity and durability characteristics to the container. Optionally, the one or more container reinforcing members comprises an absorbent. The absorbent may be impregnated within the one or more container reinforcing members. In the event of damage to the primary receptacle, the absorbent prevents the sample from leaking out of the container. Optionally, the container reinforcing member comprises one or more inserts, around which the sheet material of the container is formed. Multiple inserts may be stacked one on top of another and then secured in place once the sheet material is erected around them. Optionally, the one or more inserts are made from a sufficiently rigid foam or from corrugated cardboard. Such materials improve the rigidity of the container whilst offering a degree of absorbency.

In another embodiment of the present invention, the recess comprises a cushioning material. The primary receptacle, which is often manufactured from glass or rigid plastic, is thereby cushioned from impacts during transportation and handling. Preferably, the dimensions of the recess correspond accurately to those of a primary receptacle whose lid portion has been correctly closed. Accordingly, the recess is physically incapable of accommodating a receptacle

whose lid has been incorrectly closed, thereby prompting a user to take action. Moreover, providing a recess whose dimensions correspond closely to those of the receptacle being transported prevents the lid, cap or stopper of such a receptacle from becoming detached or dislodged during transit. The risk of spillage or leakage is therefore even further reduced.

In yet another embodiment of the present invention, the recess comprises an absorbent material. In the event of damage to the primary receptacle, the absorbent prevents the sample from leaking out of the container. Optionally, the quantity of absorbent material is sufficient to absorb the entire contents of a biological sample to be transported. The risk of any biological material reaching the outer extremities of the container is thereby significantly reduced.

Optionally, the absorbent material is a foam or cotton wool. Such materials provide adequate absorbency characteristics, whilst at the same time affording a degree of cushioning.

In still a further embodiment of the present invention, the recess further comprises a fluid impermeable holder for housing a biological sample to be transported. The holder confers additional fluid impermeability characteristics to the portion of the container being in contact with the primary receptacle. Optionally, the holder is integrally formed within the recess. An additional burden on the user is thereby eliminated. Optionally, the holder is made from plastic. Plastics are typically lightweight, fluid impermeable and inexpensive.

In yet another embodiment of the present invention, the recess further comprises one or more cutaway portions for facilitating access to the recess. The usability of the container for less dexterous persons, such as the elderly, is therefore increased.

In still another embodiment of the present invention, the recess may be substantially larger than the receptacle which it is intended to receive. In such an embodiment, the recess may further comprise receptacle retaining means to retain the receptacle in a given part of the recess, such that container opening means, such as a blade or guillotine, may safely shear through an empty part of the recess. Optionally, the receptacle retaining means comprises a constricted portion. The constricted portion may be formed into a single side wall of the recess. Alternatively, opposing side walls of the recess may be constricted at a given point.

In a further embodiment of the present invention, the container further comprises sample releasing means for accessing the recess other than via the container closing member. The container therefore provides means for accessing the packaged sample once it has reached its destination. The means are located away from the container closing member so that its integrity is not weakened. Optionally, the sample releasing means comprises a perforated release tab complementarily shaped to at least one of the faces of the recess. The tab may be simply removed by tearing along the perforation, thereby exposing one or more faces of the packaged sample. Optionally, the perforated release tab is disposed on the base of the container. Alternatively, the sample releasing means may comprise a line of weakness extending through the container and intersecting the recess along one of its faces. The packaged sample may therefore be accessed by breaking the container over the edge of a flat surface, such as a work top, so as to expose one or the faces of the packaged sample. Alternatively, the sample releasing means may comprise a line of weakness extending through the container and intersecting the recess at any point along its length. Once the container is broken along the line of weakness, a portion of the receptacle may protrude from the recess. Such sample releasing



means may prove advantageous when numerous containers are to be opened, by reducing the risk posed by repetitive strain injuries (RSIs).

In accordance with a second aspect of the present invention, there is provided a kit of parts for transporting a biological sample, the kit comprising a fluid impermeable container of the present invention, and a receptacle capable of containing a biological sample to be transported.

In accordance with a third aspect of the present invention, there is provided a pre-cut and pre-creased blank comprising sheet material which is erectable to form a fluid impermeable container of the present invention.

One or more embodiments of the invention will now be described with reference to the accompanying figures, in which:

Figure 1 is a view from the front, one side and above of the container of the present invention in a fully open configuration.

Figure 2 is a view from one side of the container of the present invention in a partially open configuration.

Figure 3 is a view from the front, one side and above of the container depicted in claim 1, further depicting the optional fluid impermeable holder for housing a biological prior to insertion into the recess.

Figure 4 is a view from the rear, one side and below of the container of the present invention in a closed configuration.

