The technology further contemplates compositions comprising a sealed container, *e.g.*, an ergonomic device as described above, the composition comprising a stool sample produced by the method described above, wherein the sealed container comprising the stool sample is enclosed in an enclosing holder according the technology, wherein the first engagement feature of the holder base is engaged with the mated engagement feature of the holder top. The technology further contemplates a mechanical shaker containing the composition.

In an aspect, there is provided an ergonomic device for collecting and containing a stool specimen, the device comprising: a) a bucket having an internal volume of at least 300 mL, comprising: i) a top edge defining a top surface; ii) an interior side defining an interior circumferential vertical surface, and a plurality of sample disruption ridges on said interior circumferential vertical surface distributed radially with respect to a bucket central axis; iii) an exterior comprising an exterior circumferential vertical surface and a gripping feature comprising a plurality of vertical gripping ridges on the exterior circumferential vertical surface distributed radially with respect to said bucket central axis; and iv) a first threaded engagement portion; b) a lid comprising: i) an exterior top surface comprising a gripping feature; ii) an interior top surface; iii)a mated threaded engagement portion adapted to removeably engage with said first threaded engagement portion of said bucket; and iv) a lid central axis; and c) a seal disposed within said lid and covering the interior top surface of said lid and configured to contact the entire top surface of bucket to seal a junction between said bucket and said lid when said first threaded engagement portion of said bucket and said mated threaded engagement portion of said lid are engaged with each other, said seal comprising a floating plate comprising an upper horizontal surface comprising at least one raised feature, and a bottom horizontal surface, wherein when threads of said first threaded engagement feature of said bucket and of said mated threaded engagement feature of said lid are engaged with each other, said bucket central axis and said lid central axis are collinear; wherein said seal is configured to travel independently of said bucket and said lid during engagement or disengagement of said first threaded engagement portion and said mated threaded engagement portion, and wherein, when said first threaded engagement portion of said bucket and said mated threaded engagement portion of said lid are engaged with each other, said upper horizontal surface of said seal is disposed toward said interior top surface of said lid and said raised feature of the upper horizontal surface of the floating plate contacts said interior top surface of said lid, and said bottom horizontal surface of said floating plate is

disposed toward said interior of said bucket, and is essentially perpendicular to said interior circumferential vertical surface of said bucket.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features, aspects, and advantages of the present technology will become better understood with regard to the following drawings:

Figure 1 is a drawing of an embodiment of a stool specimen container, a bucket (1) having a flange (1b), gripping features (4), and a lid (2) having a central crossed gripping feature and edge gripping features.

Figure 2A is a cross-sectional side view of an embodiment of a stool specimen container showing a lid (2), seal (3) with a vertical component (3b) and bucket (1). Figure 2B is a perspective top view of an embodiment of a floating plate seal (3) having raised features (3a) and a vertical component 3(b).

Figure 3 is a drawing of an embodiment of a lid (2) and a floating plate seal (3) and an engagement portion (5).

Figure 4 is a perspective exterior view of an embodiment of a bucket (1) showing a flange (1b), gripping features (4), and an engagement portion that is a threaded portion (7).

Figure 5 is a perspective interior view of an embodiment of a bucket (1) showing a top surface (1a), gripping features (4) and an engagement portion that is a threaded portion (7). The interior of the bucket shows radially disposed ridges providing sample disruption features (1c).

Figure 6 is a drawing showing three embodiments of lids (2) having different top and edge gripping features. Figures 6A and 6C show different embodiments of crossed gripping features (4a), combined with edge gripping features (4b). Figure 6B shows a handle gripping feature.

Figure 7 is a drawing of an embodiment of a bucket (1) having a threaded engagement portion (7) and a lid (2) having a mated threaded portion (8).

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 16A-16E 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 17A shows an embodiment comprising a pop-over plate (14), configured to expand seal (3) when lid (2) is engaged with bucket (1).

Figure 17B shows an embodiment wherein the seal (3) is an expandable seal, configured to expand outward when lid (2) is engaged with bucket (1).

Figure 18 is a cross-sectional view of a separate gasket (13).

Figures 19A-19B show cross-sectional views of an embodiment of an alignment ring (15) and a bucket comprising guide ribs (16).

Figures 19C-19D show cross-sectional views of an embodiment of an a support ring (17).

Figures 20A-20B show cross-sectional views of an embodiment of a skirt (18) on lid (2).

Figure 21 is a cross-sectional detail view of a portion of a bucket (1), showing a funnel portion (19) on bucket (1).

