Validated shipping of filled Labtainer Pro BioProcess Containers (BPCs)

Scope

Wet shipping tests are performed to ensure that Thermo Scientific[™] Labtainer[™] Pro BioProcess Containers (BPCs) maintain integrity, keeping contents contained and protected. During shipping, wave action within a fluid-filled BPC exerts stress on the film, which can lead to cyclic fatigue of the materials. A variety of shipping tests were conducted on the Labtainer Pro BPC product line, including vibration testing, compression testing, and drop testing. Following the completion of this testing, all chambers were integrity-tested for leaks.

Testing

The packaging and shipping of liquid-filled Labtainer Pro BPCs were tested per International Safe Transit Association (ISTA[™]) 2A and 3E standards. Four packaging configurations were developed and qualified to support the range of sizes for the Labtainer Pro BPCs (Tables 2–4).

All porting configurations are included in the liter chamber testing (2-, 3-, and 4-ports). All chambers were gamma-irradiated at 40–80 kGy, and filled to nominal volume with water.

Results

All configurations were tested for both the ISTA 2A standard (individually packaged product testing) and the ISTA 3E standard (palletized testing). The Labtainer Pro BPCs passed 13 different tests as detailed in Tables 6 and 7.



Table 1. Labtainer Pro BPC configurations used forshipping tests.

Cat. No.	BPC configuration	Film
PL30005.02	Labtainer Pro, 1,000 mL, 2-port	CX5-14
PL30020.02	Labtainer Pro, 1,000 mL, 3-port	Aegis5-14
PL30013.01	Labtainer Pro, 2 L, 4-port	CX5-14
PL30026.02	Labtainer Pro, 5 L, 4-port	Aegis5-14
PL30009.03	Labtainer Pro, 10 L, 2-port	CX5-14
PL30023.03	Labtainer Pro, 10 L, 3-port	Aegis5-14
PL30013.03	Labtainer Pro, 10 L, 4-port	CX5-14
PL30022.04	Labtainer Pro, 20 L, 2-port	Aegis5-14
PL30010.04	Labtainer Pro, 20 L, 3-port	CX5-14
PL30026.04	Labtainer Pro, 20 L, 4-port	Aegis5-14



Packing configurations-packaging and BPCs

Table 2. Shipping validation configuration for Labtainer Pro BPCs, 50–1,000 mL

1,000 mL tested, as this volume presents the most risk of damage during shipping.

Item No.	Details	Quantity
1	Polyethylene bag, 6 mil 30.48 x 45.72 cm (12 x 18 in.)	2
2	Corrugated cardboard outer box 39.37 x 25.4 x 8.26 cm (15.5 x 10 x 3.25 in.)	1
3	Polyurethane packing foam over and under BPC 39.37 x 25.4 x 2.54 cm (15.5 x 10 x 1 in.)	2
4	Labtainer Pro BPC, 1,000 mL, nominally filled with water, CX5-14 or Aegis5-14 film	1



Table 3. Shipping validation configuration for Labtainer Pro BPCs, 2 and 5 L.

Item No.	Details	Quantity
1	Polyethylene bag, 6 mil 30.48 x 45.72 cm (12 x 18 in.)	2
2	Corrugated cardboard outer box, 275 pound 55.88 x 35.56 x 10.16 cm (22 x 14 x 4 in.)	1
3	Polyurethane packaging foam over and under BPC 39.37 x 25.4 x 2.54 cm (15.5 x 10 x 1 in.)	2
4	Labtainer Pro BPC, 5 L, nominally filled with water, CX5-14 or Aegis5-14 film	1
5	Corrugated cardboard box insert 55.24 x 34.93 x 9.53 cm (21.75 x 13.75 x 3.75 in.)	1
6	Polyurethane packaging foam under lineset 39.37 x 25.4 x 2.54 cm (15.5 x 10 x 1 in.)	1



Table 4. Shipping validation configuration for Labtainer Pro BPC, 10 L.

