

WPHL Transport Temperature Project



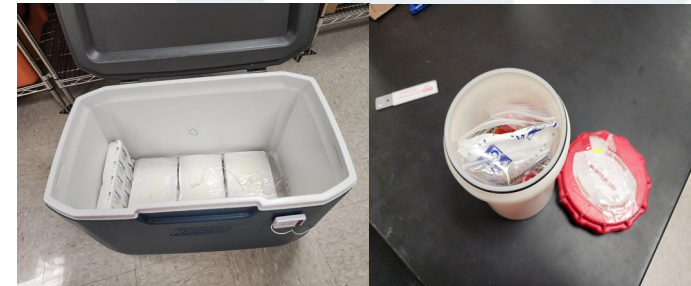
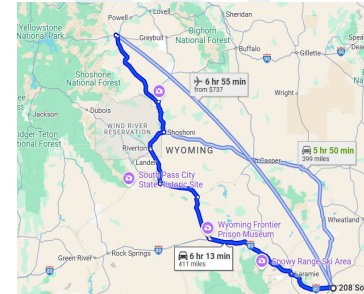
PUBLIC HEALTH
DIVISION



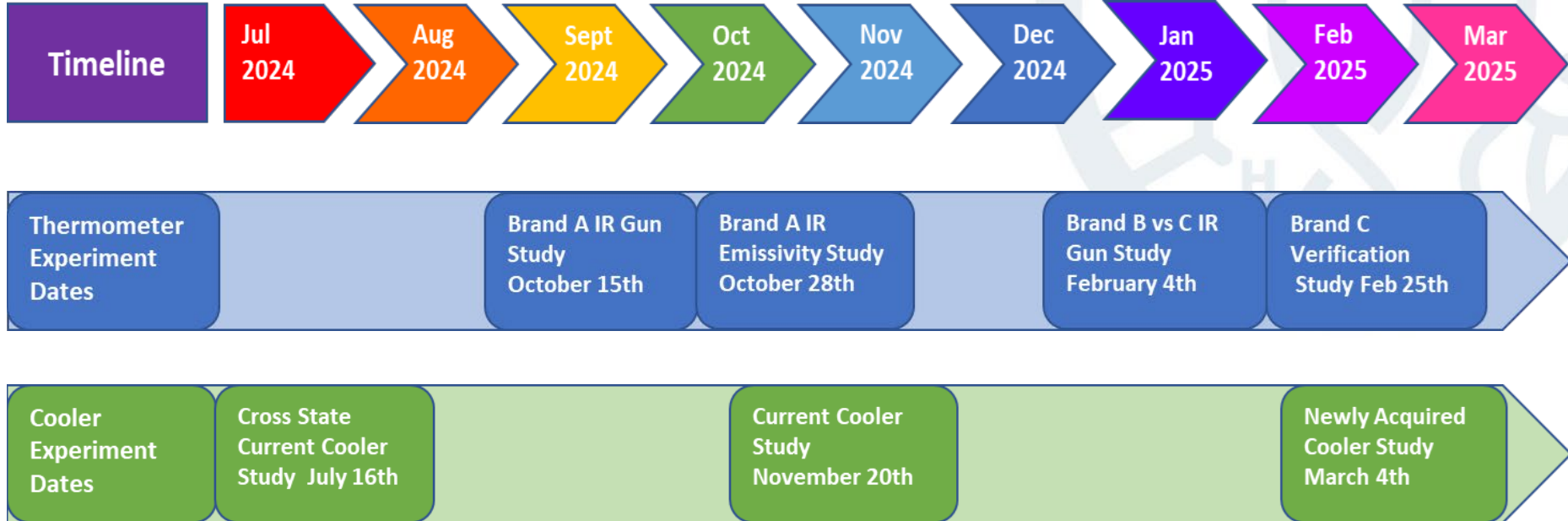
WYOMING PUBLIC
HEALTH LABORATORY

Overview

- WPHL identified the need for more accurate thermometers and improved coolers through multiple studies:
 - IR Thermometer Brand Performance Comparison
 - Brand C IR Thermometer Verification
 - Current Cooler Study
 - Newly Acquired Cooler Study
- WPHL developed the Sample Submission Guide, a resource outlining submission criteria for submitters.



