Figure 8 is a drawing of an embodiment of a bucket (1) having a bayonet mount engagement portion (9) and a lid (2) having a mated bayonet mount portion (10). Figures 8A and 8B show the bucket (1) and lid (2) engaged and separated, respectively.

Figure 9 is a drawing of an embodiment of a bucket (1) having a snap engagement portion (11) and a lid (2) having a mated snap portion (12). Figures 9A and 9B show the bucket (1) and lid (2) engaged and separated, respectively.

Figure 10 is a drawing of an embodiment of a bucket (1) having both a bayonet mount and snap engagement features. Figures 10A and 10B show the bucket (1) and lid (2) separated and engaged, respectively.

Figures 11A-11C is a cross sectional view of different embodiments of seals (3) between lids (2) and the top edge and/or side of a bucket (1).

Figures 12A-12C is a cross sectional view of different embodiments of seals (3) between lids (2) and the top edge and/or side of a bucket (1).

Figures 13A-13C is a cross sectional view of different embodiments of seals (3) between lids (2) and the top edge and/or side of a bucket (1).

Figure 14A is a drawing of an embodiment of a floating plate seal (3) showing raised features (3a) on the top surface. Figures 14B-D show cross sectional views of embodiments of a floating plate seal (3) in place in a lid (2) engaged to a bucket (1), showing a raised feature (3a) on the top surface of floating plate seal (3) contacting lid (2), and vertical component (3b) of the floating plate seal (3) forming a seal with the interior surface of bucket (1). Compressible components (3c) are indicated.

Figures 15A-15E show cross sectional views of different embodiments of vertical component (3b) of floating plate seal (3) as they contact the top edge and/or side of bucket (1).

Figure 16A shows an embodiment comprising a pop-over plate (14), configured to expand seal (3) when lid (2) is engaged with bucket (1).

Figure 16B shows an embodiment wherein the seal (3) is an expandable seal, configured to expand outward when lid (2) is engaged with bucket (1).

Figure 17 is a cross-sectional view of a separate gasket (13).

Figures 18A-18B show cross-sectional views of an embodiment of an alignment ring (15) and a bucket comprising guide ribs (16).

Figures 18C-18D show cross-sectional views of an embodiment of an a support ring (17).

Figures 19A-19B show cross-sectional views of an embodiment of a skirt (18) on lid (2).

Figure 20 is a cross-sectional detail view of a portion of a bucket (1), showing a funnel portion (19) on bucket (1).

Figures 21A-21E show views of an embodiment of an enclosing holder for an ergonomic stool specimen container.

DEFINITIONS

To facilitate an understanding of the present technology, a number of terms and phrases are defined below. Additional definitions are set forth throughout the detailed description.

As used herein, "a" or "an" or "the" can mean one or more than one. For example, "a" widget can mean one widget or a plurality of widgets.

As used herein, the term "analyte" is to be construed broadly as any compound, molecule, element, ion, or other substance of interest to be detected, identified, or characterized.

As used herein, the terms "subject" and "patient" refer to an animal, preferably a human, from which a stool specimen is collected. In some instances, the subject is also a "user" (and thus the user is also the subject or patient).

As used herein, the transitional phrase "consisting essentially of" as used in reference to compositions, steps, or other features is to be read as "consisting of" the specified materials, steps, or features, plus only unavoidable additional elements that do not materially affect the basic and novel characteristic(s) of the materials, methods, steps, *etc*., *e.g.*, unavoidable contaminants, unavoidable steps.

As used herein, the term "sample" and "specimen" are used interchangeably, and in the broadest senses. In one sense, sample is meant to include a specimen or culture obtained from any source, as well as biological and environmental samples. Biological samples may be obtained from animals (including humans) and encompass fluids, solids, tissues, and gases. Biological samples include blood products, such as plasma, serum, stool, urine, and the like. Environmental samples include environmental material such as surface matter, soil,

For example, the seal may be configured to curve away from the interior sidewall of the bucket as shown (*e.g.*, as diagrammed in Figure 15A-C) to provide a gap to lead the top edge of the bucket into the correct position between the vertical component (3b) of the seal (3). Such an inward curve at the lower edge of the vertical component also reduces the risk of catching the edge of vertical component (3b) on the top surface (1a) at the rim of the bucket. In some embodiments, the vertical component 3(b) may be shortened, *e.g.*, as shown in Figure 15B, and/or a stiffer seal material may be selected to reduce the probability of the lip of the bucket catching on and damaging the seal. In some embodiments, a seal may be configured to have a short vertical component (3b), as exemplified in Figures 15D and 15E. In certain embodiments, the seal cups the top surface (1a) of the rim of bucket (1), *e.g.*, as shown in Figure 15E.