Item No.	Details	Quantity
1	Corrugated cardboard outer box 86.36 x 46.99 x 13.97 cm (34 x 18.5 x 5.5 in.)	1
2	Corrugated cardboard box insert 76.84 x 46.36 x 13.34 cm (30.25 x 18.25 x 5.25 in.)	1
3	Labtainer Pro BPC, 10 L, nominally filled with water, CX5-14 or Aegis5-14 film	1
4	Polyurethane packaging foam under BPC 76.2 x 45.72 x 2.54 cm (30 x 18 x 1 in.)	1
5	Polyurethane packaging foam under lineset 45.72 x 30.48 x 2.54 cm (18 x 12 x 1 in.)	1
6	Polyurethane packaging foam over lineset 45.72 x 25.4 x 2.54 cm (18 x 10 x 1 in.)	2
7	Polyethylene bag, 6 mil 50.8 x 101.6 cm (20 x 40 in.)	2
8	Polyurethane packaging foam inside and on each end of box insert 45.72 cm x 30.48 cm x 2.54 cm (18 x 12 x 1 in., folded)	4



Table 5. Shipping validation configuration for Labtainer Pro BPC, 20 L.

Item No.	Details	Quantity
1	Corrugated cardboard outer box 86.36 x 46.99 x 13.97 cm (34 x 18.5 x 5.5 in.)	1
2	Corrugated cardboard box insert 76.84 x 46.36 x 13.34 cm (30.25 x 18.25 x 5.25 in.)	1
3	Labtainer Pro BPC, 20 L, nominally filled with water, CX5-14 or Aegis5-14 film	1
4	Polyurethane packaging foam under BPC 76.2 x 45.72 x 2.54 cm (30 x 18 x 1 in.)	1
5	Polyurethane packaging foam under lineset 45.72 x 30.48 x 2.54 cm (18 x 12 x 1 in.)	1
6	Polyurethane packaging foam over lineset 45.72 x 25.4 x 2.54 cm (18 x 10 x 1 in.)	3
7	Polyethylene bag, 6 mil 60.96 x 121.92 cm (24 x 48 in.)	2
8	Polyurethane packaging foam inside and on each end of box insert $45.72 \times 30.48 \times 2.54$ cm (18 x 12 x 1 in.)	4



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Results from Labtainer Pro BPC shipping tests

Table 6. Individually packaged product (per ISTA 2A standards).

Test No.	Test description	Quantity	Requirements	Status
1	Compression: mechanically apply and release pressure (calculated test force x 1.4); testing done on empty box only	Two of each box type	Box must resist minimum calculated force per ISTA 2A standards	Pass
2	Random vibration (2 hours): select random vibration profile per ISTA 2A standards	Use samples from test 1	ISTA 2A standards—box must remain integral; no tears 1 in. or larger or collapse of faces is acceptable; no liquid leak from BPC	Pass
3	Free-fall drops: box drop height was dependent upon packaged weight, per ISTA 2A standards; refer to standard regarding testing protocols	Use samples from test 2	ISTA 2A standards—box must remain integral; no large tears (1 in. or greater) or collapse of faces is acceptable	Pass
4	Random vibration (1 hour): select random vibration profile per ISTA 2A standards	Use samples from test 3	ISTA 2A standards—box must remain integral; no large tears (1 in. or greater) or collapse of faces is acceptable	Pass
5	Visual inspection: open each box and inspect outside of box, outer polybags, and BPC for any damage	Use samples from test 4	No liquid leak from BPC	Pass
6	Rotary vibration for 12 hours	Use samples from test 5	Open each box at 1 hour intervals, and examine for any leaks; if no leak present, continue rotary vibration for up to 12 hours	Pass
7	Pressure leak hold test—include pass/fail criteria	Use samples from test 6	Perform pressure decay test	Pass

Table 7. Palletized testing (per ISTA 3E standards).

Test No.	Test description	Quantity	Requirements	Status
8	Shock: incline impact of 1.1 m/sec	1 pallet of each chamber size	ISTA 3E standards—box must remain integral; no tears 1 in. or larger or collapse of faces is acceptable	Pass
9	Shock: rotational edge drop of 8 in.	User samples from test 8	ISTA 3E standards—box must remain integral; no tears 1 in. or larger or collapse of faces is acceptable	Pass
10	Compression: machine apply and release	Use samples from test 9	Box must meet minimum calculated force per ISTA 3E standards	Pass
11	Random vibration: random vibration profile from ISTA 3E, 4 hour profile	Use samples from test 10	ISTA 3E standards—box must remain integral; no tears 1 in. or larger or collapse of faces is acceptable	Pass
12	Visual inspection: inspect BPC, polybag, box, and tape for any damage	Use samples from test 11	No liquid leak from BPC	Pass
13	Pressure leak hold test	Use samples from test 12	Perform pressure decay test	Pass

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