

Supplemental Materials

Supplemental Tables

Supplemental Table 1. Reproducibility and Precision of Temperature Monitors Used in Study. Reliability of probes used in this study was determined over 2 trial runs for 15 of 17 temperature monitors. Data based on equipment testing prior to initiation of preliminary shipping evaluation.

	Run 1 ^A		Run 2	
Temperature Monitors				
Number tested	3		12	
Testing period (in hours)	94.5		45.9	
Number of readings per monitor	2,836 (8,508 total)		1,378 (16,536 total)	
Time between readings (in min.)	2		2	
	Mean ±SD	Min, Max	Mean ±SD	Min, Max
Between-monitor Pearson, r^B	0.97±0.01	0.95, 0.98	0.93±0.05	0.82, 1.00
Max difference from mean (°C) ^C	0.49±0.32	0.00, 1.35	0.98±0.49	0.19, 2.13
Coefficient of Variation (%) ^D	3.20±2.22	0.00, 9.73	3.74±2.01	0.56, 8.87
^A Two temperature monitors had incomplete data and were not included. ^B Reproducibility statistic, defined as a measure of linear agreement across probes using the Pearson's correlation coefficient for between-monitor observations ^C Precision statistic, defined by comparing the maximum absolute difference of the mean value across all tested monitors at each observation time. ^D Calculated as standard deviation over the mean for each reading across all monitors used in a run				

Supplemental Table 2. Gel-Pack Temperature During Packing of Islet Shipping Containers. Instructions to ICR laboratories specified gel-packs to be warmed to room temperature. Temperatures >20.0 to 26.0°C met this criterion. Data based on preliminary shipping evaluation.

ICR Centers	Gel-Pack Temperature Range (°C) During Packing of Shipment ^A						Packed At ^B	
							≤20.0°C No. (%)	>20.0- 26.0°C No. (%)
	1	2	3	4	5	6		
1	18.4-20.5	20.5-21.3	14.6-19.5	6.9-19.4	18.8-19.2	18.4-18.9	5 (83%)	1 (17%)
2 ^C	15.5-17.5	ND ^D	17.7-18.3	15.7-17.0	14.0-16.1	18.9-19.6	5 (100%)	0 (0%)
3	22.4-26.3	24.5-26.6	18.7-18.7	19.9-21.2	15.5-16.8	21.6-22.8	2 (33%)	4 (67%)
4 ^C	10.6-11.6	ND ^D	10.4-23.6	18.7-20.9	18.0-19.3	19.0-22.7	3 (60%)	2 (40%)
5	22.1-23.9	21.5-22.4	22.7-23.4	21.9-22.2	22.8-24.6	22.8-23.0	0 (0%)	6 (100%)
6	24.6-24.9	20.2-23.8	19.0-19.5	25.5-25.8	21.7-22.2	22.6-23.1	1 (17%)	5 (83%)
7	21.9-22.9	21.7-21.9	20.1-20.9	21.6-22.0	19.9-20.9	16.9-18.9	1 (17%)	5 (83%)
8	20.1-20.6	21.7-22.8	20.9-22.6	20.9-21.9	20.9-22.4	20.6-21.4	0 (17%)	6 (100%)
Total	--	--	--	--	--	--	17 (37%)	29 (63%)

^A Packing period defined as the hour prior to Fed-Ex pickup.
^B Determined using median value when temperature range did not exclusively fall within either category.
^C Percentages based on 5 shipments.
^D No data (ND) obtained for 2 delayed shipments.

Supplemental Table 3. Two-Way Agreement Between Temperature Monitoring Methods. Assessment was performed from the time of Fed-Ex pickup to arrival at the data coordinating center in Duarte, CA. Data based on preliminary shipping evaluation

Disposable Temperature Indicator ^A	Reusable Temperature Data Logger ^B				
	≤15 °C reached	Between 15 to 29 °C	≥29 °C reached	No data	Total
≤15 °C reached	11	4	0	1	16
Between 15 to 29 °C	3	25	0	1	29
≥29 °C reached	0	0	0	0	0
No data	0	3	0	0	3
Total	14	32	0	2	48