In some embodiments, a container may comprise a feature that repositions vertical component (3b) of seal (3) to contact the circumferential vertical surface of bucket (1) only after lid (2) is properly seated on bucket (1). For example, Figure 16A shows a lid (2) comprising a seal having a vertical component (3b) that is in a first position curving away from the circumferential vertical surface on the interior of bucket (1), providing a better approach for inserting the rim of bucket (1). A pop-over plate (14) having a lens-like geometry is configured flex when lid (2) is properly engaged to bucket (1), thereby moving vertical component (3b) of the seal into a second, sealing position. In the embodiment shown in Figure 16A, pressure of lid (2) and/or bucket (1) on pop-over plate (14) upon engagement of lid (2) to bucket (1) causes the pop-over plate to flex in a manner that moves vertical component (3b) radially outwards and into contact with the circumferential vertical surface of bucket (1). The same effect may be achieved using a number of different sealing configurations. For example, as diagrammed in Figure 16B, in some embodiments seal (3) itself is an expanding seal that is configured to flex upon engagement of lid (2) to bucket (1), such that pressures of lid (2) and/or the bucket (1) on the seal cause vertical component (3b) of the seal to flex radially outward toward the circumferential vertical surface of bucket (1) when the lid is properly engaged to the bucket.. In other embodiments, a separate gasket (13) that is not part of a lid may be provided, *e.g.*, on the top edge of the bucket, such that a seal is formed when the lid is engaged with the bucket, as shown in Figure 17.

In some embodiments, both the lid (2) and bucket (1) may comprise components that guide the bucket and lid into proper alignment during the container closing process. For example, in some embodiments, lid (2) comprises an alignment ring (15) that positions the top edge of bucket (1) at it approaches the seal during the closing process as shown in Figure

18A and 18B. In some embodiments, bucket (1) may comprise guide ribs (16) that interact with an alignment ring to properly position the lid and bucket for engagement, as shown in Figure 18A and 18B. In other embodiments, lid (2) may comprise an internal support ring (17), *e.g.*, as shown in Figures 18B and 18C, configured to assure that the mated engagement portions of the lid and bucket are properly aligned when they contact for engagement.

In yet other embodiments, the lid (2) may comprise an external feature that restricts the angle at which the top edge of the bucket can be brought into contact with the seal within the lid. For example, an external skirt (18) feature, as shown in Figures 19A and 19B may be provided. In preferred embodiments, the external skirt is sufficiently long and of sufficient rigidity that the mated engagement portions of the lid and bucket cannot be brought into contact unless and until the lid and bucket are in sufficiently proper alignment to prevent crimping, tearing, or other damage to a seal or gasket during engagement of the lid to the bucket, and to ensure proper engagement of the mated engagement portions. The skilled person can readily determine by measurement and/or testing a length and diameter of an external skirt suitable for providing proper alignment between lids and buckets of containers having a wide array of different dimensions. In some embodiments, an external skirt (18) on lid (2) is manufactured as an integral part of the body of lid (2), while in other embodiments, an external skirt (18) is a separate component part that is reversibly or irreversibly affixed to lid (2).

In yet other embodiments, bucket (1) may comprise a funnel portion (19) that provides a wider opening for the approach of the vertical component (3b) of seal (3) into the bucket opening, and gets progressively narrower, such that the seal (3) contacts the circumferential vertical surface of bucket (1) below the funnel portion (19) of bucket (1), *e.g.*, as diagrammed in Figure 20.

The guiding features discussed above are not limited to any particular construction. For example, alignment rings, guide ribs, support rings, skirts, *etc.* may be made of the same material as the lid and/or bucket, or of different material. In some embodiments, for example, these features are manufactured as integral parts of the component on which they appear and in some embodiments, they are provided as separate parts that are reversibly or irreversibly attached to the component on which they are used. In certain embodiments, the ergonomic bucket of the container comprises gripping features designed to facilitate grasping of the bucket by an adult person with limited hand size and/or strength, *e.g.*, a geriatric patient. For example, the bucket may comprise gripping ridges configured to permit an adult to grasp the ridges with several fingers of one hand, *i.e.*, ridges of sufficient height (top to

in the bucket of the device, and sealing the device by engaging the lid to the bucket using the engagement features, and sending or delivering the container and specimen for analysis, *e.g.*, to a physician's office or testing lab.

