The invention relates to a dried-blood-spot-card shipping and storage container, the container comprising at least one compartment, the at least one compartment being adapted to receive at least one dried-blood-spot-card (3) and being openable and being air-tight closable with a closure, preferably each compartment having a respective closure, preferably a closure being a cover (2, 2a, 2b), preferably a hinged cover (2, 2a, 2b) and at least one outlet port (8), the outlet port (8) being in fluid connection with at least one compartment, preferably the gas flow direction (9) of the port out (8) of the compartment being defined by a one-way check valve, preferably the one-way check valve being incorporated in the outlet port (8). The invention also relates to a method of shipping and/or storing dried-blood-spot-cards.
The invention relates to a dried-blood-spot-card shipping and storage container. Dried-blood-spot-cards, abbreviated as DBS-cards are typically used for collecting, packaging, storing and shipping of blood samples as dried blood spots. These dried blood spots are prepared by applying a small amount of blood to cards, which are typically made of paper, particularly filter paper. An example of a suitable card is Whatman protein saver 903 paper.

The blood becomes dry on the card and may be shipped for further processing, for example to a laboratory in order to analyse the blood, particularly regarding the existence of drugs or other analytes in the blood. Accordingly DBS-cards can also be used for analyzing blood samples of athletes.

Generally dried-blood-spots are prepared far away from the laboratory for example directly at a competition site. Consequently there is a need to ship the DBS-cards to the laboratory what is typically done by using storage bags, made of flexible plastic. DBS-cards are inserted into such a bag, typically together with a desiccant pack, the bag is closed under environmental atmospheric conditions and shipped.

Prior to packing the DBS-cards are labeled, generally with a barcode that is assigned to the person from which the blood sample or samples originate. Not mentioning any clear text names on the cards keeps the blood sample anonymous during processing in the laboratory.

As a drawback in the state of the art it is known that during long storage periods a dried blood sample stored under ambient atmospheric conditions may deteriorate, for example due to microbial growth, decomposition of proteins and particularly of the drugs for which the blood is to be tested. Furthermore drying of the blood spots takes some time and during this time a DBS-card is potentially unprotected and in worst case may be manipulated since it is not yet covered in the known shipping bag, even if drying is accelerated in a drying rack.

According to known procedures DBS-cards are frozen for long term storage, which is expensive, involves special technical devices and is problematic regarding humidity monitoring.

It is an object of the invention to provide a container and a method that facilitates shipping and storage of DBS-cards and to extend the time period between packing the cards and processing in the laboratory, preferably without the need of further technical devices after packing for storage purposes.

According to the invention this object is solved with a DBS-card shipping and storage container, the container comprising at least one compartment, the at least one compartment being adapted to receive at least one dried-blood-spot card and being openable and being airtight closable with a closure, preferably the at least one compartment having a respective closure, preferably a closure being a cover, preferably a hinged cover.

According to the invention the container furthermore comprises at least one outlet port, the outlet port being in fluid connection with at least one compartment, preferably the gas flow direction of the port out of the compartment being defined by a one-way check valve, preferably the one-way check valve being incorporated in the outlet port. Fluid connection through the port thus exist if the incorporated valve is open.

It is an essential characteristic of the invention that the container comprises at least one compartment that is adapted in its size, particularly length and width so that typical DBS-cards may be received in the compartment without any manipulation on the card like cutting. A preferred internal length and internal width may be for example at least 8.6 cm x 5.8 cm.

The internal height of at least one compartment of the container may be adapted to receive at least one DBS-card, preferably more than one DBS-card in the compartment. For stacking DBS-cards in a compartment, the respective compartment may comprise spacers that allow stacking of the cards without contact between the cards.

Such spacers may be arranged, particularly fixed on an internal surface of a wall of the compartment, preferably on opposite wall surfaces or may be separate elements like frames, particularly the frames having the size of a respective card, particularly the frames at least having spaces at the positions where blood spots are located on the cards. Fixed spacers may be used to put cards into the compartment, solely the rim of the cards contacting the spacers. Separate, particularly frame shaped spacers may be stacked between two respective cards to keep a distance between the cards according to thickness of the spacer.

