Shipping capillary electrophoresis running buffer at ambient temperature reduces environmental impact and retains its quality and stability

Abstract

In order to minimize the adverse environmental impact of packaging and shipping products on ice, Life Technologies investigated the feasibility of shipping its capillary electrophoresis (CE) running buffers at ambient temperature. This report describes stability and performance testing on these buffers. Our results indicate that these buffers can withstand the rigors of ambient shipping without impact on performance. By shipping at ambient conditions, we can eliminate the environmental impact of shipping product in expanded polystyrene (EPS) loaded with frozen gel packs.

Introduction

Life Technologies has been systematically evaluating novel ways to minimize the environmental impact of shipping refrigerated and frozen products. One way to achieve this is to ship our products at temperatures consistent with their demonstrated stability.

The adverse environmental impact of shipping refrigerated products is tremendous. The annual carbon footprint to manufacture the expanded polystyrene (EPS) and convert it into coolers used to ship Life Technologies CE running buffers is approximately 40 metric tons (CO_2-equivalents). It takes more than 80 barrels of crude oil equivalents and 230 MW-hr of power annually to make these coolers. Additionally, 26,500 L of water are consumed in the manufacturing of the coolers.

An average of 18 pounds of gel packs are added to each cooler to ensure the product is delivered refrigerated to our customers, further increasing the mass and dimensions of each package. Factoring in the number of shipments, average distance traveled per package each year, and the fact that most packages are shipped via air, an additional 3,500 metric tons (CO_2-equivalents) of greenhouse gases are generated from the transport of the coolers. By combining the elimination of the coolers and reduction in carbon footprint attributed to transporting the added weight of the gel packs, we reduce the annual total carbon footprint from product delivery by over 3,500 metric tons.

By systematically evaluating the temperature tolerance of our products, we have found that many can be shipped at ambient conditions without any impact on performance or stability. This paper describes the testing performed to qualify the CE running buffers for ambient shipping. By eliminating the need for a cooler and refrigerant, products can be shipped in smaller boxes, improving the carrier's freight density (less fuel and lower emissions per box) while reducing consumption of raw materials to make the packaging. This enables Life Technologies to eliminate an annual total of nearly 9 metric tons (28,000 ft^3) of waste from our customers' landfills and incinerators and replace it with recyclable corrugated paper packaging.

This paper describes the results from functional and analytical tests conducted on CE running buffers exposed to established summer shipment simulation profiles. Based on scientific knowledge of the buffer composition and its stability at reduced temperatures, it was decided that simulated winter conditions would not need to be tested. We demonstrate that ambient shipping has no impact to product shelf-life or time on the instrument. This is a win for the planet (reducing wasteful resource consumption and total carbon footprint), and a win for our customers (minimizing packaging waste).

Materials and methods

Test article selection

Two CE running buffers were chosen as representative test products for this study (Table 1). Test products were chosen at random from existing product inventory. The ABC and CBC buffers for the 3500 Genetic Analyzers have the same composition as those tested here, albeit at a 1x concentration (see Results and discussion). All materials were tested in environmental chambers without tertiary (corrugated box) packaging to minimize insulation.

Table 1. CE running buffer test articles

Product	Cat. No.	Size
10x Running Buffer, for 3730 Series Genetic Analyzers	4335613	500 mL
10x Running Buffer, for 310, 3100, and 3130 Series Genetic Analyzers	402824	25 mL

Simulated shipping

To simulate temperatures potentially incurred during shipping, we based our study on summer ambient shipping models developed at Amgen Corporation (Cowland, 2007). These models were validated against 2,500 shipments between the latitudes of 59.9° north and 37.8° south.

We selected the Amgen model over the ISTA 7E Standard (2011) because it was more rigorous in temperature extremes and maintained a comparable mean kinetic temperature. The Amgen summer model provides for a 144-hour cycle. To increase the stringency of the model, we duplicated the cycle, exposing the product to at least 288 hours of summer shipping simulations (Figure 1).