WPHL Temperature Management Experiment Timeline



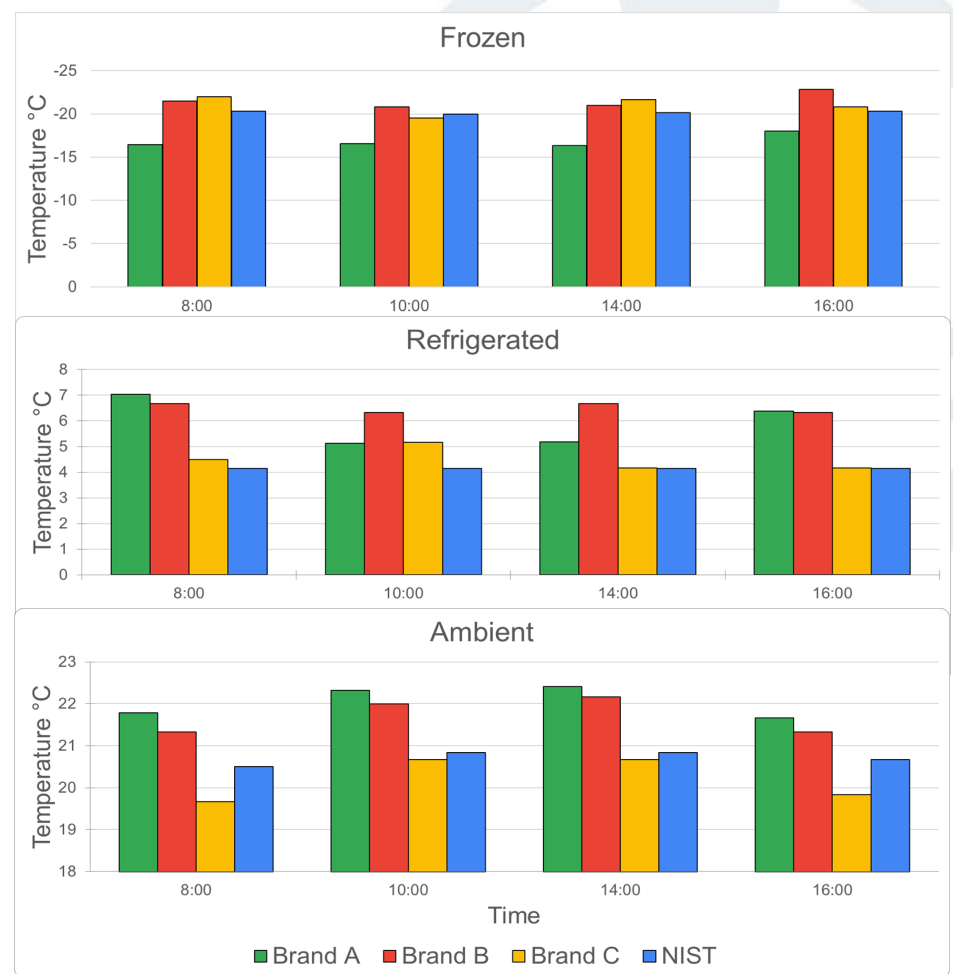
Thermometer Experiment

- **Purpose:**
 - Identify the most accurate IR thermometer for sample temperature measurement.
 - Procure selected units for operational use.
 - Verify consistency across all purchased devices.
- **Studies Performed:**
 - IR Thermometer Brand Performance Comparison Study
 - Brand C IR Thermometer Verification Study



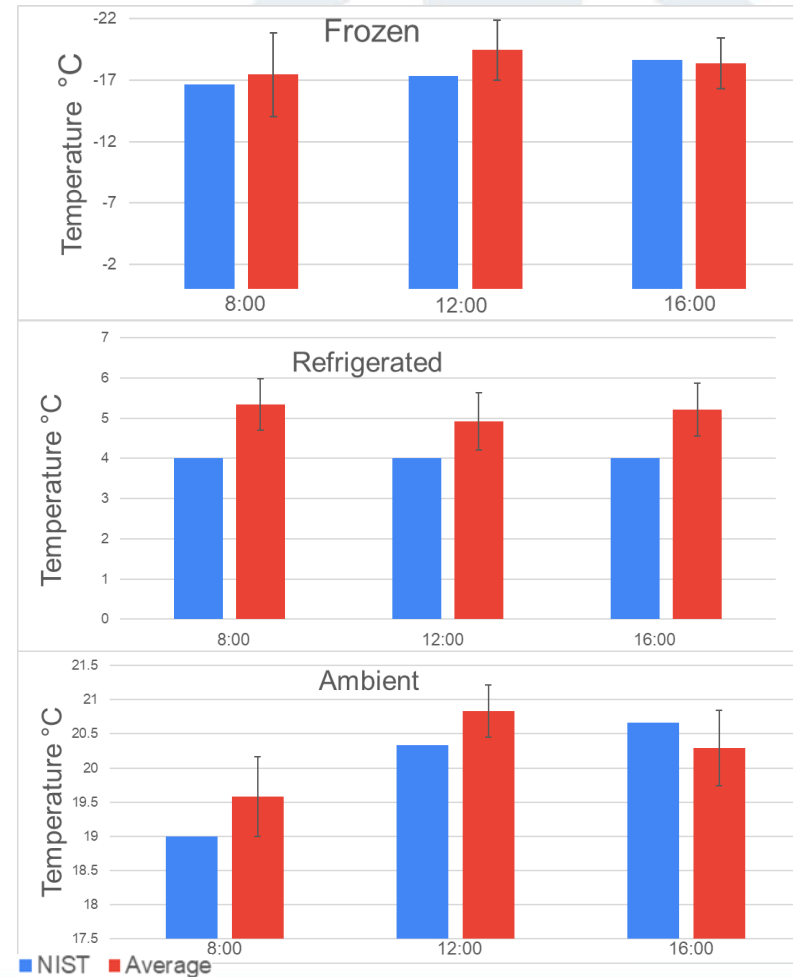
IR Thermometer Brand Performance Comparison

- **Purpose:**
 - Determine which IR thermometer brand provides the most accurate temperature measurements.
- **Overview:**
 - Brand A, B, and C thermometers were tested across frozen, refrigerated, and ambient temperature ranges (°C).
 - Averages of the readings from each Thermometer were compared to a known calibrated thermometer (NIST).
- **Result:** Brand C demonstrated the highest accuracy. (Fluke IR)



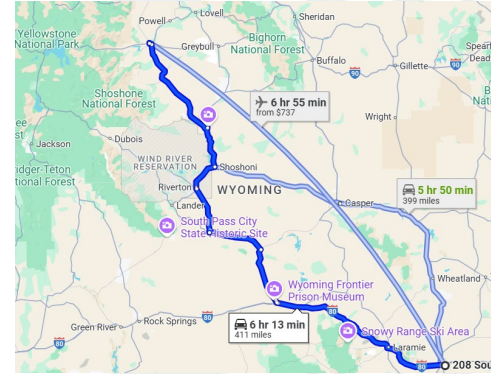
Brand C IR Thermometer Verification

- **Purpose:**
 - 6 additional Brand C Thermometers were purchased and tested for accuracy.
- **Overview:**
 - Each thermometer was tested across frozen ($\leq -20^{\circ}\text{C}$), refrigerated (2°C to 8°C), and ambient (15°C to 25°C) temperature ranges.
 - Measurements were compared against a NIST-calibrated reference thermometer to verify accuracy.
- **Result: Despite observed differences between the NIST reference and average readings, all measurements fell within acceptable ranges.**



