Claims

WHAT IS CLAIMED IS:

1. A container, comprising a sample receptacle and a cap, wherein:

the cap comprises a reservoir for retaining a composition, a first piercing member and a first pierceable barrier for sealing said composition within said reservoir;

the sample receptacle comprises a first open end for receiving a sample, and one or more second piercing members, said first open end is configured for closure by said cap and for receiving said composition;

said first piercing member and said one or more second piercing members are configured to disestablish the first pierceable barrier from opposite side of said first pierceable barrier when said first open end is closed by said cap;

wherein said cap comprises a wall defining the outer perimeter of said reservoir, wherein an outer surface of said wall is made from or is coated with an elastomeric material for sealingly engagement against an inner surface of said sample receptacle when said first open end is closed by said cap;

wherein at least a portion of an interior surface of the sample receptable, configured to be in contact with said wall of the cap when the cap is closed, is made from or is coated with an elastomeric material substantially coextensive with said elastomeric material of the outer surface of the wall; and

wherein pressure inside said container is greater than atmospheric pressure when said first open end is closed and pressed by said cap.

~~2.~~ The container according to claim 1, wherein said ~~first piercing member extends downwardly toward said first open end of the sample receptacle when said first open end is closed by said cap.~~

~~3. The container according to any of claims 1-2, wherein said cap comprises a top inner surface, and said first piercing member extends from the top inner surface of said cap.~~

~~4. The container according to claim 3, wherein said first piercing member extends approximately perpendicularly from said top inner surface.~~

~~5. The container according to any of claims 1-4, wherein said first piercing member comprises a blunt or curved upper edge.~~

~~6. The container according to any of claims 1-5, wherein said sample receptacle comprises an inner base surface, and the width of said first open end is greater than or equal to the width of said inner base surface.~~

~~7. The container according to any of claims 1-6, wherein said one or more second piercing members extend upwardly toward said first open end of the sample receptable.~~

~~8. The container according to any of claims 6-7, wherein said one or more second piercing members extend from the inner base surface of said sample receptable.~~

~~9. The container according to any of claims 6-8, wherein said one or more second piercing members extend approximately perpendicularly from said inner base surface of said sample receptable.~~

~~10. The container according to any of claims 1-9, wherein said sample receptacle comprises two of said second piercing members arranged opposite one another on either side of a vertical plane extending through the length of said sample receptable.~~

~~11.~~2. ~~The container according to any of claims 1-10, wherein said~~ sample receptacle comprises two of said second piercing members configured to allow said first piercing member to be positioned between two of said second piercing members when said first open end is closed by said cap.

~~12. The container according to any of claims 1-11, wherein each of said one or more second piercing members comprises a blunt or curved upper edge.~~

~~13. The container according to any of claims 1-12, wherein said first and second piercing members are configured to disestablish said first pierceable barrier without a twisting action during closure of said cap.~~

~~14. The container according to any of claims 1-13, wherein said first pierceable~~

~~barrier comprises a pierceable plastic film or a foil film.~~

~~15. The container according to any of claims 1-14, wherein said first pierceable barrier comprises a pierceable film made from a material selected from the group consisting of polyethylene terephthalate (PETE), polycarbonate, polyethylene, and polyvinyl chloride (PVC).~~

~~16. The container according to any of claims 1-15, wherein said sample receptacle comprises an outlet, and said outlet is in fluidic communication with said sample receptable.~~

~~17. The container according to any of claims 25-26, wherein said elastomeric material is independently selected from the group consisting of polytetrafluoroethylene (PTFE), polycarbonate (PCTE), polyethylene (PE) and polypropylene (PP).~~

~~18. The container according to any of claims 1-27, wherein the reservoir is sized to accommodate no less than about 500 µL fluid.~~

~~19. The container according to any of claims 1-28, wherein the reservoir is sized to accommodate about 500 µL to about 3000 µL of said composition.~~

~~20. The container according to any of claims 1-29, wherein said sample receptacle is configured to receive about 0.5 ml to about 1.5 ml of said sample.~~

~~21. The container according to any of claims 1-30, wherein said sample is a biological sample.~~

~~22.~~ The container according to claim ~~31, wherein said biological sample is saliva.~~