Figures 22A-22E 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,

As used herein, the term "central axis," as used in reference to a container or ergonomic device, refers to an axis about which the container device has rotational symmetry. For example, in ergonomic devices depicted in Figures 1, 6A-6C, and 7-10, the central axis is defined by the line between the point at the center of the bottom of the bucket and the point at the center of the lid, when the lid is engaged with the bucket.

The term "geriatric" as used in reference to a subject or patient or a user of a device, refers to an aged or elderly person, *e.g.*, a person over about 65 years of age. There is no defined age for "geriatric" thus in some instances it may be *e.g.* a person over about 50 years of age.

DETAILED DESCRIPTION OF THE INVENTION

Embodiments of the invention are described in this Detailed Description of the Invention, and in the Summary above, which is incorporated here by reference. Although the invention has been described in connection with specific embodiments, it should be understood that the invention as claimed should not be unduly limited to such specific embodiments. Those skilled in the art who review this disclosure will readily appreciate that many modifications are possible (*e.g.,* variations in sizes, dimensions, structures, shapes and proportions of the various elements, values of parameters, mounting arrangements, use of materials, orientations, *etc.*) without materially departing from the novel teachings and advantages of the subject matter of the technology. Accordingly, all such modifications are intended to be included within the scope of the present invention as defined in the appended claims.

Provided herein is technology relating to collecting samples and particularly, but not exclusively, to technology for collecting, a stool specimen. As discussed above, a particular challenge when subjects or patients collect stool samples, *e.g.*, in the home, is the need for a collection container that is 1) sufficiently easy to manipulate that the container can be reliably and securely closed and sealed by subjects who may have conditions and/or disabilities that make manipulating containers difficult, *e.g.*, arthritis, muscle weakness, carpal tunnel syndrome, epicondylitis, vision impairment, *etc.*, but that, when closed, is sealed with a sufficiently reliable seal that there is little or no chance of leakage during transport and/or downstream processing, *e.g.*, shaking homogenization.

Provided herein is technology for acquisition of a stool specimen by a subject providing the stool specimen, the technology having features directed to ensuring proper sealing, even when used by subjects having disabilities such as are discussed above, such that

EXAMPLE 1

As discussed above, technology herein is directed to overcoming the challenge of providing a collection container that can be reliably used and sealed by any subject in a diverse population of subjects, including subjects having conditions that may severely compromise their ability to align and/or to firmly close a container, *e.g.*, geriatric patients. For containers that are to be transported, *e.g.*, from a subject's home to a laboratory, using standard commercial shipping methods, it is especially important for the subject to achieve a leak-resistant seal on the container without the need for special tools or assistance. As discussed above, technology herein provides an ergonomic collection device that can be securely closed using minimum force.

According to an exemplary embodiment of an ergonomic device of the present invention, the bucket (1) has a wide opening for receiving a stool sample. In the embodiment, the bucket is wider than it is tall, having a height of 4.75" and an outer diameter of 5.5" exclusive of the flange, (6.11" at the edge of the flange). The volume of the bucket is approximately 1400 mL (1.4L).

The bucket features a series of eight gripping ridges disposed around the circumference, starting about 1.13" below a flange and extending to the base of the bucket. The sides of the bucket (at the outermost dimensions that exclude the threads and flange) are essentially straight and slightly off of parallel, with the base outer diameter being slightly smaller than the outer diameter at the top edge (5.09" vs. 5.5").

The interior of the bucket has a series of protruding ridges that correspond to the grooves on the outside of the bucket (such as are shown in Figure 5). Also as shown in Figure 5, the interior side of the bucket comprises a smooth circumferential vertical surface immediately below the top edge.

The lid has a cross-shaped handle gripping feature on its top, with four arms at right angles to each other and extending from a central circular hub to the edge of the lid. The height of the gripping feature from the surface of the lid is approximately 0.6" at the hub, with each arm tapering slightly downward in height toward the edge of the lid. The lid further comprises arrows and markings indicating the direction the lid is to be turned to engage or disengage the lid from the bucket. The lid is 5.75" in diameter; 6.125" to edge of flange on its bottom edge. The lid is 0.85" high to top of body of the lid and 1.45" high to top of handle.

According to an exemplary embodiment, there is provided a floating plate seal for use with the lid and the bucket. The floating plate is 5.62" diameter to edge of plate and has a gasket seal of 5.393" diameter. The gasket seal has a "7" shape in cross-section, such that it can contact and seal against both the top edge and interior vertical surface of the bucket. The overall height of the floating plate with the gasket is approximately 0.5". The lid and the floating plate seal can be assembled into a lid assembly ready for use, with the floating plate inside the lid.