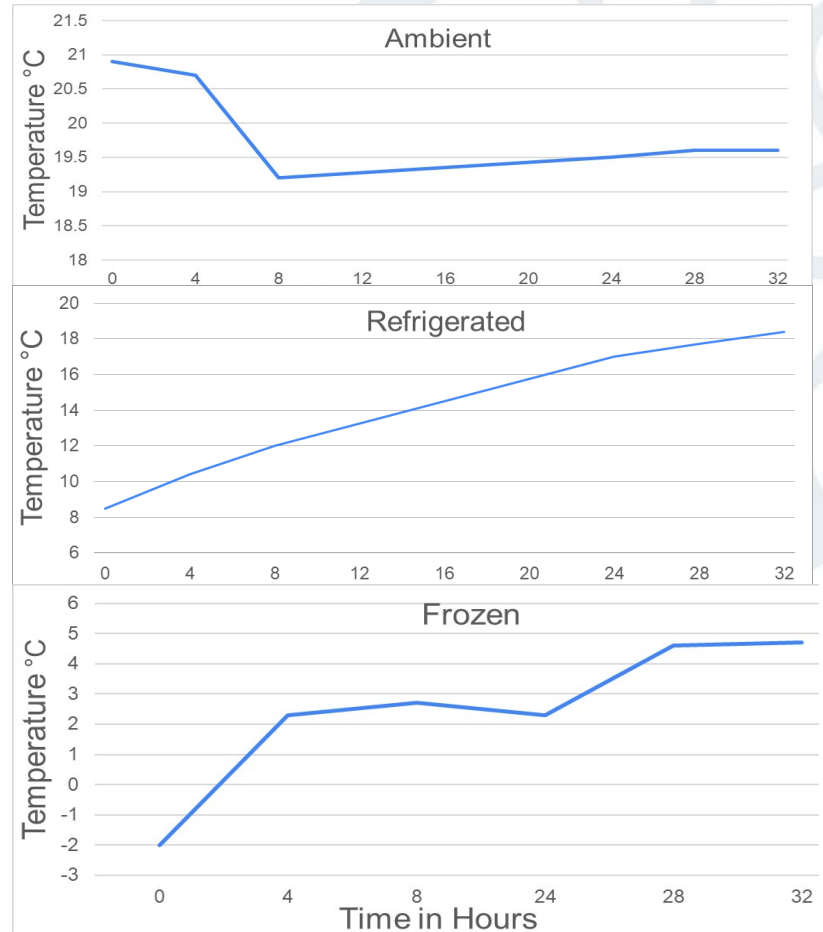
Cooler Experiment

- **Purpose:**
 - Identify a cooler capable of maintaining stable sample temperatures.
- **Studies Performed:**
 - Current Cooler Study
 - Current Cooler Cross-State Study
 - Newly Acquired Cooler Temperature Retention Study



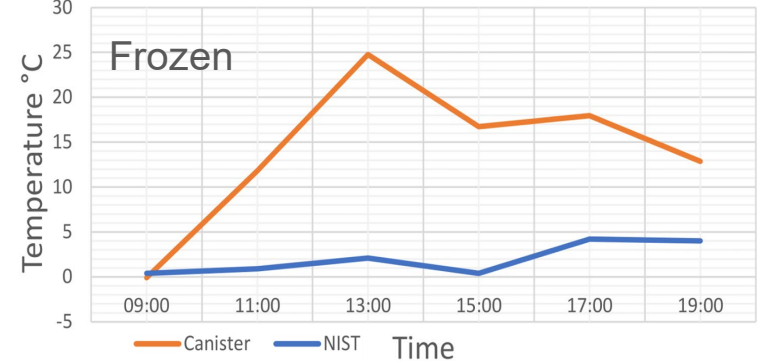
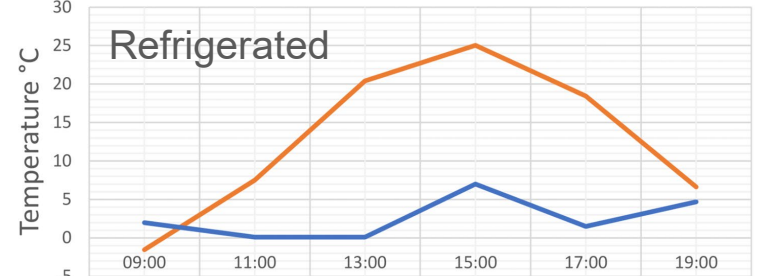
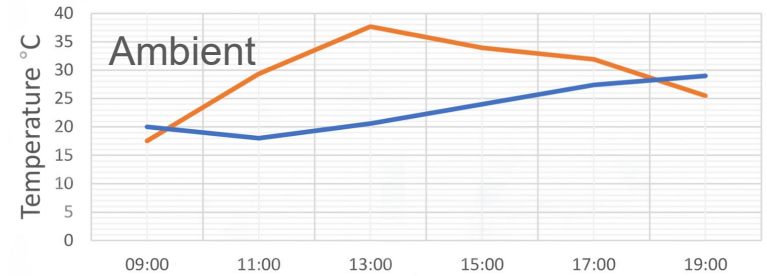
Current Cooler Study: In -House

- **Purpose:**
 - Assess temperature stability within WPHL's original coolers.
- **Overview:**
 - Three coolers (ambient, refrigerated, and frozen) were placed in a controlled 21°C environment.
 - Temperature stability was measured using a NIST-calibrated thermometer.
- **Result:** Only the ambient cooler successfully maintained its target temperature.



