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Sealing cap for sealing a sample tube for receiving a liquid

Abstract

A sealing cap seals a sample tube for receiving a liquid, in particular blood. The sealing cap includes a cavity delimited by a membrane and a base having an opening that can be sealed by a non-return valve. In order to reduce the volume of liquid which, during centrifugation of the sample tube sealed by the sealing cap, flows out of the sealing cap through the then open opening into the sample tube, the cavity of the sealing cap has a separating wall that divides the cavity into a first and a second sub-area. Only the second sub-area is above the opening, also meaning that only the volume of liquid in the second sub-area can flow into the sample tube.

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Background/Summary

TECHNICAL FIELD

(1) The invention relates to a sealing cap for sealing a sample tube for receiving a liquid, in particular a human or animal liquid, further in particular blood. The disclosure also relates to a blood collection tube comprising, inter alia, the sealing cap in accordance with the disclosure and a method for handling the blood collection tube.

BACKGROUND

(2) The main requirement for a blood collection tube, consisting of a sample tube and a sealing cap, for taking samples of fluids from a body, is that it seals tightly and prevents the contamination of the samples.

(3) From the international patent application WO2017/162 574 A1 along with the Japanese patent application JP2005 287 955, sealing caps for sample tubes are known in principle. The sealing caps comprise a non-return valve on their side facing the sample tube. The opposite side is sealed by a membrane that can be punctured with a cannula. A cavity is formed between them. The cannula can be used to withdraw a fluid, for example from a human or animal body. The liquid from the body flows through the cannula into the cavity in the sealing cap and then through the non-return valve into the sample tube. When the cannula is pulled out of the sealing cap, the membrane seals automatically. An appropriate design of the non-return valve ensures that the sample tube is securely sealed against leakage of the liquid. Various embodiments are disclosed for non-return valves, each of which opens under the action of a centrifugal force in the axial direction of the sample tubes.

(4) To prepare fluid from the body, in particular blood for later analysis, it is common and necessary to separate it into its light and heavy components. This is typically done by centrifuging the fluid in the blood collection tube.

(5) Before a sample is taken, that is before the blood collection tube is filled with the liquid, an anticoagulant or a coagulation accelerator, both of which are also referred to below as preparation, is usually introduced into the sample tube by the manufacturer. In the blood collection tube, the preparation mixes with the incoming liquid. The preparation ensures that the blood components are available for later analysis in a desired clotted or non-clotted state.

(6) To achieve the desired coagulation state, it is important to maintain a predetermined quantitative ratio between liquid and preparation.

(7) In the embodiments proposed in the above prior art, there is still a relatively large residual amount of liquid in the cavity of the sealing cap after sampling.

(8) Due to the typical preparation of a sample in a centrifuge, a tensile force is exerted in the axial

direction on the installed non-return valve, causing it to open. The relatively large amount of liquid contained in the cavity of the sealing cap enters the sample tube, where it contaminates the sensitive sample material with the blood that has coagulated and become hemolyzed by then. This can negatively influence the results of the subsequent analysis.

(9) Transport processes, such as those that can occur in a tube delivery system, also pose the risk of contamination of the liquid by liquid residues stored upstream of the valve that still originate from the blood collection.

SUMMARY

(10) The invention improves a known sealing cap for sealing a sample tube, a known blood collection tube and a known method for handling the blood collection tube in such a way that the volume of the liquid that flows out of the sealing cap into the sample tube during centrifugation of the blood collection tube is reduced and delimited in such a manner that it does not lead to any disruption during subsequent analysis of the liquid, in particular of blood, or that the result of the analysis is not falsified.

(11) The improved sealing cap is characterized in that the cavity comprises a separating wall for dividing the cavity into first and second sub-areas; in that the first sub-area is formed above a region of the base without the opening; in that the second sub-area is formed above the opening in the base; and in that the first and second sub-areas are formed above the base in a manner in fluid communication with each other.

(12) The cavity in the sealing cap is divided into at least two sub-areas. For this reason, the volume of each of the sub-areas is smaller than volume of the original whole cavity. Only the amount of liquid from the second sub-area can flow into the sample tube during a centrifugation of the blood collection tube, because only the second sub-area is formed above the opening. In this manner, it is ensured that only a part of the volume of liquid found in the entire cavity of the sealing cap can flow into the sample tube. In this respect, the volume of liquid draining into the sample tube is advantageously reduced compared to the total volume of liquid enclosed in the cavity of the sealing cap.