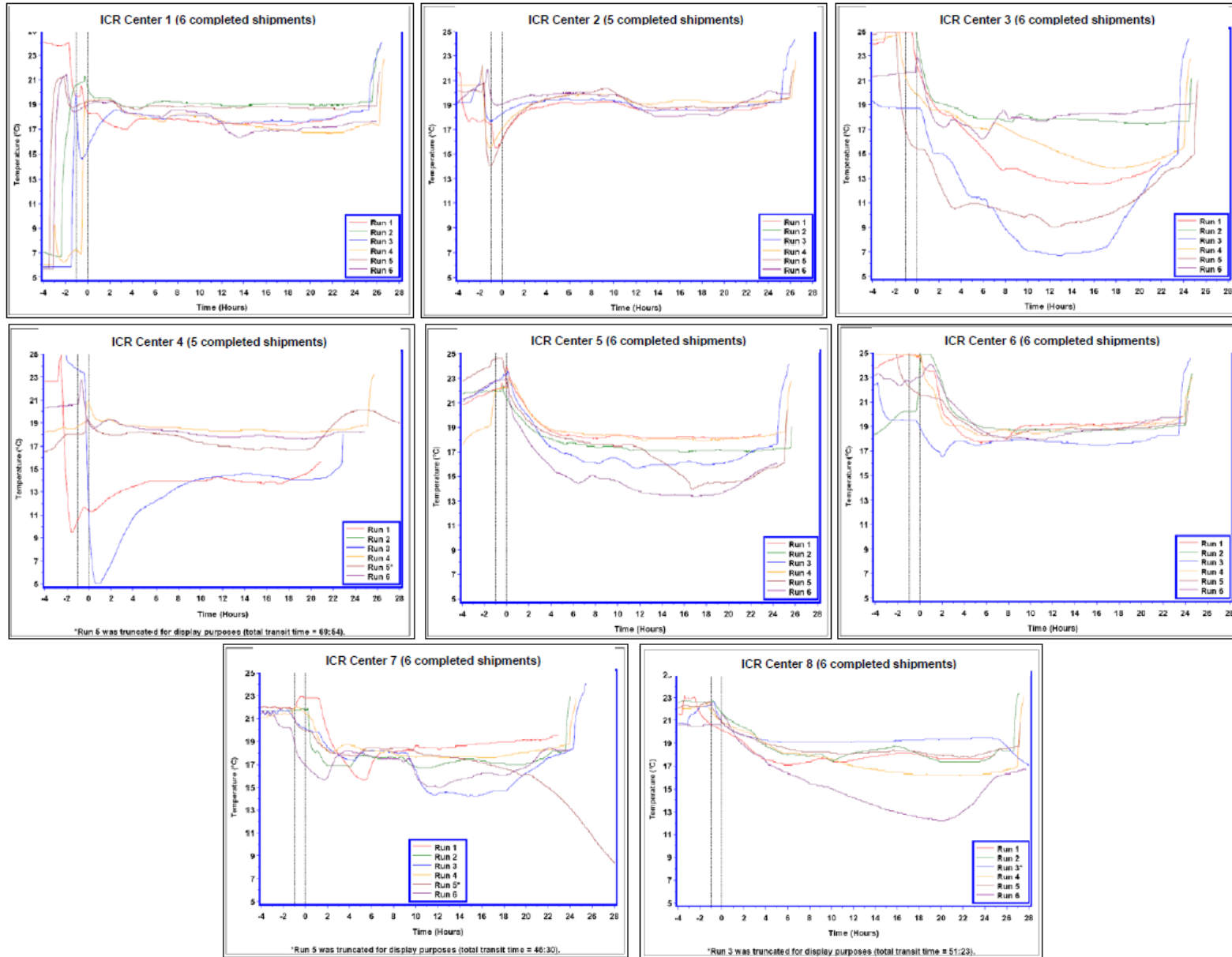
^ADisposable temperature indicators are cold activated at or below 15°C, not activated between 15-29°C, and warm activated at or greater than 29°C

^BCoding of continuous to categorical data for reusable temperature data logger was based on disposable indicator groupings. For values falling between 15-16°C, ≤ 15.50°C was rounded down to 15 and those >15.50°C were rounded up to 16.

Supplemental Table 4. Effects of Using Gel-Packs at Different Temperatures During Packing of Islet Containers. Shipping parameters were stratified by gel-pack temperature and analyzed. Data based on preliminary shipping evaluation.

