

An evaluation of leakproof specimen container performance

Comparative studies with the Thermo Scientific Samco Clicktainer Specimen Containers

Authors

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Introduction

In the clinical environment, specimen containers are used to collect, transport, and store valuable patient samples for diagnostic and screening purposes. To meet the requirements of these tasks, the container must protect the sample from loss or contamination and the clinician from the hazards that may potentially be stored within. The following study compares the leakproof characteristics of the Thermo Scientific™ Samco™ Clicktainer™ Specimen Containers to three leading specimen container brands with similar features.

Methods and results

To investigate leakproof performance, the newly redesigned Samco Clicktainer Specimen Container was compared to several competitive products using three tests. The first test was a passive leak test performed in accordance with BS EN 14254 Annex D.2, which involves filling the container with a dye, placing the closed receptacle on a roller mixer for 2 minutes, and then inverting the receptacle in a water bath at 15°C to 25°C for 60 minutes. The second test investigated the performance of the products while under a vacuum of 95 kPa. Lastly, the third test evaluated the leakproof performance of the products when transported in a pneumatic tube transport system.

For the passive leak test, each tested specimen container ($n = 60$ for each product tested) was filled to its nominal volume with a fluorescein dye solution diluted in water.



The containers were then closed in accordance with their manufacturer's instructions to obtain a proper leakproof seal. For the Clicktainer Specimen Containers, the instructions for use specify the container should be tightened until the cap no longer clicks and the arrow on the cap goes past the lock symbol on the base to provide leakproof performance. Once closed, each of the containers were placed on a roller mixer for 2 minutes and then inverted, to ensure the closure was covered, into 100 ml of water at 15°C to 25°C for 60 minutes. Afterwards, the 100 ml water and containers were inspected with blue light for the presence of any fluorescein dye outside of the closed containers. After testing, each container was opened, rinsed and then re-tested, with each specimen container tested a total of 4 times. The results of the passive test for each product are provided in Table 1. The results indicate with 95% confidence that under these test conditions $\geq 95\%$ of the Clicktainer Specimen Containers will pass this leak test and remain leakproof. In comparison, the other leading brands demonstrated to be

less likely to pass this test with only $\geq 94\%$ Brand A and $\geq 89\%$ of Brand C passing this test. Brand B was not tested in this case.

To test the robustness of the leakproof performance while under vacuum, each of the products (n = 60 for each product) were subjected to a 95 kPa vacuum leak test. Tested samples were first filled to nominal volume with a solution of the surfactant Triton X-100 diluted in water containing red food colouring for improved visibility. Once filled, the containers were closed using the same procedure specified in the passive leak test. Each container was then placed on its side on a white blotting paper inside the vacuum chamber, where vacuum (95 kPa) was applied. After sustaining a vacuum of 95 kPa for 10 minutes, the vacuum was released and the white blotting paper was inspected for the presence of red food colouring, indicating the surfactant solution had leaked from the products. Each tested product was then opened, rinsed and then re-tested following the same procedure with each sample tested a total of 4 times. The result, provided in Table 1, confirmed (with 95% confidence) that $\geq 95\%$ the Samco Clicktainer Specimen Containers will be able to maintain a leakproof seal while subjected to 95 kPa of vacuum. However, the other brands are less capable of maintaining the leakproof seal when exposed to 95 kPa vacuum, with $\geq 94\%$ of Brand A, $\geq 92\%$ of Brand B, and $\geq 50\%$ Brand C being capable of passing the 95 kPa vacuum leak test.

To safely transport and track specimens, some healthcare facilities have deployed pneumatic tube transport systems to efficiently and securely move specimens from the collection site to the laboratory for testing. During this process, it is critical that the specimens remain secure and do not leak from their container. To validate the Clicktainer Specimen Containers and two of the leading brands for use in pneumatic tube transport systems, 60 samples of each of the sterile specimen containers were first filled to

their nominal volume with water. Once again following each manufacturer's instructions to ensure a proper leakproof seal, the products were closed. One at a time, each closed container was then sealed into a Ziploc® bag, placed into a standard 6" carrier (without padding to create a worst-case scenario), and then transported in a pneumatic tube transport system. The pneumatic tube transport system (Pevco) consisted of a sending station, a receiving station, 4 diverters and 15 bends, transporting samples a distance of over 400 feet. After transportation in the pneumatic tube transport system, the specimen containers were visually inspected for leaks by looking in the inside of the Ziploc® bag for any water that had leaked from the containers. The results, provided in Table 1, demonstrated with 95% confidence that under these test conditions $\geq 95\%$ of the sterile Samco Clicktainer Specimen Containers will be effective in maintaining a leakproof seal while being transported in a pneumatic transport system. In contrast, the results of the other leading brands tested indicated that only $\geq 77\%$ of Brand A and $\geq 71\%$ of Brand C products tested will be capable of remaining leakproof while being transported through the pneumatic tube transport system.