(13) In this application, the term “fluid” is used to refer to fluids that can be withdrawn from a human or animal body, in particular blood.

(14) “Preparation” refers to a defined amount of an active ingredient (anticoagulant or coagulation accelerator) to adjust a desired coagulation property of a liquid, for example in a sample tube.

(15) A “non-return valve” can also be formed as a one-piece sealing element within the scope of the present disclosure.

(16) The volume of the second sub-area and, accordingly, the residual amount of body fluid or blood, as the case may be, that only flows into the sample tube are dimensioned so small that the adverse effect on the ratio of body fluid to preparation in the sample tube caused by them is negligible; in particular, the residual amount is so small that subsequent analysis of the (blood) sample taken is possible without any appreciable falsification.

(17) In accordance with a first exemplary embodiment, the volume of the first cavity is larger than the volume of the second cavity. Accordingly, the second sub-area is smaller than the first sub-area. The smaller and larger sub-areas together make up at least a partial volume of the entire cavity. The term “larger sub-area” does not rule out that the larger sub-area is in turn subdivided again into a plurality of smaller chambers, the individual volumes of which can also be even smaller than the volume of the smaller sub-area. However, none of the chambers then have an opening in their respective bases.

(18) In accordance with further embodiments, the separating wall is configured such that the separating wall comprises, at its end facing the membrane, an overflow edge and/or a perforation, for enabling fluid communication between the second, preferably larger, and the first, preferably smaller, sub-area. Thereby, the separating wall can extend into the cavity from the base of the cavity.

(19) A further exemplary blood collection tube is characterized in that it comprises, on the one hand, the sample tube having a sealable end for receiving the liquid and, on the other hand, the sealing cap for sealing the sample tube at its sealable end.
(20) A method for handling the blood collection tube has advantages which correspond to the advantages mentioned above with reference to the claimed sealing cap.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
(1) FIG. **1**: Illustration of the blood collection tube;
(2) FIG. **2**: Illustration of the flow-through sealing cap;
(3) FIG. **3**: Illustration of a detail from FIG. **2** showing an overflow edge or perforation, as the case may be;
(4) FIGS. **4***a-d*: Illustration of the filling process of the sealing cap over time;
(5) FIG. **5**: Illustration of the sealing cap with connected sample tube; and
(6) FIG. **6** Illustration of a cross-section through the sealing cap.
DETAILED DESCRIPTION
(7) The invention is described in detail below with reference to the specified figures in the form of exemplary embodiments. In all figures, the same technical elements are designated with the same reference signs.
(8) FIG. **1** depicts a blood collection tube **500** consisting of a sealing cap **100** and a sample tube **200** for receiving a fluid **300** from a human or animal body.
(9) Preferably, the sealing cap **100** comprises a connecting part **140** for connecting the sealing cap **100** to the sample tube **200** or for sealing the sample tube **200**, as the case may be. The connecting part **140** can be configured as a screw, bayonet or plug-in connection. The connection must be liquid-tight and/or air-tight according to the requirements. It may be necessary to use additional sealants for this purpose. The connecting part may also be completely dispensable, for example if the sealing cap is simply plugged onto the sample tube.
(10) FIG. **2** shows an illustration of the sealing cap **100** through which a liquid **300** flows and which seals the sample tube **200**. A cavity **130** is formed in the sealing cap **100**, which is delimited by a membrane **110** and a base **120**. An opening **121** is formed in the base, which can be opened or sealed by a non-return valve **160**. The non-return valve **160** is configured to allow fluid **300** to flow from the cavity **130** in the sealing cap **100** into the sample tube **200**, but to block the opposite direction.
(11) The membrane **110** can be pierced by a cannula **400**. The cannula **400** establishes a fluid-conducting connection between the sealing cap **100** and the body from which the fluid is withdrawn, and directs the fluid **300** into the cavity **130** of the sealing cap **100**. The cavity **130** is divided by a separating wall **150** into a first, preferably larger, sub-area **131** and a second, preferably smaller, sub-area **132**. The larger sub-area **131** does not have an opening **121** in its base **120**. The smaller sub-area **132** is formed above the opening **121** in the base **120**. For example, the volume of the smaller sub-area is in a range between 0-70 µl (microliter).
(12) The design of the separating wall **150** is such that a flow-through area is created between the two sub-areas **131**, **132**. The flow-through area can result from a gap between an overflow edge **151** of the separating wall **150** and the membrane **110** above it and/or a perforation **152** in the separating wall **150** (FIG. **3**). The flow-through area must be large enough to ensure sufficient liquid flow during sampling. Both sub-areas **131**/**132** are thus connected to each other in a fluid-conducting communicating manner. The separating wall **150** preferably extends from the base **120** of the sealing cap in the direction of the membrane **110**.
(13) The vector arrows in FIG. **2** indicate a direction of flow of the fluid **300** through the two sub-