~~23. The container according to any of claims 6-32, wherein said sample receptacle includes an interior surface that is sloped downward from said first open end toward said inner base surface of the sample receptable, wherein said sloped interior surface defines a flow path for said composition following release of said composition from said reservoir when said first pierceable barrier is disestablished by said first and second piercing members.~~

~~24. The container according to any of claims 1-33, wherein said cap further~~

~~comprises said composition sealed within said reservoir.~~

~~25. The container according to any of claims 1-34, wherein said composition comprises one or more selected from the group consisting of: redox reagent, nucleic acid, nonionic detergent, DNA intercalating redox reporter, and ribonuclease inhibitor.~~

~~26. The container according to claim 35, wherein said DNA intercalating redox reporter comprise methylene blue.~~

~~27.~~3. ~~The container according to any of claims 1-36~~1, wherein said sample receptacle comprises one or more of a third piercing member located on an outer base surface of said sample receptacle, one or more said third piercing members extend outwardly from said outer base surface.

~~28.~~4. The container according to claim ~~37~~1, wherein sample receptacle comprises an extension, said extension extends outwardly from said outer base surface of said sample receptacle and an inner of said extension is in fluidic communication with said first open~~.~~, and wherein said sample receptacle comprises a filter, said filter is configured to filter out debris from sample.

~~29.~~5. The container according to claim ~~38~~3, wherein ~~the diameter of an outer surface of~~ said ~~extension is smaller~~one or ~~equal to the diameter of an inner surface of~~ more third piercing members are configured to disestablish a ~~sample receiving inlet~~pierceable barrier of an adapter~~.~~, when said container is mounted on said adapter.

~~30.~~ The container according to claim ~~39~~5, wherein said sample receptacle comprises one or more outer rings, said one or more outer ~~surface of said extension is made~~ring extends outwardly from ~~or is coated with an elastomeric material for sealingly engagement against said inner~~said outer base surface of said sample ~~receiving inlet when said container is mounted on said adapter.~~

~~31.~~6. ~~The container according to any of claims 39-40,~~receptacle, and wherein at least a portion of inner surface of said ~~inner surface of said sample receiving inlet~~adapter, configured to be in contact with said ~~extension~~one or more outer rings of said container when said container is mounted on said adapter, is made from or is

coated with an elastomeric material substantially coextensive with said elastomeric material of said outer surface of said ~~extension~~one or more outer rings, to form a fluid tight seal when said container is mounted on said adapter.

~~32. The container according to any of claims 37-41, wherein said one or more third piercing members extend outwardly from an outer base surface of said extension.~~

~~33. The container according to any of claims 37-42, wherein said one or more third piercing members extend approximately perpendicularly from said outer base surface of said sample receptacle.~~

~~34. The container according to any of claims 37-43, wherein said one or more third piercing members extend in a direction substantially oppositely to said one or more second piercing members.~~

~~35. The container according to any of claims 39-44, wherein said one or more third piercing member are arranged in a generally circular fashion on said outer surface of said extension.~~

~~36. The container according to any of claims 37-45, wherein said one or more third piercing members are arranged surrounding said outlet of the sample receptable.~~

~~37. The container according to any of claims 37-46, wherein said one or more third piercing members are configured to disestablish a pierceable barrier of an adapter, when said container is mounted on said adapter.~~

~~38. The container according to any of claims 37-47, wherein said one or more third piercing members comprise a blunt or curved lower edge.~~

~~39. The container according to any of claims 37-48, wherein said one or more third piercing members have a height of no less than about 0.5 mm.~~

~~40. The container according to any of claims 47-49, wherein said one or more third piercing member extends downwardly toward a sample receiving inlet of an adapter, when said container is mounted on said adapter.~~

41. The container according to claim ~~50, wherein said one or more third piercing member extends approximately perpendicularly downwardly toward said sample~~

~~receiving inlet of said adapter.~~

~~42. The container according to any of claims 37-51, wherein said sample receptacle comprises one or more outer rings, said one or more outer ring extends outwardly from said outer base surface of said sample receptacle.~~

~~43. The container according to claim 52, wherein an outer surface of said one or more outer rings is made from or is coated with an elastomeric material for sealingly engagement against an inner surface of an adapter, when said container is mounted on said adapter.~~

~~44. The container according to claim 53, wherein at least a portion of said inner surface of said adapter, configured to be in contact with said one or more outer rings of said container when said container is mounted on said adapter, is made from or is coated with an elastomeric material substantially coextensive with said elastomeric material of said outer surface of said one or more outer rings, to form a fluid tight seal when said container is mounted on said adapter.~~

~~45.~~7. ~~The container according to any of claims 1-54~~1, wherein said cap comprises a first snap feature and said sample receptacle comprises a second snap feature, said first snap feature and said second snap feature are configured for said first open to be irreversibly closed by said cap.