In some embodiments, the invention provides an enclosing holder adapted to receive and enclose an ergonomic container according to the invention, *e.g.*, during processing for mixing the contents within the sealed container, *e.g.*, through agitation of the sealed container (by, for example, shaking, rotating, vibrating, gyroscopic mixing, *etc.*). In some embodiments, the enclosing holder is configured to securely seal, such that any contents leaking from an ergonomic stool collection container, *e.g.*, during vigorous agitation, are completely contained within the enclosing holder, thereby reducing risk of accidental worker exposure to leaked biological samples. In preferred embodiments, an enclosing holder is configured with internal features that mate to external features on the ergonomic sample container, such that a sample container is securely held within the enclosing holder when the enclosing holder is secured in a closed state. For example, Figure 21B shows a cross-sectional view of an embodiment of an enclosing holder comprising a sample adaptor (32) that comprises ridges configured to mate with gripping features (4) on the exterior of the container shown in Figure 1, such that when the container is fitted within the sample adaptor (32) and the enclosing holder is closed, rotational movement of the bucket within the enclosing holder is restricted or, preferably, prevented.

In some embodiments, an enclosing holder comprises a holder top assembly (21) attached to holder base (20), *e.g.*, via a hinge. As shown in an exemplary embodiment in Figure 21B, a hinge may comprise a hinge body (27) attached to the holder base (20), with or without a spacer, and a hinge top (28) attached to the holder top assembly (21).

In some embodiments, a holder top assembly (21) comprises a handle configured to actuate engagement of the top assembly (21) to the base (20) of the enclosing holder. For example, in some embodiments, when the holder top assembly is positioned on the top of the holder base in preparation for engaging, rotation of a handle actuates engagement of mated engagement features on the holder top assembly and the holder base. For example, in some embodiments, the holder top assembly (21) and holder base (20) comprise mated engagement features, such as mated flange features (21b, 20a), *e.g.*, as shown in Figure 21D, which are engaged by placing the holder top assembly on the holder base and twisting the handle so as to lock the holder top assembly to the holder base in a manner similar to a bayonet-style lens mount. In preferred embodiments, the holder top assembly (21) and/or the holder base comprise a gasket (26) to seal the enclosing holder when the lid assembly (21) is closed upon

holder base (20), *e.g.*, as shown in Figures 21B and 21E. In certain embodiments, the holder top assembly comprises a top cover (23) comprising markings to show proper positioning of a rotatable handle for locking (and unlocking the closed holder, *e.g.*, as shown in Figure 21A, showing locked position (23a) and unlocked position (23b). In certain embodiments, holder top assembly (21) comprises a top (21a) comprising flange features (21b), wherein the top (21b) is rotated by twisting of handle (24), *e.g.*, to engage with mated flange features on holder base (2). In preferred embodiments, a top cover (23) does not rotate upon rotation of handle (24) and top (21b).

In certain embodiments, the top assembly (21) comprises a locking feature that prevents accidental opening of the enclosing container, *e.g.*, during agitation or transportation to and from an agitating device such as an homogenizer. In an embodiment shown in Figure 21B, handle (24) comprises a locating pin (29) that fits into a locating hole (33) in top cover (23) of lid assembly (21) when handle (24) is moved to lock the top assembly (21) in a closed position. In preferred embodiments, lid assembly (21) further comprises a releasing feature to disengage the locking feature. For example, in the embodiment shown in Figure 21A, handle (24) comprises a release button (25) that withdraws locating pin (29) from locating hole (33), thereby enabling the handle to rotate from the locked position (23a) into unlocked position (23b), said rotation also serving to disengage the mated flange features of the top assembly and the holder base. In some embodiments, a release button (25) is configured with a spring (34) to maintain the release button in an unreleased position until it is actuated or pressed. A release button is not limited to any particular configuration or size. In certain preferred embodiments, the release button covers a substantial portion the top of handle (24), *e.g.*, so that it is readily actuatable by gripping handle (24), and so it is not actuated by pressure from below the handle, as might occur, *e.g.*, when a locked enclosing container is lifted via the handle (24), *e.g.*, for removal from an homogenizer/shaker device, or for transport.

In some embodiments, an enclosing holder comprises a lid-engaging feature (31) configured to engage with lid (2) of a sealed container within the enclosing holder. For example, in some embodiments, the interior of the holder top assembly (21) comprises lid engaging features (31) that engage crossed gripping features (4a) on lid (2), as exemplified in the container shown in Figure 1. In preferred embodiments, the combination of the lid engaging features (31) and the sample adaptor (32) are configured to restrict or prevent any movement, *e.g.*, rotation, of lid (2) relative to bucket (1) of the sealed container when the sealed container is secured inside a closed enclosing holder. In some embodiments, the

process of securing the top assembly of the enclosing holder to the base of the enclosing holder, *e.g.*, by turning a handle into a closed and locked position, applies a rotational pressure on lid (2) relative to bucket (1) such that lid (2) is further tightened onto the bucket (1).