areas **131**/**132** and the opened sealing element **161** into the sample tube **200**.
(14) The handling method in accordance with the disclosure is described below with reference to FIGS. **2** to **5**. The sealing cap **100** is used to seal a sealable end **210** of the sample tube **200**. Prior to sealing, a preparation can be added to the sample tube **200**. The optional insertion of the preparation and/or the necessary sealing of the blood collection tube can be performed by the manufacturer. The blood collection tube **500** thus assembled can be filled with the fluid **300**.
(15) For this purpose, the body is punctured, for example with a cannula **400**. One side of the cannula **400** pierces the body, and the other side pierces the membrane **110** in the sealing cap **100**, see FIG. **4***a*.
(16) The fluid **300** flows out of the body through the cannula **400** into the cavity **130** of the sealing cap **100**, due to an existing negative pressure in the sample tube. Depending on the type of construction of the blood collection tube, the vacuum in it is already introduced there by the manufacturer. Other blood collection techniques, such as the vacuum principle or the aspiration principle, are conceivable. Interaction by the user is then required to build up pressure in the sample tube.
(17) If a plunger or piston, as the case may be, of the sample tube is manually pulled into a rear locking position before puncturing a vein in the body, the vacuum in the blood collection tube is thereby built up only if required shortly prior to blood collection and the collection of the blood then takes place analogously to the manufacturer's pre-evacuated tube with vacuum technology (vacuum principle). We speak of aspiration technique when coupling with the vein occurs initially and blood sampling occurs in parallel with the piston stroke.
(18) In the cavity **130** of the sealing cap **100**, the large sub-area **131** is preferably filled initially, see FIG. **4***b*. Subsequently, the liquid **300** flows over the overflow edge **151** and/or through the perforation **152** into the small sub-area **132**, see FIG. **4***c*. Optionally, only the smaller sub-area can be filled.
(19) Due to an existing pressure difference between the negative pressure in the sample tube **200** and the pressure in the sealing cap **100**, the non-return valve **160** opens during a blood sample collection. The liquid **300** then drains from the sealing cap **100**, and in particular from its smaller sub-area, into the sample tube **200**, see FIG. **4***d*.
(20) Once the sample tube **200** is sufficiently filled with the fluid **300**, the sampling is interrupted by cutting off the fluid line between the body and the blood collection tube. This results in a pressure equalization in the blood collection tube; in particular, it relieves the negative pressure in the sample tube. Once the pressure difference between the blood collection tube **500** and the volume **130** in the sealing cap **100** is equalized, this causes the non-return valve **160** to close again. The sample tube **200** is then sealed in a fluid-conducting manner with respect to the sealing cap.
(21) Upon a processing of the liquid **300** in the blood collection tube **500** in a centrifuge, which follows the sampling, a force F directed towards the base of the sample tube acts on the blood collection tube **500**; see the arrow in FIG. **5**. This causes the heavy components to separate from the light components in the liquid **300**. This force F, if sufficient, will also reopen the non-return valve **160** and the liquid **300** will flow unintentionally from the cavity of the sealing cap into the sample tube **200**.
(22) However, as shown in FIG. **5**, only the volume of liquid from the second, preferably smaller, sub-area **132** flows into the sample tube **200**. In contrast, the liquid **300** remains in the first, preferably larger, sub-area **131** in the sealing cap **100**.
(23) If the dimensions of the second, preferably smaller, sub-area **132** in the sealing cap **100** are sufficiently small relative to the total amount of liquid in the sample tube, the quality of the liquid required for subsequent analysis can be ensured, even if the liquid **300** flows from the smaller sub-area **132** into the sample tube **200**.
(24) FIG. **6** shows a cross-section through the sealing cap **100** in accordance with the invention. In particular, an exemplary arrangement and configuration for the separating wall **150** and for the

larger sub-area **131** and the smaller sub-area **132** can be seen.
REFERENCE SIGNS
(25) **100** Sealing cap **110** Membrane **120** Base **121** Opening **130** Cavity **131** First, preferably larger sub-area **132** Second, preferably smaller sub-area **140** Connecting part **150** Separating wall **151** Overflow edge **152** Perforation **160** Non-return valve **170** Sealing region **200** Sample tube **210** Sealable end **300** Liquid **400** Cannula **500** Blood collection tube