~~46.~~ The container according to claim ~~55, wherein said first snap feature comprises at least one protruding element and said second snap feature comprises at least one recess element configured to irreversibly catch said at least one protruding element.~~

~~47. The container according to any of claims 1-56, wherein said sample receptacle comprises one or more third snap features, said one or more third snap features are on bottom of said sample receptable.~~

~~48. The container according to claim 57, wherein said one or more third snap features and one or more snap features of an adapter are configured for said container to be irreversibly mounted on said adapter.~~

~~49. The container according to claim 58, wherein said one or more third snap features comprise at least one protruding element, and said one or more snap features of said adapter comprise at least one recess element configured to irreversibly catch said at least one protruding element.~~

~~50. The container according to any of claims 58-59, wherein said container and said adapter form a tight seal when said container is mounted on said adapter.~~

~~51. The container according to any of claims 57-60, wherein said one or more third snap features are arranged opposite one another on either side of said outer base surface of said sample receptable.~~

~~52. The container according to any of claims 57-61, said one or more third snap features have a height of about 2 mm to about 5 mm.~~

~~53. The container according to any of claims 57-62, wherein said one or more third snap features comprise at least one protruding element or at least one recess element.~~

~~54.~~8. ~~The container according to any of claims 1-63~~1, wherein said sample receptacle has a height of no less than about 10 mm.

~~55. The container according to claim 64, wherein said sample receptacle has a height of about 10 mm to about 500 mm.~~

~~56. The container according to claim 65, wherein said sample receptacle has a height of about 250 mm.~~

~~57. The container according to any of claims 6-66, wherein said inner base surface of said sample receptacle has an area of about 200 mm^2 to about 600 mm^2.~~

~~58.~~9. A device comprising a first layer, said first layer comprises a sample receiving inlet, and at least one fluid channel extending from and in fluidic communication with said sample receiving inlet, the terminus of each fluid channel is in fluid communication with a vent sealed by a hydrophobic vent material; said device further comprises an adapter for operably coupling to a container of claim 1; wherein at least a portion of the inner surface of the adapter, is made from or is coated with an elastomeric material substantially coextensive with an elastomeric material of the

outer surface of said outer rings of said container~~, wherein said first layer has an average thickness of about 0.1 mm to about 0.3 mm~~.

~~59.~~10. The device according to claim ~~68~~9, wherein said at least one fluid channel is configured to be completely filled with about 20 μL to about 150 μL fluid.

~~60.~~ The device according to ~~any of claims 68-69, wherein said at least one fluid channel comprises two or more fluid channels substantially equidistant from said sample receiving inlet.~~

~~61. The device according to any of claims 68-70, wherein said at least one fluid channel comprises two or more fluid channels with substantially equal channel width.~~

~~62. The device according to any of claims 68-71, wherein pore size of said vent has an average diameter of about 0.1 μm to about 10 μm.~~

~~63. The device according to any of claims 68-72, wherein said vent is a self sealing vent.~~

~~64. The device according to any of claims 68-73, wherein said hydrophobic vent material is selected from the group consisting of: polytetrafluoroethylene (PTFE), polycarbonate (PCTE), polyethylene (PE) and polypropylene (PP).~~

~~65. The device according to any of claims 68-74, wherein side walls of the at least one fluid channel is not coated with a hydrophilic material.~~

~~66.~~11. ~~The device according to any of claims 68-75~~claim 9, wherein said fluid channel and/or said sample receiving inlet comprises a lyophilized reagent.