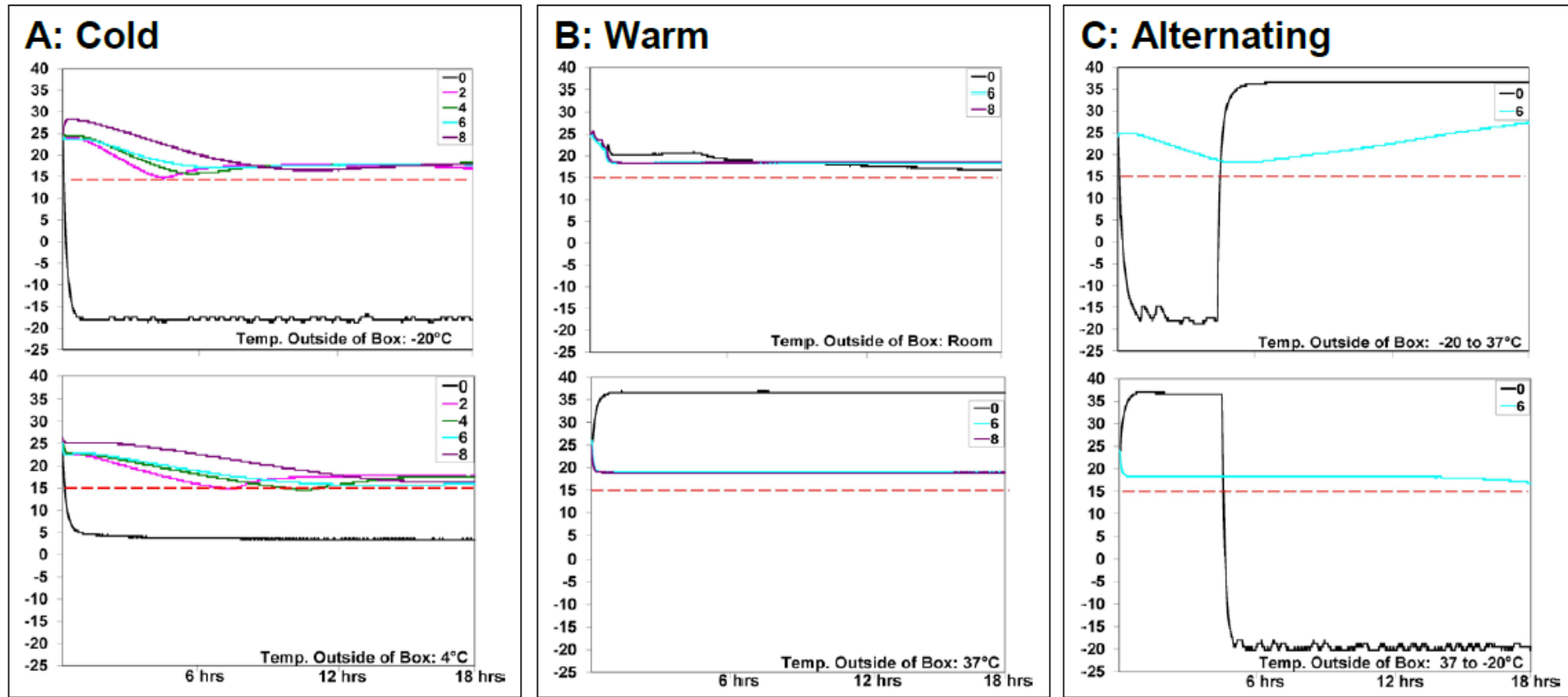
	No.	Mean	SD	Med	Min	Max	p-value ^A
Temperature within Container^B							
Lowest temp. reached (°C)							
if gel-packs >20-26 °C	29	15.6	3.4	17.0	4.7	18.7	0.311
if gel-packs ≤20 °C	17	14.5	3.9	15.7	6.7	18.6	
Highest temp. reached (°C)							
if gel-packs >20-26 °C	29	23.4	1.5	23.1	20.6	26.6	0.005
if gel-packs ≤20 °C	17	21.5	2.4	21.7	15.7	24.6	
Range of temp. change (°C)							
if gel-packs >20-26 °C	29	7.8	3.4	7.1	3.5	18.9	0.472
if gel-packs ≤20 °C	17	6.9	4.5	5.1	2.1	17.7	
Fastest change rate (°C/min)							
if gel-packs >20-26 °C	29	0.3	0.2	0.3	0.1	1.0	0.934
if gel-packs ≤20 °C	17	0.3	0.3	0.2	0.1	1.3	
^A Obtained using two-group t-tests							
^B Defined from time of Fed-Ex pickup to arrival at the data coordinating center in Duarte, CA.							

Supplemental Figures



Supplemental Figure 1. Temperature Profiles During Cross Country Shipments Using Standardized Islet Shipping

Containers. All shipments originated from geographically distinct laboratories and centrally delivered to the data coordinating center at City of Hope in Duarte, CA. First dotted line at -1 hour represents packaging begin time. Second dotted line at 0 hours signifies Fed-Ex pick up time.



Supplemental Figure 2. Optimization of Internal Temperature Control During Mock 18-Hour Islet Shipments. Standardized islet shipping containers were exposed to A) cold, B) warm, and C) alternating external temperatures for at least 18 hours. Number of ambient temperature stabilization gel packs inside the containers based on the temperature condition being tested. Red dashed line represents the target minimum threshold value of 15°C. Duration of time in hours (x-axis) and temperature in degrees C (y-axis) displayed.