Conclusion

The ability of a specimen container to remain sealed without leaking during transportation and handling is important to the safety of those handling the container and its contents. The newly redesigned Samco Clicktainer Specimen Containers provide users improved audible, visual and tactile confirmation that a leak-tight seal has been achieved and as shown in this study, the design outperforms the leading competitive brands in passive leak testing, 95kPa performance, and when transported in pneumatic tube systems. In addition to leakproof performance, the Samco Clicktainer Specimen Containers also offer users quality that they can trust, are manufactured within an ISO13485 certified site, and every lot is tested in accordance with BS EN14254*.

*Harmonized European standard for IVD medical device leak testing.

Table 1. Leak performance for Samco Clicktainer Specimen Containers vs. leading brands

	Clicktainer	Brand A	Brand B	Brand C
Passive leak test	$\geq 95\%$	$\geq 94\%$	Not tested	$\geq 89\%$
95 kPa vacuum	$\geq 95\%$	$\geq 94\%$	$\geq 92\%$	$\geq 50\%$
Pneumatic transport system	$\geq 95\%$	$\geq 77\%$	Not tested	$\geq 71\%$

Samco Clicktainer Specimen Containers ordering information

Description	Closure color	Label type	Product configuration	Quantity (pk x pks per case)	Catalog number
120mL/53mm sterile					
120mL/53mm CLK SPC LBL OR CAP ST	Orange	Tabbed	Pre-assembled	75x4	120ORG53-1000
120mL/53mm CLK O/R N/LBL OR CAP ST	Orange	None	Peel pouch	1x100	120ORG53-4000
120mL/53mm CLK SPC LBL WT CAP ST	White	Tabbed	Pre-assembled	75x4	120WHT53-1000
120mL/53mm CLK MSU, NO FUNNEL, ST	White	Tabbed	Mid-stream kit	1x100	120WHT53-3000
120mL/53mm CLK O/R POUCH WT CAP ST	White	None	Peel pouch	1x100	120WHT53-4000
120mL/53mm non-sterile					
120mL/53mm CLK SPC LBL OR CAP NS	Orange	Tabbed	Pre-assembled	75x4	120ORG53-2000
120mL/53mm CLK SPC N/LBL WT CAP NS	White	None	Bagged separate	300x1	120WHT53-2000
90mL/53mm sterile					
90mL/53mm CLK SPC LBL OR CAP ST	Orange	Tabbed	Pre-assembled	100x4	90ORG53-1000
90mL/53mm CLK SPC LBL OR CAP ST DISP	Orange	Tabbed	Dispenser box	20x16	90ORG53-1001
90mL/53mm CLK SPC LBL WT CAP ST	White	Tabbed	Pre-assembled	100x3	90WHT53-1000
90mL/53mm CLK SPC TSLBL WT CAP ST	White	Label w/temp strip	Pre-assembled	100x3	90WHT53-1001
90mL/53mm CLK SPC TS WT CAP ST	White	Temp strip only	Pre-assembled	100x4	90WHT53-1002
90mL/53mm CLK SPC LBL GN CAP ST	Green	Tabbed	Pre-assembled	100x4	90GRN53-1000
90mL/53mm non-sterile					
90mL/53mm CLK SPC LBL WT CAP NS	White	Tabbed	Pre-assembled	75x4	90WHT53-2000
90mL/53mm CLK SPC TSLBL WT CAP NS	White	Label w/temp strip	Pre-assembled	300x1	90WHT53-2001
90mL/53mm CLK SPC N/LBL WT CAP NS	White	None	Bagged separate	300x1	90WHT53-2002
90mL/53mm CLK SPC N/LBL WT CAP NS	White	None	Pre-assembled	300x1	90WHT53-2003
90mL/53mm CLK SPC TS WT CAP NS	White	Temp strip only	Pre-assembled	100x4	90WHT53-2004
Non-sterile closures and containers					
53mm CLK CAP ORANGE NS	Orange	None	Bulk closures only	1500x1	CAPORG53-1000
53mm CAP WHITE NS	White	None	Bulk closures only	1500x1	CAPWHT53-1000
53mm CLK CAP GREEN NS	Green	None	Bulk closures only	1500x1	CAPGRN53-1000
120mL/53mm CLK SPC N/LBL NO CAP NS	120mL	None	Bulk container only	300x1	12000-5300
90mL/53mm CLK SPC N/LBL NO CAP NS	90mL	None	Bulk container only	300x1	9000-5300