Furthermore it is an essential characteristic of the invention, that an outlet port, preferably at least one outlet port is connected to the compartment of the container, i.e. to the internal volume of the compartment, particularly when the container or compartment is airtight sealed. Airtight sealing the container means in this context that no gas exchange is possible between the internal volume of the container and the external environment on condition of typical environmental atmospheric pressure, i.e. typ. 1013 mbar and a given pressure interval surrounding this pressure value. Gas exchange may be possible and intended through the valves furthermore described in this specification on condition of overpressure or underpressure compared to the environmental pressure or pressure interval boundaries.

Such a port may be a tubular or channel-like connector in the external surface of the container providing a fluid connection between the internal volume of the compartment and the external environment of the container. It is essential that the outlet port is closable, for example by means of a closable valve, preferably a self-closable valve, most preferred by means of an one-way valve that may have a typical construction of a check
valve. The valve itself may be adapted to define the gas flow direction of the outlet port, i.e. from the internal volume of the compartment towards the external environment. The valve may be incorporated into the outlet port.

A container just having a single compartment may have only one outlet port associated with this compartment. A container having more than one compartment, preferably two separate compartments may have at least one respective outlet port for each compartment. Furthermore a possible embodiment may have at least one outlet port that is associated with all compartments, meaning that a fluid connection exists between all compartments and this at least one outlet port. For this purpose the compartments may be connected to each other by means of a valve, for example a valve situated in a wall separating two respective compartments. Also this valve is closable, particularly self-closable and most preferred embodied as a one way valve, defining a gas flow direction towards the outlet port.

Consequently according to the invention an outlet port may be used to change the atmosphere in the at least one compartment to which it is connected, preferably by evacuating the at least one compartment through the outlet port. For this purpose a vacuum pump may be connected to the outlet port. All valves situated in the gas flow will preferably close automatically if the vacuum pump is disconnected or switched off. Of course manually operating the valve or valves is possible.

Reducing the pressure in the respective compartment or compartments will improve storage times since reducing the content of oxygen and/or humidity in a compartment comprising at least one DBS-card will prevent deterioration of blood.

According to an even more preferred embodiment the container also comprises at least one inlet port, the inlet port being in fluid connection with at least one compartment. Also an inlet port is closable, preferably by means of a valve. In a preferred embodiment the gas flow direction of the inlet port, i.e. from the outside of the container into a compartment may be defined by a one-way valve, preferably the one-way valve being incorporated in the inlet port. Also here the one-way valve may be a check valve of common construction. Outlet port an inlet port may be identical in construction.

According to the invention it is possible to change the atmosphere in the at least one compartment by means of flushing a respective compartment with a gaseous fluid via the inlet and outlet port. Preferably an inert gas is used for that like nitrogen or noble gases. Gaseous fluid is forced for example by overpressure into the inlet port. A pressurized gas bottle may be simply connected to the at least one inlet port for that purpose. The pressurized gas automatically opens all one-way valves in the line of gas flow and escapes from the outlet port of the container to the environment.

Except a pressurized gas bottle containing a suitable flushing gas no other device is needed for preserving the blood samples in the container. Also by flushing humidity and oxygen is removed from the compartment(s) and consequently possible storage times are extended.

In order to provide an optimal cross flow through a respective compartment the at least one inlet port and the at least one outlet port may be arranged on opposite sides of a compartment or at least the container.

In a preferred embodiment the container comprises a first and a second compartment, each compartment being adapted to receive at least one dried-blood-spot card and each compartment being independently air-tight closable with its closure and openable without breaking the air-tightness of the other compartment, particularly each compartment having its own openable and air-tight closable cover, preferably hinged cover. No matter how many compartments are comprised in the container the respective cover may also be transparent in order to get optical / visual access to the labeled information on a DBS-card, for example for laser scanning without the need to open the container.