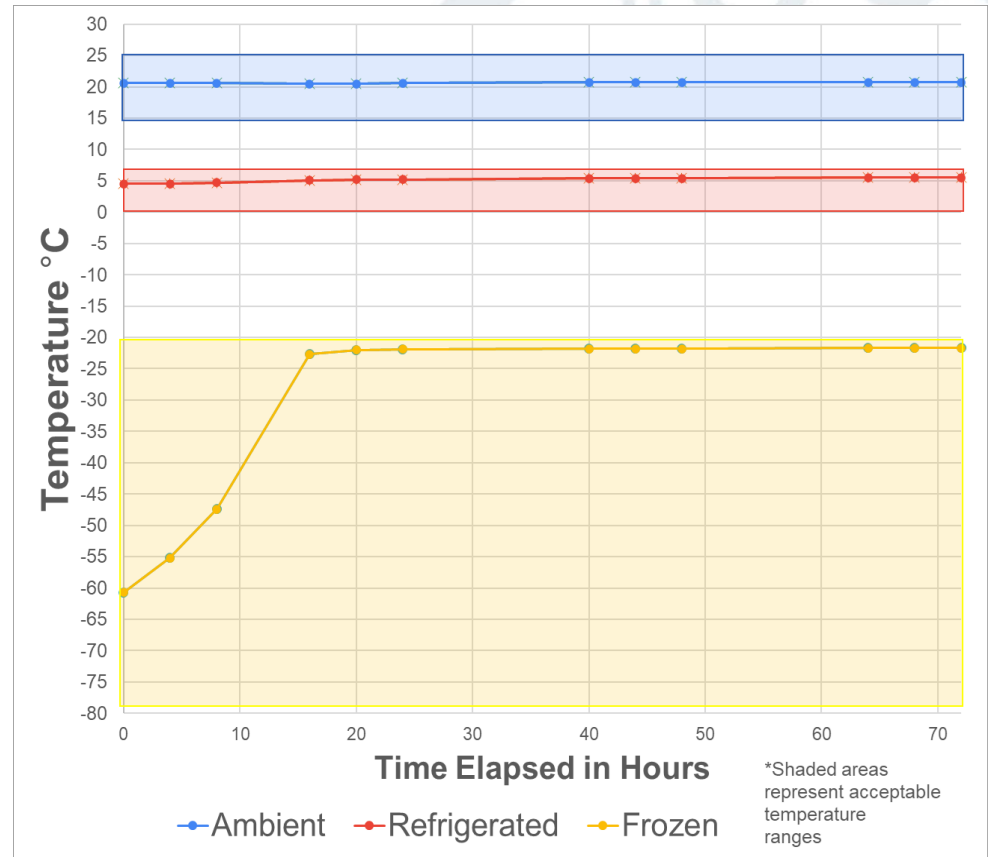
Current Cooler Cross -State Study

- **Purpose:**
 - Assess temperature fluctuations in WPHL's original coolers during cross-state transport.
 - Evaluate the ability of WPHL's sample canisters to maintain temperature.
- **Overview:**
 - Transported three coolers (ambient, refrigerated, and frozen) from Cheyenne, WY to Cody, WY.
 - Measured internal cooler temperatures using a NIST-calibrated thermometer.
 - Recorded the interior temperatures of specimen canisters within each cooler with an IR thermometer.
- **Result:**
 - Coolers failed to maintain acceptable temperature ranges.
 - Specimen canisters acted as insulators, retaining heat and remaining warmer than the cooler temperature.



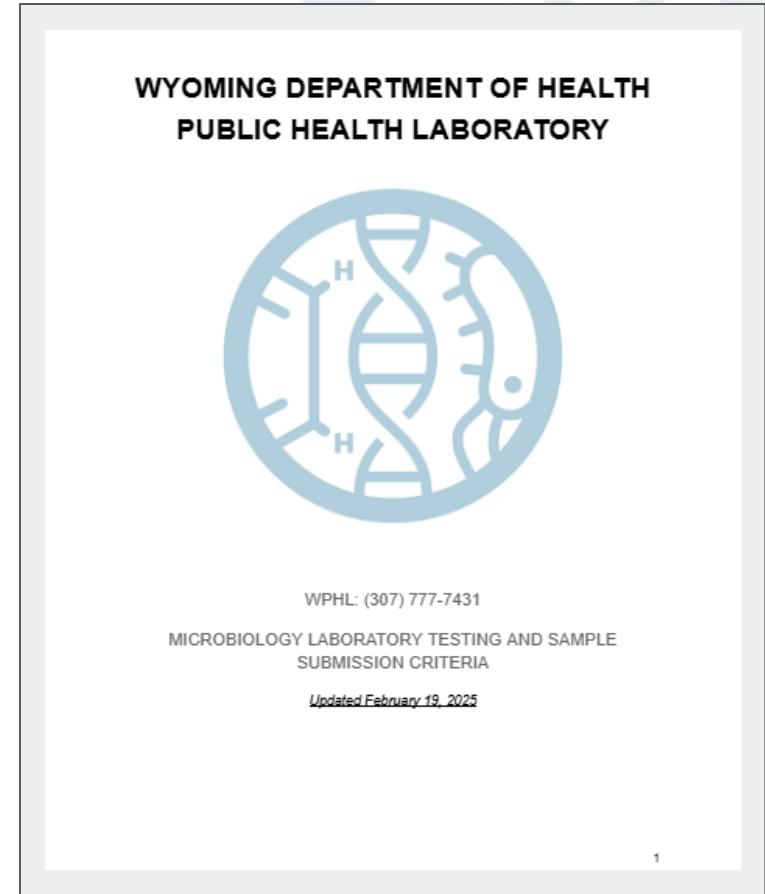
Newly Acquired Cooler Study

- **Purpose:**
 - Evaluate the temperature retention performance of a newly acquired cooler.
- **Overview:**
 - Three coolers (ambient, refrigerated, and frozen) were placed in a controlled 21°C environment.
 - Temperature stability was monitored using a NIST-calibrated thermometer.
- **Result:** All three coolers successfully maintained temperatures within acceptable ranges for their respective categories.



WPHL Sample Submission Guideline Document

- **Purpose:**
 - Provide a comprehensive reference document to assist submitters in meeting WPHL's submission requirements.
- **Overview:**
 - The guideline will contain information such as:
 - type of test
 - cost of tests
 - specimen requirements
 - turnaround times
 - By standardizing submission requirements, the guide helps reduce submitter errors



Future Action Plans

- Push forward with the brand of newly acquired coolers.
 - The Newly Acquired Cooler Study confirmed that these coolers perform exceptionally well.
- Push forward with brand Fluke IR Guns.
 - Brand C demonstrated superior performance, including in frozen temperatures, where other brands struggled.
- Sample Submission Guideline 2.0
 - The updated guideline will provide comprehensive criteria for all sample types and tests offered by WPHL.





**PUBLIC HEALTH
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HEALTH LABORATORY**

Overview

In response to increased scrutiny of preanalytical conditions by CLIA, SDPHL launched studies to evaluate packaging/shipping/temperature monitoring solutions for human biological specimens submitted for CLIA-regulated testing.

Packaging

- SDPHL evaluated packaging solutions and cooler from multiple vendors.
- SDPHL worked with HighQ to perform drop-testing of two light-weight and efficient coolers from Vericor

Shipping

- SDPHL worked with clients and couriers to improve the transport of clinical specimens bound for CLIA-regulated testing.
- SDPHL placed additional cold storage devices at courier hubs.

Temperature Monitoring

- SDPHL evaluated multiple temperature monitoring solutions.
- SDPHL performed studies across a temperature range.