Claims

1. A sealing cap (**100**) for sealing a sample tube (**200**) containing blood (**300**), comprising: a membrane (**110**) that can be pierced by a cannula (**400**); a base (**120**) arranged below the membrane, the base (**120**) having an opening (**121**); a cavity (**130**) formed between the membrane (**110**) and the base (**120**) for receiving the blood (**300**); and a non-return valve (**160**) arranged at the base (**120**) and configured for unblocking the opening (**121**) in the base (**120**) to allow the blood (**300**) to flow out of the cavity (**130**) into the sample tube (**200**) and for sealing the opening (**121**) to not allow the blood (**300**) to flow out of the sample tube (**200**) into the cavity (**130**), wherein the cavity (**130**) has a separating wall (**150**) for dividing the cavity into a first sub-area (**131**) and a second sub-area (**132**), wherein the separating wall (**150**) extends into the cavity (**130**) from the base (**120**) of the cavity (**130**), wherein the first sub-area (**131**) is formed above a region of the base (**120**) without the opening (**121**), wherein the second sub-area (**132**) is formed above the opening (**121**) in the base (**120**), and wherein the first sub-area (**131**) and the second sub-area (**132**) are in fluid communication with each other, and wherein the separating wall (**150**) comprises, at an end facing the membrane (**110**), an overflow edge (**151**) and/or a perforation (**152**), for enabling the fluid communication between the first sub-area (**131**) and the second sub-area (**132**).
2. The sealing cap (**100**) according to claim 1, wherein the first sub-area (**131**) is larger than the second sub-area (**132**).
3. The sealing cap (**100**) according to claim 1, wherein the non-return valve (**160**) is directly coupled to the opening (**121**) in the base (**120**).
4. A blood collection tube (**500**) comprising: a sample tube (**200**) for receiving blood (**300**) having a sealable end (**210**); and the sealing cap (**100**) according to claim 1 for sealing the sample tube at its sealable end (**210**).
5. A method for handling the blood collection tube (**500**) according to claim 4, comprising the steps of: sealing the sample tube (**200**) at its sealable end (**210**) with the sealing cap (**100**); piercing the membrane (**110**) in the sealing cap (**100**) with one end of a cannula (**400**); withdrawing blood (**300**) from a body with the other end of the cannula (**400**), wherein the blood (**300**) flows through the cannula (**400**) and the membrane (**110**) into the cavity (**130**) of the sealing cap (**100**) and subsequently flows through the opening (**121**) in the base (**120**) of the sealing cap (**100**), which is opened in a flow direction by the non-return valve (**160**), into the sample tube and fills it; removing the cannula (**400**) from the membrane (**110**), whereupon the membrane (**110**) automatically seals again; and centrifuging the blood collection tube (**500**) to separate the blood (**300**) into heavier and lighter components, wherein the non-return valve (**160**) releases the opening (**121**) in the base (**120**) of the sealing cap (**100**) due to a centrifugal force, such that the blood (**300**) flows out of the cavity (**130**) into the sample tube (**200**); wherein, upon the withdrawal of the blood (**300**), both the first sub-area (**131**) and the second sub-area (**132**) of the cavity (**130**), which are connected to one another in a fluid-conducting communicating manner, are filled with blood (**300**); wherein during centrifugation, only blood (**300**) from the second sub-area (**132**), in the base (**120**) of which the opening (**121**) is formed, flows into the sample tube (**200**); and wherein, upon withdrawing the blood from the body, the blood first flows into and fills the first sub-area (**131**) of the sealing cap (**100**), and then flows via the overflow edge (**151**) and/or through the perforation (**152**) into the second sub-area (**132**).

6. The method according to claim 5, wherein the sample tube (**200**) has been provided with a preparation for blood prior to sealing with the sealing cap (**100**).