A container with two or more compartments also provides the possibility to handle A and B samples or even more samples of athletes. The compartment of Sample B may remain air-tight closed during examination of Sample A and only be opened if the result of sample A needs to be rechecked.

According to a first embodiment in a container having more than one compartment each compartment may have an own respective outlet port only or an own respective set of outlet and inlet port, the respective port or set of ports being in fluid connection to this compartment only, particularly on condition of opened valves, i.e. at least during evacuation or flushing.

According to a second embodiment in a container having more than one compartment all compartments may have a common outlet port or a common set of outlet and inlet port, the common port or common set of ports being in fluid connection to all compartments simultaneously (i.e. at least during evacuation or flushing) and neighboring compartments may be separated from each other by a respective internal wall of the container, the wall comprising at least one closable passage port, preferably a one-way valve, particularly a check valve defining a gas flow in all compartments towards the common outlet port.

In such a case gas from a specific compartment may enter at least one other compartment in advance of escaping through the common outlet port. All compartments may be arranged in line regarding their fluid connection. Their fluid connection may be: INLET PORT -> compartment 1 -> compartment 2 -> ... -> compartment n -> outlet port; and n >= 2.

The containers of all possible embodiments, particularly of all aforementioned embodiments may be formed of at least two - preferably rigid - shells, particularly formed of one lower - preferably rigid - shell forming a bottom part of the container and for each compartment formed of a respective - preferably rigid - upper shell, the
at least one upper shell forming an air-tight closable top part of the container, preferable all ports being arranged in the lower shell. An air tight seal may be formed by a sealing, particular sealing lid, effective between bottom shell and upper shell(s).

[0028] A rigid shell may be formed of a plastic material, particularly thermoplastic or duroplast, and preferably PVC.

[0029] A preferred embodiment of a container may comprise an intermediate bottom in a compartment, particularly in each of more compartments, a drying agent (desiccant) being positioned or at least positionable under the intermediate bottom. The intermediate bottom may comprise through holes or is formed as a grid. Consequently any humidity remaining after evacuation or flushing may be absorbed by this agent.

[0030] According to another preferred embodiment the container may have a proof of originality assigned to each closure / cover of each compartment, the closure / cover being openable only by breaking the proof of originality, the proof of originality not being restorable if broken. Such a proof of originality may be formed of a ratchet connection between lower shell and an upper shell. A compartment may only be opened upon destroying the ratchet. A broken proof of originality renders the blood sample on the DBS-card(s) in the respective compartment void, since a manipulation may have taken place in advance of further processing in the laboratory.

[0031] A method for solving the aforesaid object comprises at least the following steps:

Inserting at least one dried-blood-spot card in a compartment of a container, preferably inserting at least one dried-blood-spot card of a sample A of a person into a first compartment of the container and at least one blood-spot card of a sample B, preferably of the same person into a second compartment of the container, which is preferably constructed according to the aforesaid invention an furthermore closing the respective compartment(s) and changing the atmosphere in the respective compartment(s) by evacuating air from the respective compartment(s) though an outlet port being in fluid communication with the respective compartment(s) and/or by flushing the respective compartment(s) by forcing a gaseous flushing fluid into an inlet port being in fluid communication with the respective compartment(s) and releasing the gaseous flushing fluid through an outlet port being in fluid communication with the respective compartment(s). The steps of evacuation and flushing may be combined, particularly flushing until a measured value of humidity of the flushing gas released from the container is less than a set threshold. For this purpose the outlet port may be connected to a measuring device for measurement of the humidity in the escaping flushing gas. The measuring device may provide a signalization, particularly by light or sound if the measured value of humidity is less than the threshold. Flushing may also stop automatically in that case with or without the mentioned signalization.