Packaging

Inmark Saf-T-Pak: Category B Shipping System

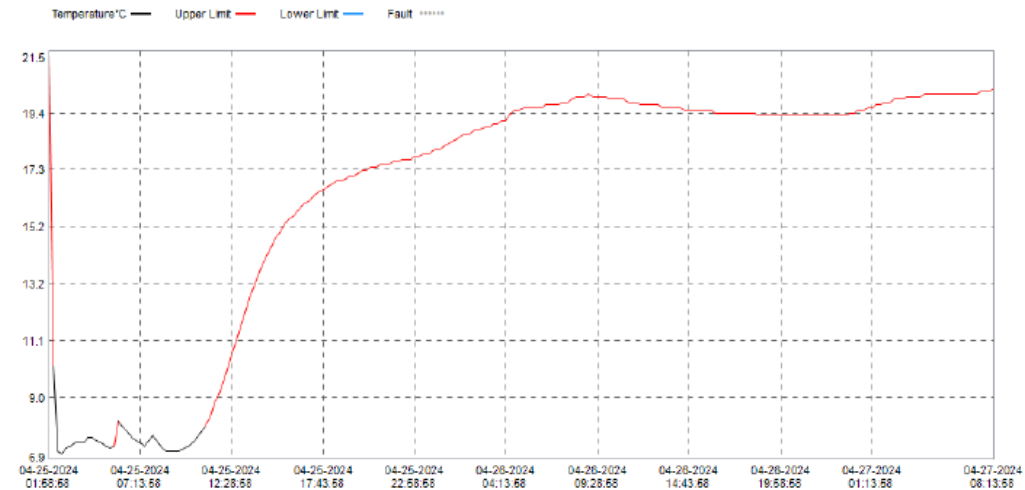


System Components:

- Outer Box – OD 9.5 x 4.25 x 4.25", pre-printed with: Biological Substance, Category B and UN 3373 Marking (Category B Side), Exempt Human/Animal Specimen Checkbox Markings (Exempt side)
- STP-150 50 mL Absorbent Strip (1 ea.)
- STP-700 Disposable 2-Part Secondary Pressure Vessel, Small (1 ea.)

Data Report

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- Inexpensive shipping system
- Certified Category B
- Evaluated at 22.5C (72.5F)
- Provided only 5 hours at 2-8C

TempArmour Medical Cooler: Model VCT-4

The TempArmour® Cooler Advantage

- Superior temperature stability and uniformity
- Temperature stays within 2-8°C (36-46°F) range up to 3 days (no batteries required)
- A Qualified Container and Packout as defined in CDC's Vaccine Storage and Handling Toolkit
- No electricity or ice packs required
- Incorporates vacuum insulated panel (VIP) technology to ensure stable temperatures
- Frozen temperature panels also available
- Pharmaceutical grade

Capacity	11 L - Holds approximately 500 x 0.5 ml vials or 120 single dose syringes (based on typical manufacturer box sizes)
PHYSICAL SPECS:	
External Cooler Dimensions (W x L x H)	17.25 x 12 x 12 in
Internal Dimensions (W x L x H)	12.75 x 7.25 x 7.25 in
Weight	20 lbs
Construction	Durable and functional nylon outer bag with handles on each side, a removable shoulder strap, and buckle closure
Cooling Technology	Temperature rated PCM (Phase Change Material)



Vericor Cool Cube Vaccine Cooler: 8 Liter

Cool Cube™ 08 at Refrigerator Temps (Vaccine & Medicine)

Model: VT-08



The Cool Cube™ 08 at Refrigerator Temperatures for Vaccine & Medicine is not an ordinary transport cooler. It is an easy-to-carry, qualified container and pack-out system that keeps temperature sensitive product (fresh vaccine, medicine) chilled between 2° and 8°C for over 3 days – without using ice or electricity! This cooler is ideal for transport, but also excels at protecting valuable product during off-site use and power outages, regardless of hot or freezing conditions. The simplified, validated, patented technology is the best compact thermal protection product available to maintain the cold chain!



4 Crêdo™ inside

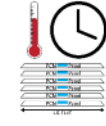
- 1 Adjustable shoulder strap with pad is removable.
- 2 Double zipper closure for easy access.
- 3 Clear external pockets for documents and/or Digital Data Logger (DDL).
- 4 Six removable, temperature-controlling, PCM panels ensure a simple, quick & effective pack-out.

Qualified Pack-Out System

Remove PCM Panels



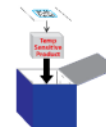
Prep PCM Panels



Assemble PCM Panels



Pack-Out Product



Close Bag



Features

- 6 patented PCM panels manage the temp
- Temp-Shield™ vacuum insulated panel (VIP) system
- Rugged, blue carrying case with a shoulder & hand strap
- Validated under ISTA Test Procedure 7D (Int'l Safe Transit Assoc)

Specifications

Temperature Range
2° to 8°C (36° to 46°F)

Performance
76+ Hours

Payload Area
11¼" x 6½" x 6½"

Exterior Dimensions & Weight
16" x 11½" x 11½" @ 16lbs

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info@VeriCorMed.com
(866) 469-6019

For more information & pricing: www.VeriCorMed.com



Vericor Cool Cube Vaccine and Medicine Cooler: 28 Liter

Cool Cube™ 28 at Refrigerator Temps (Vaccine & Medicine)

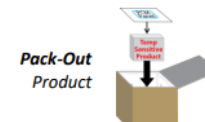
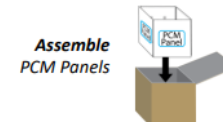
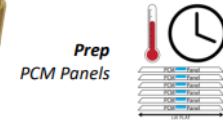
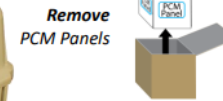
Model: VT-28



The Cool Cube™ 28 at Refrigerator Temperatures for Vaccine & Medicine is not an ordinary transport cooler. It is a lockable, wheeled, qualified container and pack-out system that keeps temperature sensitive product (fresh vaccine, medicine) chilled between 2 and 8 °C for over 4 days – without using ice or electricity! This cooler is ideal for transport, but also excels at protecting valuable product during off-site use and power outages, regardless of hot or freezing conditions. The simplified, validated, patented technology is the best compact thermal protection product available to maintain the cold chain!



