# PACKAGING FOR ASSAYS AND RELATED METHODS

## FIELD

**[0001]** The disclosure is directed to an assay kit package, an insert for same, and methods of preparing the insert and for manufacturing, assembling, storing, and reassembling an assay kit.

## BACKGROUND

**[0002]** Heretofore, it was problematic to quickly identify and correctly match assay kit reagents and components for assays for quick and accurate assembly, shipping and reassembly, including for example, where portions of the assay kit may be shipped or stored separately, including at different temperatures and/or at different locations. Such logistics typically require some disassembly of the related packages to identify contents and/or reliance on identifier coding that oftentimes requires extensive cross referencing and/or undue machinations by personnel to ensure proper assembly during manufacture or during reunification. Hence, an improved package and methods which permit the assay kit reagents and components to be quickly and reliably assembled, shipped, and subsequently reassembled by the customer is needed, and which also provide greatly improved operational experiences at the manufacturer and user level.

## SUMMARY

**[0003]** In one practice, the disclosure provides a package for a particular assay kit comprising a ~~box~~tray~~, optionally~~ having assay product information on an outer sidewall; an insert disposed within the tray~~outer box~~, the insert configured to hold a plurality of assay kit reagent containers comprising the same or different reagents, wherein each assay kit reagent container has a container bottom, wherein all or a subset ~~thereof~~of each assay kit reagent~~, has a~~ container bottom ~~on which is located~~comprises a product code that is readable by a human, a machine, or both and identifies the reagent within that particular container, the insert comprising an upper surface, a bottom surface, and a plurality of through holes extending through the insert from the upper surface to the bottom surface, each of the plurality of through holes shaped to individually

hold a respective assay kit reagent container such that the product code located on each container bottom~~s, or subset of container bottoms, comprising the product code~~ is readable through the respective through hole at the bottom surface of the insert.

**[0004]** The disclosure also provides a loaded insert that is filled or partially filled with assay kit reagent containers for a tray or a outer box, wherein the loaded insert comprises an upper surface, a bottom surface, and a plurality of through holes extending from the upper surface of the insert to the bottom surface of the insert; and a plurality of assay kit reagent containers comprising the same or different reagents, each of the plurality of assay kit reagent containers disposed within a respective through hole of the plurality of through holes, each of the plurality of assay kit reagent containers or a subset thereof having a container bottom on which is located a product code identifying the reagent within that particular container, the product code readable by a human or a machine or both through the respective through hole at the bottom surface of the loaded insert.

**[0005]** The disclosure additionally provides a method of preparing a loaded insert for an assay kit comprising providing a plurality of assay kit reagent containers associated with a particular assay kit, the plurality of assay kit reagent containers comprising the same or different reagents, each of the plurality of assay kit reagent containers or a subset thereof having a container bottom on which is located a product code identifying the reagent within that particular container, the product code readable by a human or a machine or both; providing an insert that comprises an upper surface, a bottom surface, and one or more through holes extending from the upper surface of the insert to the bottom surface of the insert; preparing a loaded insert by disposing each of the plurality of assay kit reagent containers into a respective through hole of the plurality of through holes such that the product code on each container bottom or subset comprising the product code is readable through the respective through hole at the bottom surface of the insert; inputting the product code on each container bottom or subset comprising the product code into a database accessible by a computer, the database comprising information about reagents for the particular assay kit; and comparing the product code on each container or subset comprising the product code with the information in the database about the reagents for the particular assay kit to verify

CLAIMS

What is claimed is:

1. A package for a particular assay kit comprising:

a tray having assay product information on an outer sidewall;

an insert disposed within the tray, the insert configured or adapted to hold a plurality of assay kit reagent containers comprising the same or different reagents, wherein each assay kit reagent container has a container bottom, wherein all or a subset of each assay kit reagent container bottom comprises a product code that is readable by a human, a machine, or both and identifies the reagent within that particular container, wherein the insert comprises an upper surface, a bottom surface, and a plurality of through holes extending through the insert from the upper surface to the bottom surface, and wherein each of the plurality of through holes is shaped to individually hold a respective assay kit reagent container such that the product code located on each container bottom is readable through the respective through hole at the bottom surface of the insert.