[0032] This method may be further improved by the step that drying the blood on the inserted card or cards is enhanced prior to shipping by flushing the compartment or compartments for a certain, preferably predetermined time, particularly flushing until a measured value of humidity of the flushing gas released from the container is less than a set threshold. For this purpose the outlet port may be connected to a measuring device for measurement of the humidity in the escaping flushing gas. The measuring device may provide a signalization, particularly by light or sound if the measured value of humidity is less than the threshold. Flushing may also stop automatically in that case with or without the mentioned signalization.

[0033] Preferred embodiments are depicted in the figures.

[0034] Figure 1 shows a container according to the invention comprising a rigid bottom shell 1 and a rigid upper shell 2, the shell 2 forming a top cover having a hinge connection to the bottom shell 1. Both shells, when closed, confine a compartment in the container for receiving a dried blood spot card 3 having several blood spots 4 and a label 5, i.e. barcode.

[0035] In this embodiment the bottom shell 1 furthermore comprises an intermediate bottom 6 having the shape of a grid or plate with holes. Underneath the intermediate bottom 6 a not shown desiccant may be placed. The intermediate bottom 6 is not mandatory and may be omitted.

[0036] According to the invention the prepared dried blood spot card 3 is placed into the lower shell and the container is closed by rotation of the cover shell 2. Both shells may also be separate parts. The mentioned hinge connection is not mandatory and may be omitted.

[0037] Closing the two shells forms an air-tight closed container. Air tight means in this context that there is no chance of gas exchange between the environment and the inner volume of the compartment even though the container comprises an inlet port 7 and an outlet port 8 since these port are normally (under environmental conditions) both closed by incorporated check valves defining a possible gas flow direction according to the arrows 9.

[0038] The incorporated valves are closed unless they are forced to open by pressurized flushing gas directed to the inlet port 9. The flushing gas will pass through the compartment end exit the compartment through the outlet port 8. Essentially the entire atmosphere (gas content) of the compartment is exchanged with the flushing gas, preferably an inert gas and most preferred nitrogen.

[0039] When closing the shells on each edge opposite to the hinge a ratchet element 10a engages a mating ratchet element 10b. If no hinge connection exist these ratchet elements may be arranged in all edges of the two shells. After engagement of the corresponding ratchet elements these elements may not be separated anymore unless they are destroyed. Accordingly the ratchet elements form a proof of originality ensuring that no manipulation has taken place after closing the container if the elements are undamaged.

[0040] As can be seen in the lower part of figure 1 an additional seal or pledge may be arranged on the cover 1.

[0041] Figure 2 shows a second preferred embodiment
comprising two compartments instead of one compartment in figure 1. Like elements have the like references in comparison to figure 1.

[0042] Here the bottom shell 1 is separated into to parts arranged side by side and being separated by the internal wall 12. The wall 12 comprises at least one closable, preferably self closable passage port incorporating a one way valve 13. The gas flow direction defined by this/these valve(s) 13 corresponds to the direction of inlet and outlet port.

[0043] Different blood samples, particularly sample A und sample B of the same person may be inserted into the two respective compartments and both compartments may be closed with the upper shell or upper shells 2a and 2b. These two shells may be separate or may be formed in one piece. Having two separate cover shells 2a and 2b provides the possibility to open one of the compartments independent from the other and without breaking the air tightness of the other compartment.

[0044] After closing the container the two compartments may be flushed with gas simultaneously via the common inlet and outlet ports 7 and 8 and the passage port 13. After flushing all valves in all ports 7, 8, 13 will close automatically providing an airtight seal under ambient conditions.

[0045] Here furthermore each compartment has its own set of ratchet elements 10a / 10b.

[0046] The containers of figure 1 and 2 may be shipped to the laboratory or may also be stored for a longer time compared to the state of the art in which the DBS-cards are untreated. Deterioration of the blood or its contents is retarded due to the exchange of atmosphere in the container(s) particularly by the exchange of oxygen and reduction of humidity.