Qualified Pack-Out System



- 1 Integrated towing handle for easy transport.
- 2 Holder and flexible grommet enables the use of an external temp monitor.
- 3 Tru-Trac System™ - a user-friendly wheel configuration.
- 4 Six removable, temperature-controlling, PCM panels ensure a simple, quick & effective pack-out.

Features	Specifications
<ul style="list-style-type: none"> • 6 patented refrigerator PCM panels manage the temp • Temp-Shield™ vacuum insulated panel (VIP) system • Rugged, military spec case with large lifting handles & wheels • Qualified under ISTA Test Procedure 7D (Int'l Safe Transit Assoc.) 	<p><i>Temperature Range</i> 2 to 8 °C (36 to 46 °F)</p> <p><i>Qualified Duration</i> 103+ Hours</p> <p><i>Payload Area</i> 12" x 12" x 12"</p> <p><i>Exterior Dimensions & Weight</i> 20½" x 20½" x 23" @ 61 lbs.</p>

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info@VeriCorMed.com
(608) 526-6901

For more information & pricing: www.VericorMed.com



Inmark Saf-T-Pak Category B Insulated Box Cooler

FEATURES:

- Designed for use with Saf-T-Temp® Thermal Paks.
- Combine with STP-510 Overpack System for "Dual Shipper" - two temperature requirements in one shipment.

Approximate Capacity*:

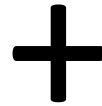
- Max. Secondary Pressure Receptacle(s) (STP-710): 2
- Max. 2mL Tubes: 162
- Max. 10mL Tubes: 20
- Max. 500mL Blood Bag(s): 2

System Components:

- Outer Box – OD 11.25 x 9.5 x 8.5" pre-printed with Biological Substance, Category B and UN 3373 Markings
- Insulated Chest – ID 7.75 x 5.75 x 5"
- STP-151 Absorbent Strip (100 mL) (1 ea.)
- STP-609 Saf-T-Rap® Sticky Bubblewrap, 6 x 12" (1 ea.)
- STP-710 Disposable Secondary Pressure Vessel (Medium) (1 ea.)
- STP-810 Block Out Label (1 ea.)
- STP-819 Exempt Human/Animal Specimen Marking (1 ea.)



Multiple Cold Packs Evaluated



Sonoco™ ThermoSafe PolarPack™ Foam Bricks

Refrigerant bricks are vacuum-sealed for consistent weight and shape. These semi-rigid foam bricks never change shape during freezing, thawing or transit, enabling superior surface contact for more consistent temperature control.



Re-Freez-R-Brix™ 64 oz. Cold Bricks - 9" x 8" x 1-1/2", 6/Case

Protects against thawing by keeping perishables chilled and at a uniform temperature for over 12 days.

- Formulated with food safe, non-toxic materials and sealed in a heavy-duty plastic pouch
- Leak proof, reusable and economical to use
- Ideal for pharmaceuticals, blood products, lab samples and bio products



Sonoco™ ThermoSafe U-tek™ Gel Pack

Phase Change Material (PCM) gel pack for shipping temperature-sensitive materials.

Temperature Monitoring

Zebra TransTracker: Heat and Freeze

Features

- Irreversible
- Easy to understand
- Single use
- Time delay heat excursion
- Multiple temperature ranges
- No device activation required
- Nontoxic materials

Benefits

- Identify and avoid administration of heat or freeze exposed products
- Extend quality management system from manufacturing to ultimate use
- Strengthen conformance to International Code on Harmonization (ICH) Q9 and Q10
- Reduce unnecessary waste by limiting the destruction of products incorrectly suspected of heat or freeze damage
- Environmentally friendly

TransTracker® CF

Performance and Use

Response Temperatures:

Heat: 17.5°C / 25°C / 31°C

Freeze: 0°C / -1°C / -6°C (±2°C)

Accuracy: ±1°C

Response Time:

Heat: Within 2 hours

Freeze: Within 30 minutes

Storage Temperature: Refrigerated temperature (2°C to 8°C)

Shelf Life: 2 to 4 years, determined by category

Usage: Single use

Temperature Monitoring: Continual

Device Size: 56mm x 108mm

Additional Features: Card design customization

Quality System

- Temptime's quality management system is consistent with FDA Quality System Requirement (QSR) 21 CFR 820 (GMP for medical devices)
- ISO 9001
- ISO 13485



SOUTH DAKOTA
DEPARTMENT OF HEALTH

Elitech: Multiple Devices



RC-5



RC-5+

	RC-5	RC-5+
Record Capacity	32,000 Temperature Points	32,000 Temperature Points
Temperature Range	-22°F~-158°F(-30°C ~+70°C)	-22°F~-158°F(-30°C ~+70°C)
Humidity Range	NO	NO
Max. Battery Life	6-month	6-month
Restart by Press Button	NO	✓
Connection Type	USB	USB
Auto PDF Report	NO	✓
Optional Password Protection	NO	✓
Cyclic Recording	NO	NO
Extra External Sensor	NO	NO



Elitech iCold Services

Service Plan	Basic	Premium	Exclusive
Real-time data viewing	✓	✓	✓
Remote real-time alarm (Email & App & Cloud & SMS)	✓	✓	✓
Data query and export	7 days	3 years	5 years
Location service	-	✓	✓
SMS quantity	0	50	300
Early warning function	-	-	✓
Multi-level alarm	-	✓	✓
FDA 21 CFR Compliant	-	-	✓
Traffic cost	✓	✓	✓
Price	Free Service	\$19.98 / y	\$39.96 / y

Specification

Sensor Type

Temperature Measuring Range

Humidity Measuring Range

Accuracy

Resolution

Capacity of Offline Data

Logging Interval

Uploading Interval

Data Storage Mode

Power Supply

Battery Life

Screen

Communication Mode

Alarm Mode

Wireless Print

Positioning

Protection Grade

Dimensions

External Probe Length

External T&H: **1 x Temperature Probe; 1 x Humidity Probe**

Dual External Temp: **2 x Temperature Probe**

Dual External T&H: **2 x Temperature-Humidity Probe**

Internal Temp: **Internal Temperature Sensor**

Internal T&H: **Internal Temperature-Humidity Sensor**

External Buffered: **1 x External Glycol Bottle Probe**

Internal: -4°F~-140°F(-20°C~+60°C)

External: -40°F~-176°F(-40°C~-80°C)

0-100% RH

Temperature: ±0.9°F/±0.5°C

Humidity: ±5%RH

Temperature: 0.18°F(0.1°C)

Humidity: 0.1%RH

100,000 readings

1min ~24hr (Default: 30min)

1min ~24hr

Circular Logging

5V/2A(DC)

3 months at least(@77°F(25°C), uploading interval: 30min, LBS positioning)

14 days at least(@77°F(25°C), uploading interval: 30min, LBS+GPS positioning)

TFT color screen

4G

Device Alarm(Sound&Light);

Cloud Alarm(Mobile app, Email, SMS)

Enabled

LBS+GPS

IP64

4.29"*2.73"*0.90"/109mm*69.4mm*22.9mm(LxWxH)

5m



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And the Winner is...