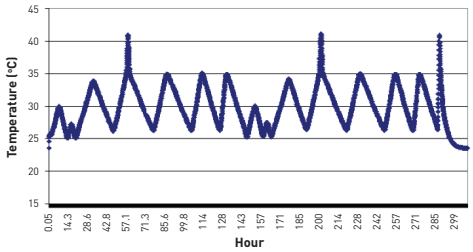


Figure 1. Actual profile for summer simulation.

Testing methodology

Controls were established as inventory product maintained at +4°C without ambient shipping simulation. Both test and control products were evaluated through functional and analytical testing.

Analytical evaluation: Per standard quality control protocol, pH and conductivity were measured. Comparisons were made both for product specifications and statistical deviation from control samples.

Functional evaluation: Single samples of controls and ambient shipped samples were functionally compared across four separate 3130xL Genetic Analyzers fitted with a 36 cm capillary array. For sequencing, we used Big Dye® Terminator V1.1 Cycle Sequencing Kit, a long read standard, and GeneScan™ 1200 LIZ® fragment sizing standard. For fragment analysis, we used the DS33 Installation Standard. For our blank injections, Hi-Di™ formamide samples were run with no-DNA standards. Several performance attributes including, but not limited to, Q20 read length as well as crossover resolution, migration times of the 500 bp peak, and time to failure for each instrument were compared.

Acceptance criteria

For all the products tested, the results must meet the specification or criteria as summarized in Table 2.

Statistical analysis

The analytical data was evaluated for equivalency from stressed and control samples, n=6.

Table 2. Acceptance criteria

Method	Acceptance criteria
pH	7.9–8.1 and no statistical difference from controls
Conductivity	1,500–1,800 µS/cm and no statistical difference from controls
Functional	Pass all QC specifications and no statistical difference from controls

Functional analysis data was compared across multiple instruments with control and sample sizes of n=4. Each data set was evaluated for equivalency by a Student's paired *t*-test with a two-tailed distribution using JMP statistical software (JMP 8.0, SAS Institute, Cary, NC) running in Microsoft Windows XP, Service Pack 3.

Results and discussion

Product integrity changes in test samples compared to controls were assessed through measurement of pH and conductivity as well as functional performance in CE.

There were no statistically significant differences in pH or conductivity between the stressed and control samples (Table 3 and Figures 2 and 3). This indicates that the inherent buffer composition and stability are not affected by ambient shipment.

Functionality was measured by comparing performance of the stressed and control samples against several basic attributes: crossover, Q20, and 500 migration time. Crossover is a measure of electrophoretic resolution, where the interval of peak separation is equivalent to the peak width. Q20 is a term representing DNA sequencing length, in which the number of bases in the read has a Phred quality score of at least 20. Finally, 500 migration time represents the migration time of a 500 bp DNA sample. This is a function of the electrophoretic mobility of the sample in the buffer and gel matrix within an applied electrical field.

Migration time would be altered if the buffer composition had changed in a way that impacted conductivity.

There were no statistically significant differences in functional performance between the stressed and control samples (Figure 4). This indicates that the inherent buffer composition is not affected by ambient shipment.

Previous tests on the 3500 series Genetic Analyzer anode and cathode buffers during product development support stability and performance with ambient shipping. A separate study was conducted on human identification products with the 3500 Series Genetic Analyzer (www.lifetechnologies.com/ambientbuffers).

Table 3. Analytical evaluation of CE running buffers (ambient-shipped vs. control)

Sample	Cat. No.	pH, average	pH, S.D.	Conductivity, average	Conductivity, S.D.
Control	402824	7.96	0.02	1,707.33	24.34
Ambient stress	402824	7.96	0.02	1,708.67	12.30
Control	4335613	7.98	0.01	1,683.00	13.7235
Ambient stress	4335613	7.98	0.14	1,682.17	9.89

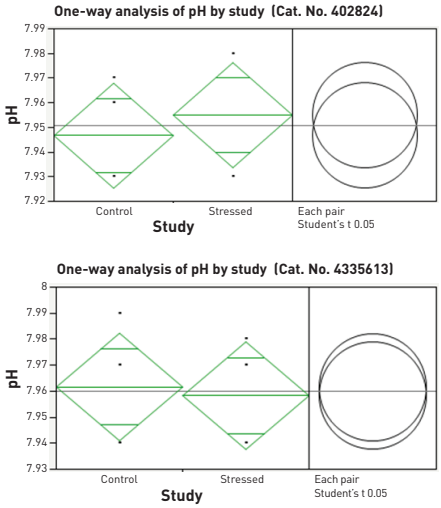


Figure 2. Statistical analysis of pH.

