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 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.

3. The container according to claim 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.

4. The container according to claim 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.

5. The container according to claim 3, 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.

6. The container according to claim 5, 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, and wherein at least a portion of 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.

7. The container according to claim 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.

8. The container according to claim 1, wherein said sample receptacle has a height of no less than about 10 mm.

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.

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

11. The device according to claim 9, wherein said fluid channel and/or said sample receiving inlet comprises a lyophilized reagent.

12. The device according to claim 9, said device further comprises a second layer, a third layer, and/or a fourth layer; 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.

13. The device according to claim 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.

14. The device according to claim 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.

15. The device according to claim 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.

16. The device according to claim 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, wherein said sample receiving inlet of said adapter comprises at least one piercing member extending upwardly toward said pierceable barrier of said adapter, and wherein said piercing member 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.

17. A system, comprising the container according to claim 1.

18. The system according to claim 17, the system further comprises 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.

19. The system according to claim 17, said system comprises a reader, said reader comprises a thermo control module and a signal detection module.

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

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.

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 claim 1,

II) mounting the container comprising the prepared sample on the 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; and

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