~~67.~~ The device according to claim ~~76, wherein said lyophilized reagent comprises an assay reagent.~~

~~68. The device according to claims 77, wherein said assay reagent comprises a nucleic acid amplification enzyme and a DNA primer.~~

~~69. The device according to any of claims 68-78, wherein a height of each fluid channel is about 0.1 mm to about 1.5 mm.~~

~~70. The device according to any of claims 68-79, wherein a width of each fluid channel is about 0.3 mm to about 1 mm.~~

~~71. The device according to any of claims 68-80, wherein a length of each fluid channel is about 50 mm to about 150 mm.~~

~~72. The device according to any of claims 68-81, wherein said first layer is made of a polycarbonate material, an acrylic material or a mylar material.~~

~~73. The device according to any of claims 68-829~~, said device further comprises a second layer ~~with at least one side coated with a hydrophilic material, and when said second layer is operably coupled with said first layer, said side coated with the hydrophilic material faces and/or is in contact with the first layer.~~

~~74. The device according to claim 83, said side is coated with said hydrophilic material via an acrylic material or a silicone material.~~

~~75. The device according to any of claims 83-84, wherein said second layer comprises a sample receiving inlet, and when said second layer is operably coupled with said first layer, said sample receiving inlet in the second layer is vertically aligned to said sample receiving inlet in the first layer.~~

~~76. The device according to any of claims 83-85, wherein said second layer is made of a polycarbonate material, an acrylic material or a mylar material.~~

~~77. The device according to any of claims 83-86, wherein said second layer has an average thickness of about 1 mm to about 4 mm.~~

~~78. The device according to any of claims 83-87, wherein said second layer is bound to said first layer with an adhesive.~~

~~79. The device according to claim 88, wherein said adhesive comprises an acrylic material and/or a silicone material.~~

~~80. The device according to any of claims 68-89, wherein said device further comprises,~~ a third layer ~~with at least one side coated with a hydrophilic material, and when said third layer is operably coupled with said first layer, said side coated with the hydrophilic material faces and/or is in contact with the first layer.~~

~~81. The device according to claim 90, wherein said third layer has an average thickness of about 0.1 mm to about 0.3 mm.~~

~~82. The device according to any of claims 90-91, wherein said third layer is bound to said first layer with an adhesive.~~

~~83. The device according to claim 92, wherein said adhesive comprises an acrylic material and/or a silicone material.~~

~~84. The device according to any of claims 90-93, wherein said third layer comprises at least one opening, when said third layer is operably coupled with said first layer, each of said at least one opening is aligned to and in fluid communication with a fluid channel in the first layer.~~

~~85. The device according to claim 94, wherein said third layer comprises two or more said openings, and when said third layer is operably coupled with said first layer, none of the openings is aligned to the same fluid channel with another opening.~~

~~86. The device according to any of claims 90-95, wherein said third layer is made of a hydrophilic material.~~

~~87. The device according to claim 96, wherein said hydrophilic material comprises polyester.~~

~~88.~~12. ~~The device according to any of claims 68-97, wherein said device further comprises a~~, and/or a fourth layer~~, and~~; the fourth layer comprises at least one vent sealed by a hydrophobic vent material, when said device is assembled, said terminus of each fluid channel in said first layer is in fluid communication with said at least one vent of the fourth layer.

~~89.~~ The device according to claim ~~98, wherein said fourth layer has a thickness of about 0.1 mm to about 0.3 mm.~~

~~90. The device according to any of claims 98-99, wherein said fourth layer is bound to said second layer with an adhesive, or said fourth layer is an adhesive.~~

~~91. The device according to claim 100, wherein said adhesive comprises an acrylic material and/or a silicone material.~~

~~92. The device according to any of claims 98-101, wherein said fourth layer is made of an acrylic material and/or a silicone material.~~

~~93. The device according to any of claims 98-102, wherein said fourth layer comprises a sample receiving inlet, and when said fourth layer is operably coupled with said second layer, said sample receiving inlet in the fourth layer is vertically aligned to said sample receiving inlet in the second layer.~~

~~94.~~13. ~~The device according to any of claims 68-103~~9, said device further comprises a fifth layer, said fifth layer comprises a substrate coated with a layer of conductive material, and said conductive material is ablated to form insulative areas on said fifth layer.