In some embodiments, an enclosing holder comprises a port or valve for altering the gas contents of a closed enclosing holder. For example, in some embodiments, it is useful to create a negative pressure within the holder as a means of preventing out-flow of contents in the event of a leak, while in other embodiments, it is useful to vent pressure, *e.g.*, pressure arising from an increase in temperature within the sealed enclosing holder. In some embodiments, it may be useful to introduce a particular gas, *e.g.*, an inert gas such as nitrogen, into the vessel. To facilitate the movement of gases into or out of sealed enclosing holder without opening the vessel, in certain preferred embodiments, the enclosing holder comprises a suitable valve, *e.g.*, a Schrader valve (36), for adding or removing gas (*e.g.*, air, nitrogen) from the enclosing holder when the enclosing holder is in a closed, *e.g.*, locked, configuration.

In some embodiments, an enclosing holder is configured to apply pressure to the bottom and/or the top of the sealed container, *e.g.*, to limit any motion of the sealed container within the enclosing holder, and/or to support or reinforce the seal between the bucket (1) and lid (2) within the enclosing holder. For example, in some embodiments, a sample adaptor within the base of an enclosing holder, *e.g.*, sample adaptor (32) in holder base (20) as shown in the embodiment in Figure 21B, is mounted on compression springs (35) that maintain a compressive pressure upon the sealed container that is within a closed enclosing holder. In preferred embodiments, the enclosing holder provides pressure in alignment with a central axis of the sealed container, so as to press lid (2) toward bucket (1), and vice versa.

In some embodiments, the enclosing holder is provided with one or more gripping features, to facilitate handling and manipulating the holder, *e.g.*, to facilitate the processes of locking and unlocking the holder. For example, in some embodiments, the enclosing holder comprises a grippable side handle (30), *e.g.*, as shown in Figure 21A.

The enclosing holder is preferably constructed of unbreakable material, selected to withstand vigorous shaking, rotation, or other agitation used, *e.g.*, in homogenizing a sample in a sealed sample container. For example, in preferred embodiments, the holder base (20) comprises or is composed of metal, *e.g.*, stainless steel, aluminum, titanium, while in other embodiments, the base comprises or is composed of plastic. In particularly preferred embodiments, holder base (20) and/or top (21a) are composed of stainless steel. Side handle

(30) and hinge parts (27,28) may be composed of the same materials as each other and as the holder base, or different materials. In preferred embodiments, the side handle (30) and hinge parts (27,28) are all metal, and in particularly preferred embodiments, they all comprise or are composed of aluminum.

The holder top assembly (21) may comprise metal, plastic, rubber, silicone and/or other suitable materials. In certain preferred embodiments, the holder top assembly (21) comprises a top cover (23), handle (24), and/or the release button (25) comprise or are composed of polyoxymethylene, *e.g.*, DELRIN®. The holder top assembly (21) preferably comprises a silicon gasket and locating pin of metal, *e.g.*, stainless steel. Top (21a) having flange features (21b), *e.g.*, as shown in Figure 21D, is preferably metal, and particularly preferably stainless steel.

Holder top assembly (21) further comprises one or more lid-engaging features and a means for holding a gasket. In some embodiments, the holder top assembly is provided with a gasket holder (22) that also comprises lid engagement feature(s) (31), as shown in Figure 21E. In certain preferred embodiments, gasket holder (22) comprises or is composed of DELRIN® plastic.

The technology finds use in kits comprising embodiments of the devices described and, in some embodiments, optional components such as, *e.g.*, an instruction for use (*e.g.*, providing the steps of a related method) and any related packaging for storage, shipping, and the like. Embodiments of the kits may comprise one or more solutions, *e.g.*, comprising a stabilizing reagent, a buffer, a salt, or a preservative for using with (*e.g.*, for treating, homogenizing, preserving, or storing) the collected specimen and the analytes it contains. Kits may also comprise other components useful for depositing a stool sample, such as a bracket or other device or hardware for mounting the bucket on or in a commode or toilet, or a separate device for conveniently securing a stool sample from subject (*e.g.*, a paper or plastic bowl; a bag or other receptacle to fit to a commode or toilet), such that the sample may be collected, *e.g.*, during use of a commode, and transferred to the device of the present invention. In some embodiments, a stool sample may be transferred to the device from an initial receptacle, while in some embodiments, the initial receptacle may be placed within a container of the present invention, along with the stool sample.

