

WHITEPAPER



Optimization of Specimen Stability during Transit for Controlled Room Temperature Range

Challenges in Optimization of Specimen Stability

Temperature management is a major challenge for the logistics industry when transporting specimens for clinical research and diagnostic laboratories. A large percentage of specimens are shipped within a controlled room temperature range of +15°C to +25°C for delivery within 24 hours. Optimizing integrity and temperature stability of specimens during transportation is priority.

Too often, unanticipated problems occur. Late pick ups and deliveries, bad traffic, incorrect and difficult pack outs, and high expenses from expedited services transpire frequently during the transit process. Replacing the compromised specimen is time consuming and costly. Most importantly, the loss in diagnostic time could be critical to patient care.

Water-based Refrigerants vs. Phase Change Materials

The majority of ambient specimen shipping kits available on the market today use water-based, gel packs which often fail to maintain the required temperature range of



+15°C to +25°C for Winter and Summer profiles. In Winter, specimens are susceptible to cold shock while in Summer, the gel packs function only to slow rising temperatures inside the shipper and lack tight temperature control. In Controlled Room Temperature range, water can't go via phase change and as a result shipping system use sensible heat (low energy) instead of the latent heat of phase change (high energy). Therefore, the thermal mass of water-based shippers must be considerably increased to achieve and maintain required safe temperatures.

Water-based thermal shipping systems are highly inefficient due to their low payload/volume ratios compared to weight and dimensions.

Suggested Solution

AkuraTemp™ CRT Specimen Transport Kits offer reliable temperature control within a range of +15°C to +25°C in smaller shippers with simple pack-outs and digital temperature monitoring to ensure specimen integrity on arrival of its destination.

In addition it:

- Ships 'overnight standard,' cutting costs.
- Reduces use of packaging materials.
- Creates a reusable packaging system.

Cost Analysis

<u>One time use of generic CRT specimen shipper using gel packs:</u>	<u>Akuratemp™ ATS2 - 24 hr CRT specimen shipper:</u>
<p>2lbs - 11-5/8" x 7-3/4" x 4-1/2"</p> <ul style="list-style-type: none"> ● Material cost of one time use: \$10.00 ● Total weight: 2lbs ● FedEx First Overnight from NC to CA: \$113.00 ● FedEx cost per shipment: \$123.00 ● Cost over 50 shipments: \$6150.00 	<p>50 uses - 4Lbs - 8x4x12 box with an insulated envelope, two 200 BTU @ 72F/22C specimen holding plates and one temperature data logger</p> <ul style="list-style-type: none"> ● Material cost: \$105.00 ● Material cost per use (50 uses): \$2.10 ● Total weight: 4lbs ● FedEx Standard Overnight from NC to CA: \$80.00* ● FedEx Ground (return): \$13 ● Total cost per shipment: \$95.10 ● Cost over 50 shipments: \$4755.00

* FedEx list prices are estimates only. Shipping costs may differ and change.

ROI:

1. 4 cycles to achieve ROI.
2. Total 23% cost savings per shipment.
3. Total \$1370.00 savings within 50 cycles.
4. No cost of disposal.

Key Benefits:

1. Protects specimen vials from physical damage.
2. Tested 24 hr specimen stability while in transit for +15°C to +25°C range.
3. Reduces shipping cost by 25%.
4. Minimizes risk of packaging errors.
5. Eliminates packaging waste .
6. Minimizes cost per use.
7. Custom branding opportunities.

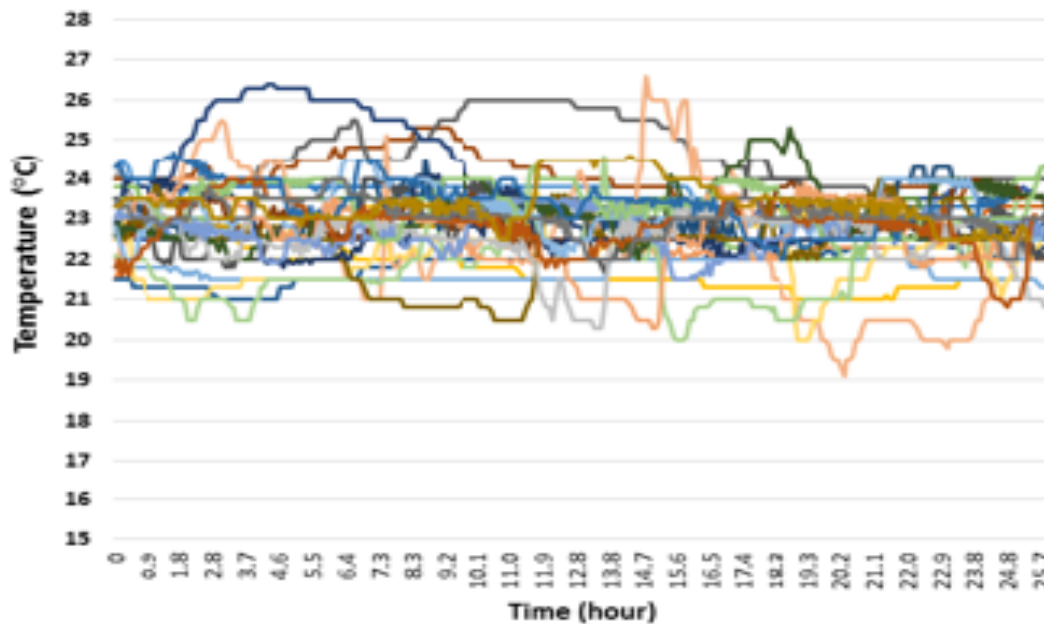
Field Trial Report

Peter Kuhn Laboratory | The Bridge Institute | USC Dornsife

Samples were shipped with FedEx priority overnight on collection day from clinical sites to the Kuhn Laboratory. Temperatures were recorded during the 24 hours prior to their arrival.

Summary of received samples recorded with Paksense labels:

- Total number of shipment events: 46
- Total number of temperature deviations (outside 14-27°C range) recorded: 4 due to incorrect storage at clinical sites or FedEx mishandling
- Total number of valid shipment events: 42
- Total number of deviations (outside range 14-27°C): 0
- Average temperature and SD: 22.4 ± 1.6 °C
- **Total of biospecimens usable upon arrival: 42/42 (100%)**



For more information on **Optimization of Specimen Stability in Transit for CRT range** please contact harshul@rgees.com or refer to www.rgees.com

About the Product



The akuraTemp™ ATS2 (CRT) Specimen Transport Kit is ideal for applications in clinical trials and for “direct-to-lab” deliveries. These are sized to fit into the “FedEx Clinical Paks” and the “FedEx UN3373 Paks.”

About the Author



Harshul Gupta is the CEO at RGEES LLC, a NC woman and minority owned business, specializing in the design and manufacturing of temperature controlled shipping systems for pharmaceutical, life science and biomedical products.