~~95.~~ The device according to claim ~~104, wherein said conductive material is gold.~~

~~96. The device according to any of claims 104-105, wherein said substrate is made from a material selected from the group consisting of polyethylene terephthalate (PETE), acrylonitrile butadiene styrene (ABS), polystyrene, polycarbonate, an acrylic, polyethylene terephthalate (PETG), polysulfone, and polyvinyl chloride (PVC).~~

~~97.~~14. ~~The device according to any of claims 104-106~~13, wherein said fifth layer comprises two symmetrically positioned insertion monitoring electrodes, and when said device is assembled, said insertion monitoring electrodes are exposed and not covered by any other layer of said device.

~~98.~~ The device according to claim ~~107, wherein said two insertion monitoring electrodes are substantially identical.~~

~~99. The device according to any of claims 107-108, wherein the length of said insertion monitoring electrode is about 2 mm to about 4 mm.~~

~~100. The device according to any of claims 107-108, wherein the width of said insertion monitoring electrode is about 1 mm to about 3 mm.~~

~~101. The device according to any of claims 107-110, wherein said insertion monitoring electrode is located in a corner of said fifth layer.~~

~~102.~~15. ~~The device according to any of claims 104-111~~13, wherein said fifth layer comprises at least one working area, said working area comprises a working electrode, a counter electrode, a reference electrode and at least two fluid fill electrodes.

~~103.~~ The device according to claim ~~121, wherein said container comprises the container according to any one of claims 1-67.~~

~~104. The device according to any of claims 121-122~~9, wherein said adapter comprises a sample receiving inlet configured to be in fluid communication with said sample receiving inlet of said first layer of an assembled device~~.~~

~~105. The device according to claim 123~~, wherein said sample receiving inlet of said adapter ~~is sealed by a pierceable barrier.~~

~~106. The device according to claim 124, wherein said pierceable barrier of said adapter comprises a pierceable plastic films or a foil film.~~

~~107. The device according to any of claims 124-125, wherein said pierceable barrier of said adapter comprises a pierceable film made from a material selected from the group consisting of polyethylene terephthalate (PETE), polycarbonate, polyethylene, and polyvinyl chloride (PVC).~~

~~108. The device according to any of claims 123-126, wherein said sample receiving inlet of said adapter comprises a blocking element having a bottom configured to prevent said lyophilized reagent from leaving said device.~~

~~109. The device according to claim 127, wherein the bottom of said blocking element has a width greater than that of the lyophilized reagent.~~

~~110. The device according to any of claims 127-128, wherein said blocking element~~ comprises at least one piercing member extending upwardly toward said pierceable barrier of said adapter~~.~~

~~111.~~16. ~~The device according to claim 129,~~ , and wherein said piercing member ~~of said blocking element~~ is configured to disestablish a pierceable barrier of a container, and a sample receptacle of said container is in fluidic communication with said sample receiving inlet of said adapter, when said container is mounted on said adapter.

~~112. The device according to claim 130, wherein said container comprises one or more piercing members, and said piercing member of said adapter is allowed to be~~

positioned between said piercing member of said container when said container is mounted on said adapter.

113. The device according to any of claims 129-131, wherein said one or more piercing members of said blocking element of the adapter has a height of less than 5 mm.

114. The device according to any of claims 131-132, wherein said piercing member of said container is configured to disestablish said pierceable barrier of said device, said piercing member of said adapter is configured to disestablish a pierceable barrier of said container and a sample receptacle of said container is in fluidic communication with said sample receiving inlet of said adapter, when said container is mounted on said adapter.

115. The device according to any of claims 129-133, wherein said piercing member of said blocking element of said adapter comprises a blunt or curved upper edge.

116. The device according to any of claims 121-134, wherein said adapter comprises one or more snap features.

117. The device according to claim 135, wherein said one or more snap features of said adapter comprise at least one protruding element or at least one recess element.

118. The device according to any of claims 135-136, wherein said one or more snap features of said adapter and one or more snap features of a container are configured for said container to be irreversibly mounted on said device.

119. The device according to claim 137, wherein said one or more snap features of said container comprise at least one protruding element, and said one or more snap features of said device comprise at least one recess element configured to irreversibly catch said at least one protruding element.

