

Whitepaper (Human created & curated content)

How to Eliminate Hidden Cold Chain Costs- Lyophilizing Diagnostic Assays

The True Costs of Cold Chain Logistics Are Not What You Think

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INTRODUCTION

In a real-world analysis, lyophilization of diagnostic assays realized financial savings compared to cold chain logistics when Total Landed Costs are considered. This article will challenge your current thinking around molecular diagnostic assay cold chain logistics by considering Total Landed Costs (TLC), and the potential savings using lyophilization. Life sciences have, understandably, relied upon cold chain support for decades. However, molecular diagnostics has reached a tipping point that challenges the scalability of the cold chain standard. Cold chain's lack of scalability will inhibit the point-of-care testing (POCT) market from growing to its full potential. Pushing the existing cold chain model down from central laboratories into the many more diversified, lower complexity facilities will require immense growth. In the US alone, there are approximately 230K physician practices, compared to approximately 172K CLIA-certified high-complexity labs. This would result in more than doubling the entire existing cold chain capacity for laboratories.

Lyophilization technology has moved product stability in ambient conditions from a "nice to have" to a "must have" for the total cost, ease of use, and environmental factors. We will focus on the TLC cost comparison of "Going Ambient" vs. cold chain because, for many organizations, the total cost is the primary driver, ahead of environmental impact or ease of use. In performing the analysis, we will reveal the hidden costs of cold chain logistics.

BACKGROUND

But first, a little background. In 2017, I attended my first American Association of Clinical Chemistry Conference (AACC). I was impressed with progress in the area of molecular diagnostics. Most progress at the time was happening in immunodiagnostics. Many new molecular diagnostics companies were showing how they had monetized the vast amount of genomic data that was beginning to become available in the industry. It was exciting, and I also observed the number of people talking about point-of-care testing

diagnostics. My trip report centered on emerging POCT assays. In early 2018, Argonaut acquired Lyogen, a lyophilization company, and its founder, Mark Nowakowski, became the CTO of Argonaut Manufacturing Services. Mark has educated me, many colleagues, and clients about the inherent value of ambient stable molecular reagents using lyophilization. His research and discoveries (dating back to his 1983-85 Masters Degree research at the University of Southern California) have unlocked incredible potential for our industry in lyophilization and how it is fundamentally changing the reagent cold chain.

COST OF DIAGNOSTIC ASSAYS WITH COLD CHAIN VS. AMBIENT

Let's walk through an example comparing Total Landed Costs for cold chain vs. ambient, starting with the definition of **Total Landed Costs (TLC)**. TLC is the sum of:

- Total, delivery-ready, purchase price of the product
- Total transportation costs, including packaging and shipping

TLC is also referred to in some cases, as **total delivered costs** and captures the obvious and not-so-obvious costs that go into every shipment. The not-so-obvious costs are hidden in packing and shipping and are often overlooked. I will include packing and shipping for the test cases but exclude landed costs that have a negligible impact on TLC: Taxes, Duty, Insurance, Customs.

Test case:

I asked our Logistics team to calculate the following cases with these assumptions:

- Use a simulated shipment with 100 units of a molecular diagnostic assay that has 8 reactions in each kit.
- Use two of the largest carriers and their published rates as of May 31st, 2022. Assume no discounts on either carrier (the logic is that the client carrier discount will apply equally to both cases of cold chain and ambient conditions).
- Evaluate shipping from Carlsbad, CA, 92010 to the following four locations:

Case #1 Cold chain liquid reagent kit

- Purchase price of \$200
- The kit consists of 2 boxes:
 - Box A ships with gel packs (2°C-8°C) and a volume of 0.21 cu ft
 - Box B ships with a dry ice box (-20°C) and a volume of 0.21 cu ft

Case #2 Ambient stable kit with lyophilized reagents

- Purchase price of \$220 (yes, there are added costs to perform the lyophilization)
- The kit consists of 1 box:
 - Lyophilized version of the same kit that ships at ambient temperature with a volume of 0.35 cu ft

A few observations that skeptics may have at this point:

- Purchase price: The lyophilization process adds an up-front cost to the product, and this comparison will evaluate if the added value reduces the TLC and other contributions.
- Case #1 has two boxes: This is a popular design of reagent kits in the molecular diagnostic market. Due to the different storage conditions required by the various reagents, two (or more) boxes are required in a cold chain shipment.
- Case #2 uses only one box but is slightly larger to accommodate the entire kit: Kits that deploy lyophilization take up less volume and typically use only one box because everything is stored and shipped at ambient temperature.

Many kit configurations exist, but these examples are typical in our industry.

ESSENTIAL BACKGROUND

Before we get to the analysis, here are some facts that professionals may not be aware of when considering the hidden costs of cold chain logistics.

Most people don't realize that the colorful boxes on the bench arrived in an "over box" i.e., a brown crate box used to protect the final kit during the shipment. This is an extra box, that impacts both material and shipping costs.

- With cold chain shipments, an additional EPS foam cooler is used to protect the shipments' cold chain requirements. While some options are a little eco-friendlier, you still need the additional large box to maintain temperature conditions.
- In a 2°C-8°C degree shipment, preconditioned gel packs maintain the proper temperature throughout the shipment.
- Finally, in the -20°C degree shipment, dry ice is used– lots of dry ice. Beyond the environmental impacts of dry ice, the FAA considers dry ice a dangerous good and limits the number of dry ice shipments allowed on planes. As a result, dry ice shipments are prone to get bumped off flights. When dry ice melts, it converts to CO2. Not good for pilots, and dry ice shipments are some of the most expensive means of transport in the industry.