In yet other embodiments, a kit may comprise components related to sample processing such as sampling devices, homogenizers and/or components for testing the sample, such as analysis reagents and/or detection reagents, *etc.*

Technology herein provides an enclosing holder that is directed toward both 1) reinforcing the integrity of the seal of a sample container during shaking, and 2) containing any sample leaking from the container such that, in the event of a leak, the mechanical shaker remains clean and usable, and contamination is contained within an article (the enclosing holder) that may be easily replaced with a clean enclosing holder, minimizing the effect of a leakage event on laboratory work-flow. Further, the contaminated enclosing holder is readily cleanable for future use.

An exemplary embodiment of an enclosing holder for an ergonomic stool collection device of Example 1 is shown in Figures 21A-E. Figure 21A shows a holder base (20) having side handle (30). The holder top assembly (21) comprises a top cover (23) with markings showing the locked position (23a) and unlocked position (23b) for handle (24). Handle (24) comprises a release button (25) that disengages locating pin (29) from locating hole (33) in top cover (23) of the top assembly. The holder top assembly further comprises holder top (21a) that engages holder base (20).

Figure 21B shows the embodiment in cross-section, showing an internal sample adaptor (32) configured to receive the ridges on the exterior of the ergonomic stool collection device of Example 1, and compression springs (35) in the holder base (20) configured to provide compressive pressure on the collection device when enclosed within the enclosing holder. Lid-engaging features (31) on the inside surface of gasket holder (22) of the holder top assembly (21) are configured to engage the cross-shaped handle gripping feature on the lid of the Example 1 container. Gasket (26) is shown positioned between the top edge of holder base (20) and the gasket holder (22) of holder top assembly (21).

Figure 21C shows an oblique bottom view of an enclosing holder. Figure 21D shows an enclosing holder with the top assembly (21) in an open position with respect to holder base (20), and with an ergonomic container device as shown in Figure 1 positioned within the base. Lid engaging features (31) on gasket holder (22) are position to engage the crossed gripping feature (4a) on lid (2) of the ergonomic device. Flanged features (20a) are shown distributed around the top of holder base (20), and are configured to engage corresponding mated features (21b) on top (21a) in holder top assembly (21). Figure 21E shows an oblique cross-sectional view of the enclosing holder having an ergonomic container device of Example 1 positioned in it.

Although the disclosure herein refers to certain illustrated embodiments, it is to be understood that these embodiments are presented by way of example and not by way of limitation. All publications and patents mentioned in the above specification are herein

vertical surface of said bucket to form a circumferential seal with said circumferential vertical surface when said first threaded engagement portion of said bucket and said mated threaded engagement portion of said lid are engaged with each other.

6. The ergonomic device of claim 1, wherein manipulation to engage said first threaded engagement portion of said bucket with said mated threaded engagement portion of said lid requires rotation of said lid around said lid central axis and with respect to said bucket no more than 180 degrees, preferably no more than 90 degrees.

7. The ergonomic device according to any one of claims 1-6, further comprising a stool sample disposed in said bucket, wherein said first engagement portion of said bucket and said mated engagement portion of said lid are engaged to form a sealed container containing said stool sample.

8. The ergonomic device of claim 7, wherein said sealed container further contains a buffer solution, preferably a buffer solution comprising a salt and/or a preservative or a stabilizing agent.

9. The ergonomic device according to any one of claims 1-8, wherein said ergonomic device is enclosed within an enclosing holder comprising:

a) a holder base comprising an interior cavity having a bottom surface and a top opening, said holder base comprising a first engagement feature;

b) a holder top comprising a mated engagement feature adapted to removeably engage with said first engagement feature of said enclosing base to form a leak-proof seal, and further comprising a lid engaging feature;

c) a sample adapter fitted to said gripping feature on said bucket; and

d) a compression feature,

wherein said sample adapter and said compression feature are configured to limit or prohibit rotation around a central axis of said ergonomic device enclosed in the enclosing holder with respect to said enclosing holder,

wherein said sample adapter and said lid engaging feature restrict or prevent rotation of lid with respect to bucket of said ergonomic device enclosed in the enclosing holder, and

wherein said enclosing holder is configured for use in a mechanical shaker.

10. A kit comprising the ergonomic device according to any one of claims 1-6 and further comprising one or more components selected from the group consisting of an instruction for use; storage, shipping, or protective packaging configured to enclose said ergonomic device; a buffer solution; a stool sampling device; and a bracket for mounting said bucket on or under a toilet seat.

11. The kit of claim 10, wherein said buffer solution comprises a salt and a preservative or stabilizing agent.

12. The kit of claim 11, wherein said stabilizing agent comprises a nucleic acid stabilizing agent.