2. The package of Claim 1 further comprising an outer box that comprises a sidewall with a window, wherein the tray is disposed within the outer box to display the assay product information through the window.

3. The package of Claim 1 wherein the assay product information comprises an assay name or an assay category or assay type.

4. The package of Claim 1 wherein the tray comprises an assay kit collection code that is human readable, machine readable, or both, wherein the assay kit collection code is unique for that particular assay product.

5. The package of Claim 1 wherein the product code comprises a 2D or 3Ddata-matrix barcode, or a QRS code.

6. The package of Claim 1 wherein the insert comprises foam.

7. The package of Claim 1 wherein the upper surface and the bottom surface of the insert are each substantially planar.

8. The package of Claim 1 further comprising a plurality of assay kit reagent containers.

9. The package of Claim 8 wherein the plurality of assay kit reagent containers comprise at least two different container shapes, at least two different container sizes, or both.

10. The package of Claim 8 wherein the reagents comprise any one or more of the following: antibodies, controls, calibrators, diluents, buffers, and combinations of any of the foregoing.

~~11. A loaded insert comprising:~~

~~an insert comprising an upper surface, a bottom surface, and a plurality of through holes extending from the upper surface of the member to the bottom surface of the insert; and~~

~~a plurality of assay kit reagent containers comprising the same or different reagents, each of the plurality of assay kit reagent containers disposed within a respective through hole of the plurality of through holes, wherein all or a subset of the plurality of assay kit reagent containers has a container bottom on which is located a product code identifying the reagent within that particular container, and wherein the product code is readable by a human or a machine or both through the respective through hole at the bottom surface of the insert.~~

~~12. The loaded insert of Claim 11 further comprising a tray that comprises a tray base, wherein the tray base has upwardly extending tray sidewalls defining an interior volume within which the insert and plurality of assay kit reagent containers is removably disposed.~~

~~13. The loaded insert of Claim 12 wherein the upper surface and the bottom surface are each substantially planar.~~

~~14. The loaded insert of Claim 13 comprising a peripheral sidewall that is in substantially continuous contact with the upwardly extending tray sidewalls.~~

~~15. The loaded insert of Claim 11 wherein the insert comprises foam.~~

~~16. A method of preparing a loaded insert for an assay kit comprising:~~

~~providing a plurality of assay kit reagent containers associated with a particular assay kit, the plurality of assay kit reagent containers comprising the same or different reagents, wherein each or a subset of the plurality of assay kit reagent containers have a container bottom on which is located a product code identifying the reagent within that particular container, the product code readable by a human or a machine or both;~~

~~providing an insert that comprises an upper surface, a bottom surface, and one or more through holes extending from the upper surface of the insert to the bottom surface of the insert;~~

~~preparing a loaded insert by disposing each of the plurality of assay kit reagent containers into a respective through hole of the plurality of through holes such that the product code on each container bottom or subset thereof comprising the product code is readable through the respective through hole at the bottom surface of the insert;~~

~~inputting the product code on each container bottom comprising the product code into a database accessible by a computer, the database comprising information about reagents for the particular assay kit; and~~

~~comparing the product code on each container comprising the product code with the information in the database about the reagents for the particular assay kit to verify that the reagents contained within the plurality of assay kit reagent containers are for the particular single assay kit.~~

~~17. The method of Claim 16 wherein the inputting comprises placing the loaded insert onto a scanner and reading, with the scanner, the product code located on each container bottom comprising the product code.~~

~~18. The method of Claim 17 wherein the loaded insert is disposed within a tray.~~

~~19. The method of Claim 16 wherein the reagents within the plurality of assay kit reagent containers comprise one or more of the following: antibodies, controls, calibrators, diluents, buffers, or combinations of any of the foregoing.~~