Claims

1. Dried-Blood-Spot-card shipping and storage container, the container comprising
   a. at least one compartment, the at least one compartment being adapted to receive at least one dried-blood-spot-card (3) and being openable and being air-tight closable with a closure, preferably each compartment having a respective closure, preferably a closure being a cover (2, 2a, 2b), preferably a hinged cover (2, 2a, 2b);
   b. at least one outlet port (8), the outlet port (8) being in fluid connection with at least one compartment, preferably the gas flow direction (9) of the port out (8) of the compartment being defined by a one-way check valve, preferably the one-way check valve being incorporated in the outlet port (8).

2. Container according to claim 1, characterized by comprising at least one inlet port (7), the inlet port (7) being in fluid connection with at least one compartment, preferably the gas flow direction (9) of the inlet port (7) into the compartment being defined by a one-way valve, preferably the one-way valve being incorporated in the inlet port (7), particularly the at least one compartment being flushable with a gaseous fluid via the inlet and outlet port (7, 8).

3. Container according to claim 2, characterized by arranging the at least one inlet port (7) and the at least one outlet port (8) on opposite sides of a compartment or the container.

4. Container according to anyone of the preceding claims, characterized by a first and a second compartment, each compartment being adapted to receive at least one dried-blood-spot-card (3) and each compartment being independently air-tight closable with its closure (2a, 2b) and openable without breaking the air-tightness of the other compartment, particularly each compartment having its own openable and air-tight closable cover (2a, 2b), preferably hinged cover (2a, 2b).

5. Container according to claim 4, characterized by each compartment having a respective outlet port or respective set of outlet and inlet port, the respective port or ports being in fluid connection to this compartment only.

6. Container according to claim 4, characterized by all compartments having a common outlet port (8) or a common set of outlet and inlet port (7, 8), the common port or ports (7, 8) being in fluid connection to all compartments simultaneously and neighboring compartments being separated from each other by a respective internal wall (12) of the container, the wall comprising a closable passage port (13), preferably a check valve (13) defining a gas flow in all compartment towards the common outlet port (8).

7. Container according to anyone of the preceding claims, characterized by at least two rigid shells (1,2), particularly one lower rigid shell (1) forming a bottom part of the container and for each compartment a respective rigid upper shell (2, 2a, 2b) forming an air-tight closable top part of the container, preferably all ports (7,8) being arranged in the lower shell (1).

8. Container according to anyone of the preceding claims, characterized by an intermediate bottom in a compartment, a drying agent being positioned under the intermediate bottom.

9. Container according to anyone of the preceding claims, characterized by a proof of originality (10a, 10b) assigned at least to each closure / cover (2, 2a,
2b) of each compartment, the closure / cover (2, 2a, 2b) being openable only by breaking the proof of originality (10a, 10b), the proof of originality (10a, 10b) not being restorable if broken.

10. Method of shipping and/or storing dried-blood-spot cards comprising blood samples to be examined in a laboratory, characterized by the following steps:

a. Inserting at least one dried-blood-spot card (3) in a compartment of a container, preferably inserting at least one dried blood-spot-card (3) of a sample A of a person into a first compartment of the container and at least one blood-spot-card (3) of a sample B, preferably of the same person into a second compartment of the container, particularly the container being constructed according to anyone of the preceding claims;

b. Closing the respective compartment and changing the atmosphere in the respective compartment by evacuating air from the respective compartment though an outlet port (8) being in fluid communication with the respective compartment or by flushing the respective compartment by forcing a gaseous flushing fluid into an inlet port (7) being in fluid communication with the respective compartment and releasing the gaseous flushing fluid through an outlet port (8) being in fluid communication with the respective compartment.

11. Method according to claim 10, characterized in that drying of the blood (4) on the inserted card (3) or cards is enhanced prior to shipping by flushing the compartment or compartments for a certain time, particularly flushing until a measured value of humidity of the flushing gas released from the container is less than a set threshold.
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The present search report has been drawn up for all claims

Place of search: The Hague
Date of completion of the search: 21 April 2015
Examiner: Ueberfeld, Jörn

**CATEGORY OF CITED DOCUMENTS**

- T: theory or principle underlying the invention
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