100 UNITS MOLECULAR DIAGNOSTIC ASSAY X 8 REACTIONS

Lyophilized Reagent Kits (Ambient Temp)			COLD-CHAIN REAGENT KITS			
PACKAGING DIMENSIONS & WEIGHT	DOMESTIC	INTERNATIONAL	DOMESTIC		INTERNATIONAL	
	Ambient temp. Load Capacity 2.474 ft ³	Ambient temp. Load Capacity 2.474 ft ³	+4C Load Capacity 1.088 ft ³	-20C Load Capacity 0.8466 ft ³	+4C Load Capacity 0.8906 ft ³	-20C Load Capacity 0.7257 ft ³
	7 Units @ 0.21ft ³ 8.5 lbs 15 XL Boxes	7 Units @ 0.21ft ³ 8.5 lbs 15 XL Boxes	5 Units @ 0.21ft ³ 17.5 lbs 20 XL Coolers	4 Units @ 0.21ft ³ 25 lbs 25 XL Coolers	4 Units @ 0.21ft ³ 29 lbs 25 XL Coolers	4 Units @ 0.21ft ³ 34.5 lbs 34 XL Coolers
TOTALS	15 XL Boxes (ambient) to support Domestic or International shipment of 100 units		45 XL Coolers to support a Domestic shipment of 100 units		59 XL Coolers to support an International shipment of 100 units	
Product Weight	100 lbs	100 lbs	100 lbs		100 lbs	
Shipping Materials	22 lbs	22 lbs	875 lbs		1,798 lbs	
Weights	122 lbs	122 lbs	975 lbs		1,898 lbs	

COST CALCULATION

To evaluate the TLC, let's start with shipping requirements for these two cases. To recall, we are shipping just 100 kits X 8 reactions. The price was \$200 for the cold chain kit and \$220 for the ambient lyophilized kit.

This reveals a few staggering hidden cold chain stats. To ship 100 cold chain kits vs. 100 lyophilized kits, you will use:

- 40x additional weight for shipping materials – Domestic
- >80x additional weight for shipping materials – International
- 45 XL Coolers vs. 15 XL standard boxes – Domestic
- 59 XL Coolers vs. 15 XL standard boxes – International

- Cambridge/Boston, MA
- South San Francisco, CA
- Raleigh, NC
- London, England

Total Landed Costs Explode

In many cases, the shipping costs are often embedded in the overall cost of doing business. However, the following data reveals the hidden cost of diagnostic assay cold chain logistics.

SHIPPING FROM CARLSBAD, CA TO:	SHIPPING RATES QUOTED FROM TWO PRIMARY CARRIERS	
	Lyophilized Reagent Kits	Cold Chain Reagent Kits
CAMBRIDGE, MA	\$1,289 ³	\$12,896 ¹
S. SAN FRANCISCO, CA	\$572 ³	\$11,494 ¹
RALEIGH, NY	\$1,289 ³	\$10,210 ¹
LONDON ENGLAND	\$5,563 ⁴	\$31,771 ²

¹ Carrier A priority Overnight

³ Carrier A Priority 3 Day EOB

² Carrier B World Wide Process

⁴Carrier B Expedite

Note that 3-day delivery is standard for lyophilized products, since the products are ambient stable and there is no need to rush shipments. Further savings are possible utilizing more flexible shipping times. Calculating the TLC for our four ship-to locations (lanes), reveals.

TOTAL COSTS (USD)		LANE 1 Carlsbad to Cambridge, MA	LANE 2 Carlsbad to S. San Francisco, SA	LANE 3 Carlsbad to Raleigh, NC	LANE 4 Carlsbad to London, UK
COLD-CHAIN SHIPMENT	Product Price	20,000	20,000	20,000	20,000
	Freight Cost	12,896	11,494	10,210	31,771
	TLC complete shipment	32,896	31,494	30,210	51,771
	TLC per kit	329	315	302	518
	TLC per reaction	41.12	39.37	37.76	61.71
LYOPHILIZED SHIPMENT	Product Price	22,000	22,000	22,000	22,000
	Freight Cost	5,685	3,843	5,685	7,724
	TLC complete shipment	27,685	25,843	27,685	29,724
	TLC per kit	277	258	277	297
	TLC per reaction	34.61	32.30	34.61	37.16
% SAVINGS USING LYOPHILIZED KITS		16%	18%	8%	43%

SUMMARY

In every case, lyophilization of a molecular diagnostic assay realized financial savings compared to cold chain logistics when Total Landed Costs are considered. Not surprisingly, savings using lyophilization may increase the more remote the shipping target. In our shipping examples, lyophilization revealed the hidden costs of cold chain logistics and in comparison, reduced costs by 8%-43%. While TLC may be a key factor for moving to ambient stable products, the other advantages of lyophilization, including reduced environmental impact, reduced storage cost (no refrigeration), ease of use, and reduced waste (due to longer product shelf-life) serve to make the decision even more advantageous.

Interested in learning more about [lyophilization](#)?

To find out if your products are a good match for our lyophilization technology, contact us at info@argonautms.com.