EXAMPLE 2

The technology further provides a system wherein a sealed ergonomic container received from a user is moved directly to a processing step, such as homogenization/dispersal of the sample through agitation of the container using a mechanical shaker. The forces applied to a collection container during a mixing process may be substantial, and may further increase risk of leakage from a poorly or improperly sealed collection vessel.

For standard mechanical shakers (*e.g.*, paint shakers, gyroscopic shakers, *etc.*) workers typically employ containers having particularly secure seals (*e.g.*, the friction seals on standard paint cans) that usually must be opened using a device (*e.g.*, a paint can opening tool, or a pry bar). Even containers having such strong friction seals typically must also be clamped to secure the seal during shaking.

In a clinical laboratory setting, it is highly desirable for a sample container to have a lid that requires neither tools nor particular physical strength to open after sample collection and/or processing. An easily removable lid, however, presents a greater risk of leakage, especially during mechanical shaking.

The leakage of even small amounts of a stool sample from a container during mixing is highly problematic. Leakage of medical samples not only poses a health and safety hazards to laboratory workers, it also increases risk of cross-contamination between patient samples, potentially compromising laboratory results.

Some mechanical shakers comprise enclosures, such as cabinets, that may limit the spread of sample that has leaked from a poorly sealed container during shaking. However, in the event of such leakage, the mechanical shaker and the cabinet interior are still contaminated, such that they cannot be used again until they have been thoroughly cleaned. Thus, even a small leak may take an entire shaker device off-line for an unacceptable length of time, disrupting work-flow.

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 22A-E. Figure 22A 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 22B 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 22C shows an oblique bottom view of an enclosing holder. Figure 22D 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 22E 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

CLAIMS

1. An ergonomic device for collecting and containing a stool specimen, the device comprising:

a) a bucket having an internal volume of at least 300 mL, comprising:

i) a top edge defining a top surface;

ii) an interior side defining an interior circumferential vertical surface, and a plurality of sample disruption ridges on said interior circumferential vertical surface distributed radially with respect to a bucket central axis;

iii) an exterior comprising an exterior circumferential vertical surface and a gripping feature comprising a plurality of vertical gripping ridges on the exterior circumferential vertical surface distributed radially with respect to said bucket central axis; and

iv) a first threaded engagement portion;

b) a lid comprising:

i) an exterior top surface comprising a gripping feature;

ii) an interior top surface

iii) a mated threaded engagement portion adapted to removeably engage with said first threaded engagement portion of said bucket; and

iv) a lid central axis;

and

c) a seal disposed within said lid and covering the interior top surface of said lid and configured to contact the entire top surface of bucket to seal a junction between said bucket and said lid when said first threaded engagement portion of said bucket and said mated threaded engagement portion of said lid are engaged with each other, said seal comprising a floating plate comprising an upper horizontal surface comprising at least one raised feature, and a bottom horizontal surface,

wherein when threads of said first threaded engagement feature of said bucket and of said mated threaded engagement feature of said lid are engaged with each other, said bucket central axis and said lid central axis are collinear;

wherein said seal is configured to travel independently of said bucket and said lid during engagement or disengagement of said first threaded engagement portion and said mated threaded engagement portion, and

wherein, when said first threaded engagement portion of said bucket and said mated threaded engagement portion of said lid are engaged with each other, said upper horizontal surface of said seal is disposed toward said interior top surface of said lid and said raised feature of the upper horizontal surface of the floating plate contacts said interior top surface of said lid, and said bottom horizontal surface of said floating plate is disposed toward said interior of said bucket, and is essentially perpendicular to said interior circumferential vertical surface of said bucket.

2. The ergonomic device of claim 1, wherein said bucket has an internal volume between about 300 ml and about 1400 ml.

3. The ergonomic device of claim 1, wherein said bottom horizontal surface of said floating plate comprises a compressible seating surface configured to contact said top surface of said bucket, wherein said compressible seating surface is compressed when said first threaded engagement portion of said bucket and said mated threaded engagement portion of said lid are engaged with each other.

4. The ergonomic device of claim 1, wherein said floating plate forms a seal between said lid and both said top surface and said circumferential vertical surface of said bucket when said first threaded engagement portion of said bucket and said mated threaded engagement portion of said lid are engaged with each other.

5. The ergonomic device of claim 1 or 4, wherein said bottom horizontal surface of said floating plate comprises a vertical component configured to contact the circumferential

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 a sealed 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 a sealed 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 10, wherein said stabilizing agent comprises a nucleic acid stabilizing agent.