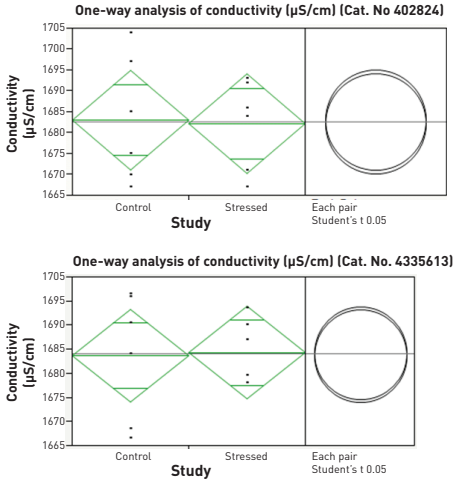
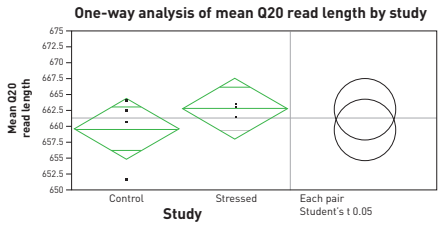
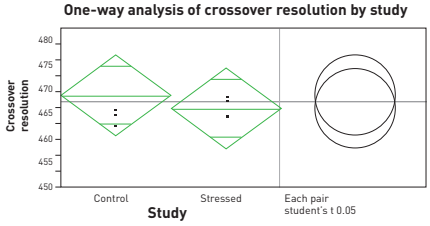
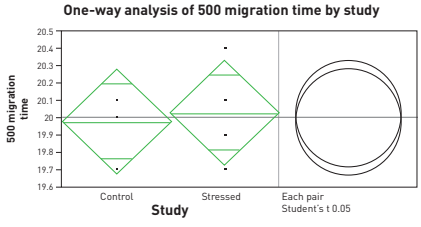


Figure 3. Statistical analysis of conductivity.

Criteria*	Control	Ambient stress	Statistical comparison
Mean Q20 read length	659.65	662.78	
Crossover resolution	468.73	466.05	
500 migration time	19.98	20.03	

*Mean time to failure for crossover and Q20 value were measured for all instruments. Each instrument reached a minimum of 240 runs without failure (data not shown).

Figure 4. Statistical analysis of performance.

Conclusions

The data described in this paper demonstrate that ambient shipping of our CE running buffers has no effect on their quality, integrity, or functional performance. The results of analytical and functional performance testing showed that the samples were not impacted when shipped under simulated summer ambient shipping for 288 hours. This work is substantiated by a previous internal study demonstrating product shelf-life and on-instrument stability after simulated ambient shipping (data not shown). Scientific knowledge of the chemical composition of these buffers precluded any need to validate stability under ambient winter shipping conditions.

For both of the 10x running buffers for the Genetic Analyzer series, analytical tests showed no statistical difference in the chemical nature of the buffers when subjected to simulated ambient shipping.

The data clearly show that it is not necessary to ship CE running buffer reagents in coolers with frozen gel packs. Because we can replace these packaging materials, we will be shipping these products in fully recyclable corrugated containers. However, when orders are placed with products that must be shipped refrigerated, we may place the CE running buffer into the cooler—this prevents having to ship a second container, avoiding additional material waste and greenhouse gas emissions.

References

1. Cowland R (2007) Developing ISTA cold chain environmental standards. *Dimensions*. 2007 Conference, Orlando, Florida (http://www.ista.org/forms/COWLAND_RAY_Dimensions07.pdf).
2. International Safe Transit Association (ISTA) (2011) 7E Standard: testing standard for thermal transport packaging used in parcel delivery system shipment (http://www.ista.org/forms/7Eoverview.pdf).