120. The device according to any of claims 121-138, wherein at least a portion of the inner surface of the adapter, configured to be in contact with one or more outer rings of an outer base surface of a container when said container is mounted on said

~~device, is made from or is coated with an elastomeric material substantially coextensive with said elastomeric material of the outer surface of said outer rings, to form a fluid tight seal when said container is mounted on said adapter.~~

~~121.~~17. A system, comprising the container according to ~~any one of claims 1-67~~claim 1.

~~122.~~18. The system according to claim ~~140~~17, the system further comprises a device ~~according to any one of claims 68-139~~comprising a first layer, said first layer comprises a sample receiving inlet, and at least one fluid channel extending from and in fluidic communication with said sample receiving inlet, the terminus of each fluid channel is in fluid communication with a vent sealed by a hydrophobic vent material.

~~123.~~ The system according to ~~any of claims 140-141, the system further comprises a thermo control module.~~

~~124. The system according to claim 142, wherein said thermo control module is configured to perform isothermal nucleic acid amplification.~~

~~125. The system according to any of claims 142-143, wherein said thermo control module is configured to maintain a temperature of about 55 °C to about 75 °C.~~

~~126. The system according to any of claims 140-144, the system further comprises a signal detection module.~~

~~127. The system according to claim 145, wherein said signal is an electrochemical signal.~~

~~128. The system according to any of claims 145-146, wherein said signal is a qualitative signal and/or a quantitative signal.~~

~~129.~~19. ~~The system according to any of claims 145-147~~claim 17, said system comprises a reader, said reader comprises ~~said~~a thermo control module and ~~said~~a signal detection module.

~~130.~~20. The system according to claim ~~148~~19, said reader comprise a heating block, said heating block is configured for uniform heating a reaction chamber of said device.

~~131. The system according to claim 149, said reader comprise a temperature sensor, said temperature sensor is embedded under said heating block.~~

~~132. A method for collecting and/or storing a sample, comprising using the container of any one of claims 1-67.~~

~~133. A method for determining the presence and/or amount of a target in a sample, comprising using the container of any one of claims 1-67, the device of any one of claims 68-139, and/or the system of any one of claims 140-150.~~

~~134.~~21. A method for preparing a sample derived from a subject, comprising:

I) introducing the sample into a sample receptacle through a first open end of said sample receptable;

II) closing said first open end irreversibly by attaching a cap to said sample receptable;

III) said cap comprises a reservoir for retaining a composition, a first piercing member and a first pierceable barrier for sealing said composition within said reservoir; wherein said cap comprises a wall defining the outer perimeter of said reservoir, wherein an outer surface of said wall is made from or is coated with an elastomeric material for sealingly engagement against an inner surface of said sample receptacle when said first open end is closed by said cap;

IV) said sample receptacle comprises one or more second piercing members; wherein at least a portion of an interior surface of the sample receptable, configured to be in contact with said wall of the cap when the cap is closed, is made from or is coated with an elastomeric material substantially coextensive with said elastomeric material of the outer surface of the wall;

V) when the first open end of the sample receptacle is closed by said cap, said first piercing member and said one or more second piercing members effect a force to disestablish the first pierceable barrier from opposite side of said first pierceable barrier.

~~135. The method according to claim 153, further comprising mixing the composition released from the cap and the sample within said irreversibly closed sample receptable.~~

~~136. The method according to any of claims 153-154, wherein said first piercing member extends downwardly toward said first open end of the sample receptacle when said first open end is closed by said cap.~~

~~137. The method according to any of claims 153-155, comprising using the container of any one of claims 1-67.~~

~~138.~~22. A method for determining the presence and/or amount of a target in a sample, comprising:

I) preparing the sample using the container of ~~any one of claims 1-67~~claim 1,

II) mounting the container comprising the prepared sample on the device ~~of any~~comprising a first layer, said first layer comprises a sample receiving inlet, and at least one ~~of claims 68-139~~fluid channel extending from and in fluidic communication with said sample receiving inlet, the terminus of each fluid channel is in fluid communication with a vent sealed by a hydrophobic vent material; and

III) inserting said device into a reader comprising a thermo control module and a signal detection module.

~~139. The method according to claim 157, wherein said first piercing member extends downwardly toward said first open end of the sample receptacle when said first open end is closed by said cap.~~

~~140. The method according to any of claims 157-158, wherein comprising using the system of any one of claims 140-150.~~