Figure 5 is a view from the rear, one side and below of the container depicted in Figure 4.

Figure 6 is a view from the rear, one side and below of the container of the present invention in a broken configuration.

Figure 7 is a view from the rear, one side and below of the container of the present invention in an alternative broken configuration

Figure 8 is a view from above of a pre-cut and pre-creased blank erectable to form a container of the present invention.

Referring to the figures, the fluid impermeable container 10 is formed from a sheet of laminated cardboard. It is generally cuboidal in shape, having a base 12, upright front 14, rear 16 and side walls 18a, 18b, an upper wall 20, and a closure flap 22. Upper wall 20 lies in a substantially identical plane to base 12, and defines an opening to a recess 24 for receiving a receptacle (not shown) containing a biological sample to be transported. Closure flap 22 has a sealing portion 26 which sealingly encloses the recess 24 when the container 10 is in a closed configuration.

Referring to Figures 1 and 8, base 12, upper wall 20 and closure flap 22 are of substantially identical dimensions to one another and are all generally oblong in shape. Base 12 is separated from upper wall 20 along long edge 30 by front wall 14. Front wall 14 is separated from upper wall 20 by long edge 32, which lies opposite long edge 30. Rear wall 16 is of substantially identical dimensions to front wall 14 and is separated from upper wall 20 by long edge 34, which

lies opposite long edge 32. Side walls 18a, 18b lie along opposite short edges 36, 38 respectively of upper wall 20. Base 12 is separated from closure flap 22 along long edge 40 by rear wall cover 28, which lies along an opposite edge of base 12 to front wall 14. Rear wall cover 28 is separated from closure flap 22 by long edge 42. Rear wall cover 28 is of substantially identical dimensions to front 14 and rear 16 wall, and lies substantially contiguous with rear wall 16 when container 10 is in a closed configuration. Sealing portion 26 is disposed towards an opposite edge of closure flap 22 to rear wall cover 28. Sealing portion 26 is distinguished from closure flap 22 by edge 43. Edges 30, 32, 34, 36, 38, 40, 42, 43 are pre-creased.

Still referring to Figures 1 and 8, front 14 and rear 16 walls each have a pair of adhesive tabs 44a, 44b and 46a, 46b respectively, extending outwardly from their respective shortest edges 48a, 48b, 50a, 50b. Each of side walls 18a, 18b also has an adhesive tab 52a, 52b respectively, each disposed along an opposite edge 54a, 54b respectively, to upper wall 20. Rear wall 16 has a further adhesive tab 56 disposed along an opposite edge 58 to upper wall 20. Edges 48a, 48b, 50a, 50b, 54a, 54b, 58 are pre-creased. During assembly of container 10, adhesive tabs 44a, 44b, 46a, 46b, 52a, 52b, 56 are secured to the inner surface of base 12 such that they are concealed from view. The performance of the adhesive is not compromised in the event of a spillage within container 10.

Turning now to Figures 1 and 3, container 10 comprises a plurality of container reinforcing members 58 provided as layers of corrugated cardboard. Reinforcing members 58 are of substantially identical dimensions to base 12 and upper wall 20, and are sandwiched therebetween when container 10 is erected from sheet material. Reinforcing members 58 have

a cutout portion complementarily shaped to recess 24, such that portions of reinforcing members 58 form the side walls of recess 24. Reinforcing members 58 are secured in place once container 10 is erected from sheet material.

Referring to Figures 1 and 8, upper wall 20 also comprises semicircular cutaways 68 located along opposite long edges of the opening to recess 24. A portion of the reinforcing members 58 comprises complementarily shaped cutaway portions to facilitate access to a receptacle located inside recess 24.

Referring to Figure 3, a sample holder 60 in the form of a tray may be provided, the sample holder 60 being complementarily shaped to recess 24. Sample holder 60 is designed to receive a receptacle containing a biological sample and is therefore manufactured from a fluid impermeable material, more specifically plastic. Sample holder 60 further comprises a lip 62, the underside of which abuts, and is adhesively secured to, the upper surface of upper wall 20 when sample holder 60 is located in recess 24. An interior portion of sample holder 60 contains a cushioning and an absorbent material, such as cotton wool or the like.

Prior to use, and referring to Figure 2, container 10 adopts a partially open configuration in which sealing portion 26 of closure flap 22 is folded inwardly along edge 43, such that sealing portion 26 lies substantially contiguous with closure flap 22. Sealing portion 26, which is generally formed from double sided adhesive tape, is prevented from adhering to closure flap 22 by backing strip 62. An empty receptacle for receiving a biological sample may then be located in recess 24 and a recipient's address, or other information, may be printed onto the uppermost

surface of closure flap 22, before an outer wrapper, such as transparent cellophane is applied. Upon receipt of container 10 in its partially open configuration, recess 24 and a receptacle contained therein are presented to a user.