~~20. The method of Claim 16 wherein the insert comprises foam.~~

~~21. A method for storing and assembling an assay kit comprising~~

~~(i) providing, to a customer, outer boxes for a particular assay kit, wherein each outer box comprises (a) an outer sidewall displaying an assay kit collection code that is human readable, machine readable or both and is uniquely associated with that particular assay kit, and (b) an insert disposed within each outer box, the insert holding a plurality of assay kit reagent containers comprising the same or different reagents;~~

~~(ii) storing respective outer boxes at storage locations which can be the same or different depending on the reagents contained within the assay kit reagent containers for a respective product box; and~~

~~(iii) retrieving, when ready to assemble the particular single assay kit, the outer boxes from the storage locations by comparing the assay kit collection code on each outer box in order to verify they are associated with the particular single assay kit.~~

~~22. The method of Claim 21 further comprising:~~

~~(iv) assembling the particular assay kit from the reagents contained within the assay kit reagent containers.~~

~~23. The method of Claim 21 wherein for (i) at least one of the outer boxes is provided to the customer separately from the remaining outer boxes for the particular assay kit.~~

~~24. The method of Claim 21 wherein (i) further comprises inputting information from the assay kit collection code located on each outer box into a database accessible by a computer.~~

~~25. The method of Claim 24 wherein (ii) further comprises inputting information about the storage locations into the database that is accessible by a computer and associating the information about the storage locations with the assay kit collection code.~~

~~26. The method of Claim 25 wherein the information about the storage locations is machine readable and is on labels located at the storage locations; and wherein the inputting comprises scanning the machine readable information on the labels.~~

~~27. The method of Claim 25 wherein (iii) comprises accessing the database to ascertain at which storage locations each product box is stored.~~

~~28. The method of Claim 21 wherein in (ii) the different locations are physically separated.~~

~~29. The method of Claim 21 wherein in (ii) the different locations are each individually kept at the same or different temperatures.~~

~~30. A method of manufacturing an assay kit comprising:~~

~~inputting customer order information for a particular single assay kit into a database accessible by computer and retrieving from the database preloaded identification of reagents for the particular single assay kit;~~

~~displaying a location map for the particular assay kit indicating where in an insert a plurality of assay kit reagent containers comprising the reagents for the particular single assay are to be located, wherein the insert comprises an upper surface, a bottom surface, and a plurality of through holes extending from the upper surface of the insert to the bottom surface of the insert, and wherein each of the through holes is configured to hold a respective assay kit reagent container;~~

~~preparing a loaded insert by providing the insert and providing the plurality of identified assay kit reagent containers and disposing in accordance with the location map each of the assay kit reagent containers into a respective through hole of the plurality of through holes, wherein all~~

~~or a subset of the assay kit reagent containers has a container bottom comprising a product code identifying the reagent within a particular container, and wherein the product code is readable by a human or a machine or both through the respective through hole at the bottom surface of the insert; and~~

~~inputting the product code on each container bottom comprising the product code within the loaded insert into the database and comparing the product code on each container with the location map to verify that the assay kit reagent containers in the loaded insert are loaded in accordance with the location map for the particular single assay kit.~~

~~31. The method of Claim 30 wherein the insert comprises foam.~~

~~32. The method of Claim 30 wherein the reagents comprise any one or more of following: antibodies, controls, diluents, calibrators, buffers, and combinations of any of the foregoing.~~

~~33. The method of Claim 30 further comprising:~~

~~retrieving from the database preloaded identification of assay kit components associated with the particular single assay kit;~~

~~providing the identified assay kit components, wherein each assay kit component has thereon a component code identifying what the component is, and wherein the component code is readable by a human or a machine or both;~~

~~inputting the component code on each assay kit component into the database and comparing the component code on each assay kit component with the preloaded information to verify that each assay kit component is for the particular single assay kit; and~~

~~assembling the particular single assay kit by combining the verified assay kit components with the verified loaded insert.~~

~~34. The method of Claim 33 wherein the assay kit components comprise one or more assay plates, one or more cartridges, and combinations of any of the foregoing.~~

35. The method of Claim 33 further comprising shipping the assembled particular single assay kit to the customer identified on the customer order information.