Vericor Cool Cube Vaccine Cooler: 8 and 3 Liter



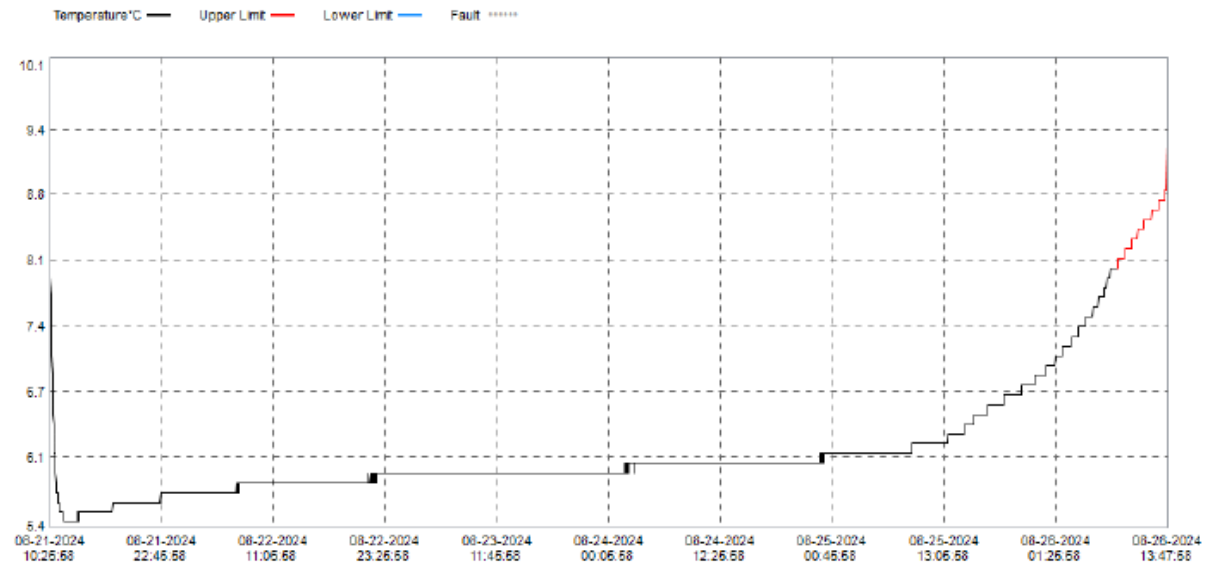
Cool Cube™ 08 at Refrigerator Temps

For Vaccine, Medicine & Other 2-8°C Products

SKU: VT-08

A laboratory qualified system that utilizes PCM technology to keep product such as fresh vaccine and medicine safely between 2°C and 8°C 2-8°C for 76+ hours without the need for electricity, ice or buffering material. Ideal for off-site vaccinations, long-term transportation and power outage backup.

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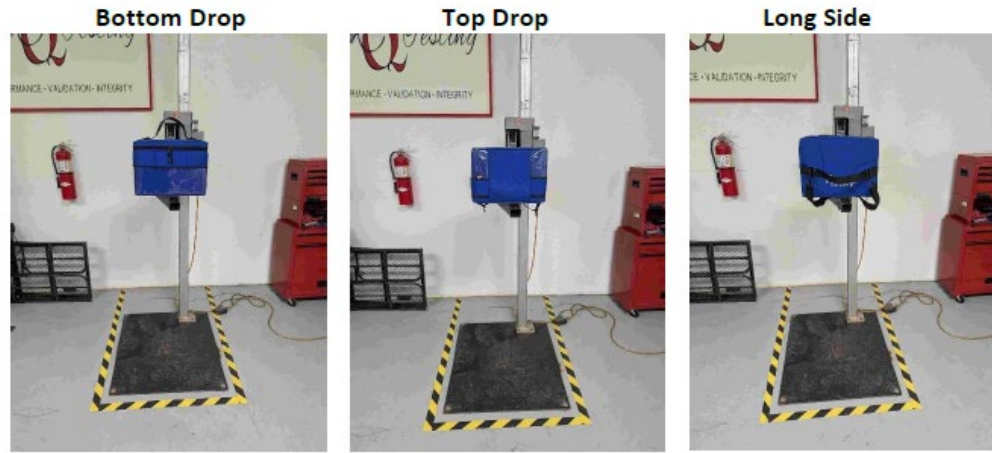


- Used with biohazard bag and pressure pack (Tyvek)
- Costly shipping system but reusable
- At 22.5C (72.5F) = 2-8C for 4d21h
- At 37.9C (100.22F) = 2-8C for 2d8h

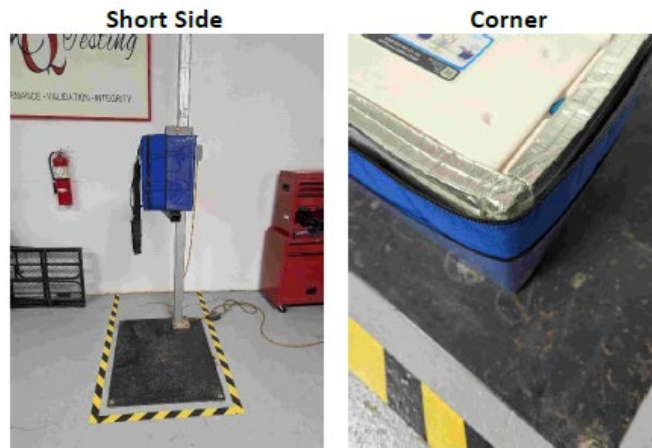
Not Category B Certified



Vericor Cool Cube Drop Test



Drop Test	8 Liter	3 Liter
Flat on to Base	Pass	Pass
Flat on to Top	Pass	Pass
Flat on to Longest Side	Pass	Pass
Flat on to Shortest Side	Pass	Pass
On to a Corner	Pass	Pass