In use, and referring to the Figures, container 10 is exposed by removal, if present, of an outer wrapper, thereby allowing container 10 to adopt a fully open configuration in which sealing portion 26 is folded outwardly along edge 43 to reveal user instructions printed onto the inner surface of closure flap 22. A user then removes the receptacle from recess 24 and inserts into it a sample of biological material. The receptacle is then sealed and relocated back into recess 24. Backing strip 62 is then removed from sealing portion 26 and discarded. Next, sealing portion 26 is lowered onto the opening to recess 24, such that the upper boundaries of recess 24 and cutaways 68 on upper wall 20 are fully and sealingly enclosed by sealing portion 26. The adhesive and sealing characteristics of sealing portion 26 are not compromised by spillages within recess 24.

Accordingly, when used as a return mailing article, container 10, being in a partially open configuration, arrives with a user in a transparent wrapper, with recess 24, and a receptacle contained therein, clearly visible. Container 10 is then unwrapped, a biological sample is introduced into the receptacle, and the receptacle then relocated back into recess 24. Container 10 is then sealingly closed by the user according to the above protocol, and conveniently mailed to a recipient, normally a laboratory or other medical institute, whose address may have been pre-printed on container 10.

In its closed configuration, container 10 complies with specific regulations governing the transportation of biological material, such as those imposed by UN3373. Container 10 is suitably sized so as to be postable through a standard letter box, and addresses or other relevant information may be printed on the outer surface of either closure flap 22 or base 12.

Once at its destination, most probably a hospital, laboratory or other medical institute, the sample of biological material must be retrieved from container 10. Referring to Figure 4, container 10 is provided with a perforated release tab 64 formed into base 12 and located over the underside of recess 24. Release tab 64 may therefore be torn away to expose a portion of recess 24 in which the receptacle containing the biological sample is contained. Alternatively, and referring to Figures 5 and 6, the sample of biological material may be retrieved by tearing along a perforation 66 that extends through a substantially median point of container 10. Perforation 66 intersects a face of recess 24, such that tearing container 10 along perforation 66 exposes a portion of recess 24, thereby allowing the sample to be retrieved. Alternatively, and referring to Figure 7, perforation 66 may intersect recess 24 at any point along its length, such that, upon tearing, the receptacle containing the biological sample protrudes therefrom and is easily retrievable.

While specific embodiments have been described herein for the purpose of reference and illustration, various modifications will be apparent to a person skilled in the relevant art and may be made without departing from the scope of the invention as defined by the appended claims. For example, container 10 may be formed from a number of other sheet materials, such as certain plastics, in which case further fluid impermeability characteristics may be conferred to container 10. The shape of container 10 may also differ from that described herein, and various

other three dimensional forms are equally envisageable. Reinforcing members 58 may be constructed from materials other than cardboard, such as rigid foams or sponges. The reinforcing members may be impregnated or dispersed with a material having absorbency characteristics, thereby minimising even further the risk of spillage. Recess 24 may be shaped to receive any number of conventional specimen receptacles. Cutaways 68 may be one or more in number, and may be of any size of shape. Where sample holder 60 is not used, recess 24 may be directly packed with one or more cushioning or absorbent materials, including fabrics, foams, sponges, pads and powders. Sealing portion 26 may comprise adhesive means other than double sided adhesive tape, such as any number of glues. The adhesives are preferably selected such that their performance is not compromised in the event of a spillage. Release tab 64 may be alternatively located to expose any accessible face of recess 24. Release tab 64 may also be located on closure flap 22, providing that the sealing characteristics of container 10 are not compromised. Perforation 66 may be relocated so as to expose, upon tearing, one or more other portions of recess 24.

## CLAIMS

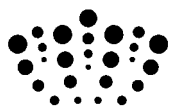
1. A fluid impermeable container for transporting a biological sample, the container comprising folded sheet material, the folded sheet material being fluid impermeable and defining a base, enclosing side walls, an upper wall, and a container closing member, the upper wall being configured to define an opening to a recess for receiving a receptacle containing a biological sample to be transported, wherein the recess is sealingly enclosed by the container closing member when the container is in a closed configuration.
2. A container as claimed in claim 1, wherein the sheet material is rigid.
3. A container as claimed in claim 2, wherein the container is sized to be postable through a standard letter box.
4. A container as claimed in claim 1, 2 or 3, wherein the folded sheet material comprises a fluid impermeable coating.
5. A container as claimed in claim 4, wherein the fluid impermeable coating is provided as a laminate coating on the sheet material.
6. A container as claimed in any preceding claim, wherein the folded sheet material comprises cardboard.
7. A container as claimed in any preceding claim, wherein the container closing member comprises an adhesive portion.