36. The method of Claim 35 wherein the shipping comprises:

packing the verified loaded insert into a tray, the tray having assay product information on an outer sidewall; and

disposing the packed tray into an outer box comprising a sidewall with a window, wherein the packed tray is disposed within the outer box to display the assay product information through the window.

37. The method of Claim 36 further comprising packing the verified assay kit components into the outer box, the packed tray, or both.

38. The method of Claim 36 wherein the assay product information comprises an assay kit collection code that is human readable, machine readable, or both, wherein the assay kit collection code unique for that particular assay product.

39. A package for an assay kit comprising:

a) an outer box; and

b) one or more removable trays,

i) wherein the outer box comprises a window and at least one of the trays comprises assay product information, and wherein the assay product information is viewable through the window; or

ii) wherein the at least one of the trays comprises an insert that comprises an upper surface, a bottom surface, and a plurality of through holes extending through the insert from the upper surface to the bottom surface, and wherein each of the plurality of through holes is shaped to individually hold a respective assay kit reagent container such that a product code located on all or a subset of the bottoms of the assay kit reagent containers is readable through the respective through hole at the bottom surface of the insert, and wherein the insert for at least one of the trays is removable from the tray, or comprises a portion that is removable from the

~~tray, and wherein the removable insert or the removable portion is adapted to be placed on a scanner to read the product code; or~~

~~iii) both (i) and (ii).~~

~~40. The package of Claim 39 wherein the assay product information comprises assay name or category of assay type.~~

~~41. The package of Claim 39 wherein the product code comprises an assay kit collection code that is human readable, machine readable, or both, wherein the assay kit collection code is unique for that particular assay product.~~

~~42. The package of Claim 39 wherein the insert comprises foam.~~

~~43. The package of Claim 39 wherein at least one insert is not removable.~~

~~44. The package of Claim 43 wherein the through holes for the at least one insert that is not removable are shaped to hold one or more bottles of the same or different shape.~~

~~45. The package of Claim 44 wherein the bottle bottoms do not comprise the product code.~~

~~46. The package of Claim 39 wherein the through holes for the removable insert or the removable portion are shaped to hold a plurality of vials or tubes or both, the vials and tubes of the same or different shape.~~

~~47. The package of Claim 46 wherein the bottoms of the plurality vials or tubes each individually comprise the product code.~~

~~48. The package of Claim 39 wherein the outer box, at least one of the trays, at least one of inserts comprises storage temperature information.~~

~~49. The package of Claim 39 wherein the outer box comprises one or more internal walls configured to create one or more internal segments within the outer box.~~

~~50. The package of Claim 49 wherein at least one tray is disposed within a respective internal segment.~~

~~51. The package of Claim 50 wherein at least one insert is removably disposed in the tray.~~

~~52. The package of Claim 51 wherein more than one removable insert is disposed within the tray disposed within the respective segment.~~

~~53. The package of Claim 52 wherein the more than one removable inserts are disposed side by side within the tray disposed within the respective segment.~~

~~54. The package of Claim 50 wherein at least one insert that is not removable is disposed in the tray.~~

~~55. The package of Claim 39 wherein the product code is on a subset of the assay kit reagent containers.~~

~~56. The package of Claim 49 wherein one or more assay plates are disposed within a respective internal segment.~~

~~57. The method of Claim 17 wherein the scanner is a flat bed scanner.~~

~~58. The method of Claim 30 wherein the inputting comprises placing the loaded insert onto a scanner and reading, with the scanner, the product code located on each container bottom comprising the product code.~~

~~59. The method of Claim 58 wherein the scanner is a flat bed scanner.~~

~~60. The method of Claim 16 wherein the product code comprises a 2D or 3Ddata-matrix barcode, or a QRS code.~~

~~61. The method of Claim 30 wherein the product code comprises a 2D or 3Ddata-matrix barcode, or a QRS code.~~