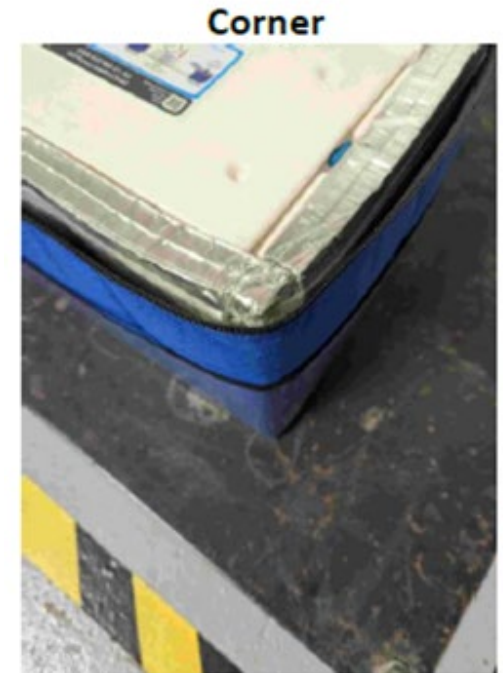
Conclusion

Results of this testing conclude that this packaging does meet the U.S. Department of Transportation 49 CFR 173.199 and IATA Packing Instruction 650 drop test criteria for shipping a liquid Biological Substance Category B specimen.

*Performed by HighQ Testing, LLC

Observations and Questions

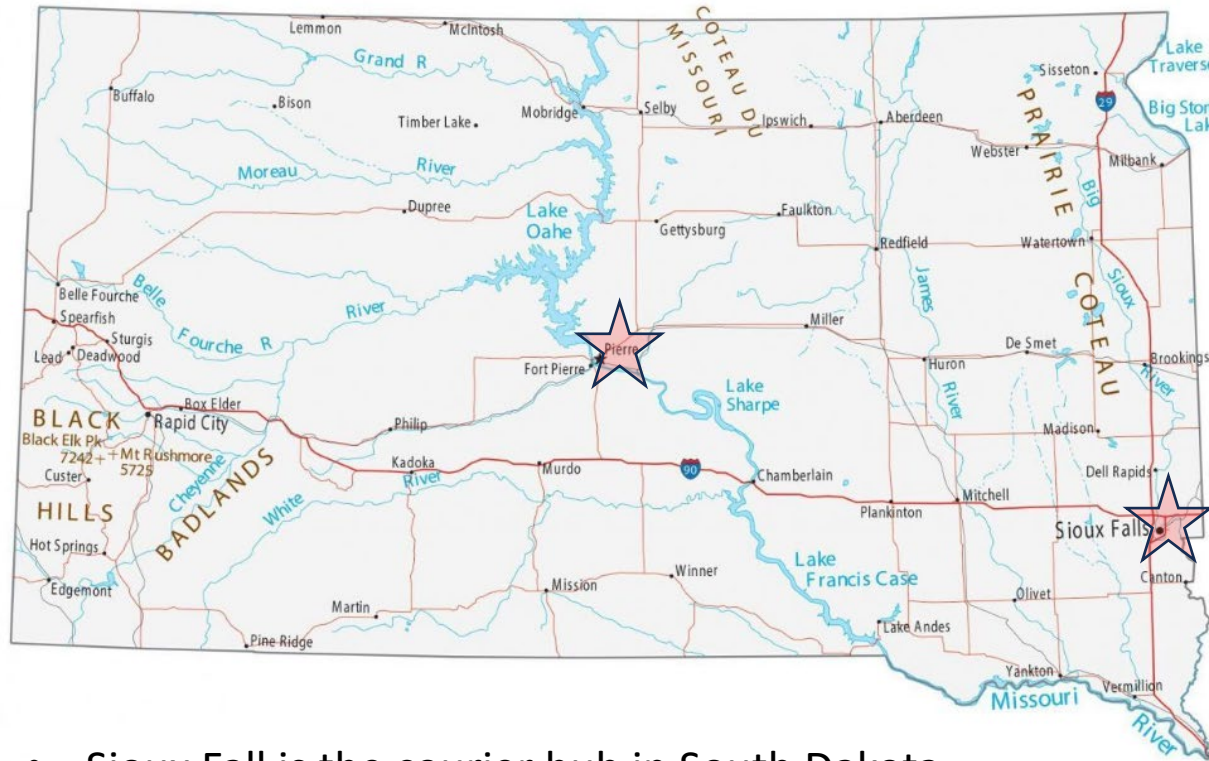
- Damage will reduce cooler efficiency.
- Certification only allows ground transport.
- Any change by the manufacturer to the cooler including outer cover, foam insert, and rechargeable panels will require drop testing (again).
- Certification is for a liquid biological substance; more investigation is needed to determine if cultures on semi-solid media can be shipped.



Additional temperature study data available

Shipping/Storage

Additional Preanalytical Improvements: Cold Storage at Courier Hub and PHL



- Sioux Fall is the courier hub in South Dakota
- No cold storage was previously available at this location
- All specimens are now held in a refrigerator while at the hub
- All specimens are now delivered into a refrigerator at SDPHL



Communication Campaign

Couriers:

- SDPHL increased cadence of communication with couriers
- Evaluated fleet details and routes
- Provided messaging that couriers can provide to drivers about vehicle conditioning, specimen handling, and other practices to help maintain optimal preanalytical conditions.

Clients:

- SDPHL created a quick reference guide for submitters that provides the following information for each test performed by the laboratory's Medical Microbiology team:
 - Sample type
 - Transport temperature
 - Holding time(s)
 - Shipping category
 - Comments/Notes (emphasis Category A; LRN submissions)
- SDPHL also increased frequency of communication with submitters to support improved preanalytical quality.