8. A container as claimed in claim 7, wherein the adhesive portion does not extend over an area of the container closing member that overlies the opening to the recess when the container is in a closed configuration.
9. A container as claimed in claim 8, wherein the adhesive is exposed by releasing a backing strip.
10. A container as claimed in any preceding claim, further comprising one or more container reinforcing members.
11. A container as claimed in claim 10, wherein the one or more container reinforcing members comprises an absorbent.
12. A container as claimed in claim 10 or 11, wherein the container reinforcing member comprises one or more inserts, around which the sheet material is folded.
13. A container as claimed in claim 12, wherein the one or more inserts are made from a foam.
14. A container as claimed in claim 12, wherein the one or more inserts are made from corrugated cardboard.
15. A container as claimed in any preceding claim, wherein the recess comprises a cushioning material.
16. A container as claimed in any preceding claim, wherein the recess comprises an absorbent material.

17. A container as claimed in claim 16, wherein the quantity of absorbent material is sufficient to absorb the entire contents of a biological sample to be transported.
18. A container as claimed in claim 16 or 17, wherein the absorbent material is a foam.
19. A container as claimed in claim 16 or 17, wherein the absorbent material is cotton wool.
20. A container as claimed in any preceding claim, wherein the recess further comprises a fluid impermeable holder for housing a biological sample to be transported.
21. A container as claimed in claim 20, wherein the holder is removable.
22. A container as claimed in claim 20 or 21, wherein the holder is made from plastic.
23. A container as claimed in any preceding claim, wherein the recess further comprises one or more cutaway portions for facilitating access to the recess.
24. A container as claimed in any preceding claim, wherein the recess is substantially larger than the receptacle which it is intended to receive.
25. A container as claimed in claim 24, wherein the recess further comprises receptacle retaining means for retaining the receptacle in a given part of the recess.
26. A container as claimed in any preceding claim, wherein the receptacle retaining means comprises a constricted portion.
27. A container as claimed in any preceding claim, further comprising sample releasing means for accessing the recess other than via the container closing member.

28. A container as claimed in claim 27, wherein the sample releasing means comprises a perforated release tab complementarily shaped to at least one of the faces of the recess.
29. A container as claimed in claim 28, wherein the perforated release tab is disposed on the base of the container.
30. A container as claimed in claim 27, wherein the sample releasing means comprises a line of weakness extending through the container and intersecting the recess along one of its faces.
31. A container as claimed in claim 27, wherein the sample releasing means comprises a line of weakness extending through the container and intersecting the recess at any point along its length.
32. A kit of parts for transporting a biological sample, the kit comprising a fluid impermeable container as claimed in any preceding claim, and a receptacle containing a biological sample to be transported.
33. A pre-cut and pre-creased blank comprising sheet material which is erectable to form a fluid impermeable container as claimed in any of claims 1 to 31.



**Application No:** GB1301645.6

**Examiner:** Miss Elizabeth Price

**Claims searched:** 1-33

**Date of search:** 24 May 2013

**Patents Act 1977: Search Report under Section 17**

**Documents considered to be relevant:**

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	1-33	WO 02/45647 A2 (BIOCRYSTAL) see whole document
X	1-5, 15-26, 32	WO 2008/146010 A1 (DAVIDSON) see whole document
X	1-6, 10-12, 14, 20-25, 32	WO 03/022199 A1 (WALBERG ) see whole document
X	1-3, 12, 15-18, 20-26, 32	US 5040678 A (LENMARK) see whole document
X	1, 3-5, 7-9, 16-19, 32, 33	WO 01/62625 A1 (TECHNICOR) see whole document
X	1, 3-5, 7-9, 32, 33	GB 2154982 A (CONSTAT BUSINESS) see whole document
X	1, 3-5, 7-9, 32, 33	DE 202004005075 U (CURTIS) see EPODOC abstract and WPI abstract accession # 2004-554986

**Categories:**

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

**Field of Search:**

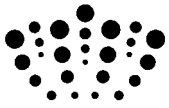
Search of GB, EP, WO & US patent documents classified in the following areas of the UKC<sup>X</sup> :

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Worldwide search of patent documents classified in the following areas of the IPC

B01L; B65D
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The following online and other databases have been used in the preparation of this search report



WPI and EPODOC
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**International Classification:**

<b>Subclass</b>	<b>Subgroup</b>	<b>Valid From</b>
B65D	0005/50	01/01/2006
B65D	0081/03	01/01/2006
B65D	0081/05	01/01/2006
B65D	0081/26	01/01/2006