

NIST Case Study: Dual-Zone Unit for Simultaneous Refrigerated and Frozen Vaccine Storage

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Background

- **Challenges in ensuring VFC providers follow good vaccine storage and temperature maintenance practices**
 - 45,000+ providers, many different storage and temperature monitoring methods
 - Suitability of commercial refrigerators for vaccine storage not well documented
 - Impact of refrigerator loading pattern, normal refrigerator use, environmental temperature fluctuations, ...unknown!
 - Inadequate temperature monitoring: improper thermometer placement, possible device inaccuracies, and absence of continuous temperature data collection
- **Multi-year NIST-CDC collaborative study designed to replicate the everyday conditions experienced by vaccine providers**
 - Focused on refrigerated vaccine storage and handling issues
 - Various refrigerator types
 - Vaccine loading patterns and storage methods
 - Temperature monitoring devices and proper use, including validation
 - Research results used to improve CDC vaccine storage and handling guidelines

The Dual-Zone Unit

- Widespread use of combined refrigerator/freezer units for vaccine storage among VFC providers
- Most VFC-distributed vaccines require refrigerated storage, but some Varicella-containing vaccines are stored frozen (-50 °C to -15°C)
- Dual-zone units appear to offer a convenient, inexpensive, and space-efficient solution, allowing simultaneous refrigerator and freezer storage
- HOWEVER.. questions remain
 - Are dual-zone units really suitable for both refrigerated and frozen vaccine storage?
 - Does changing the freezer temperature impact the refrigerator compartment temperature – even with separate control dials?
 - Anecdotal reports of vaccines freezing inside the refrigerator compartment



Our principal research focus was the storage and handling of refrigerated vaccines..

But in response to these questions, we decided to set up a brief dual-zone case study exploring the issue of simultaneous refrigerator and freezer operation

Dual Zone Case Study:

Does freezer setting affect refrigerator performance?

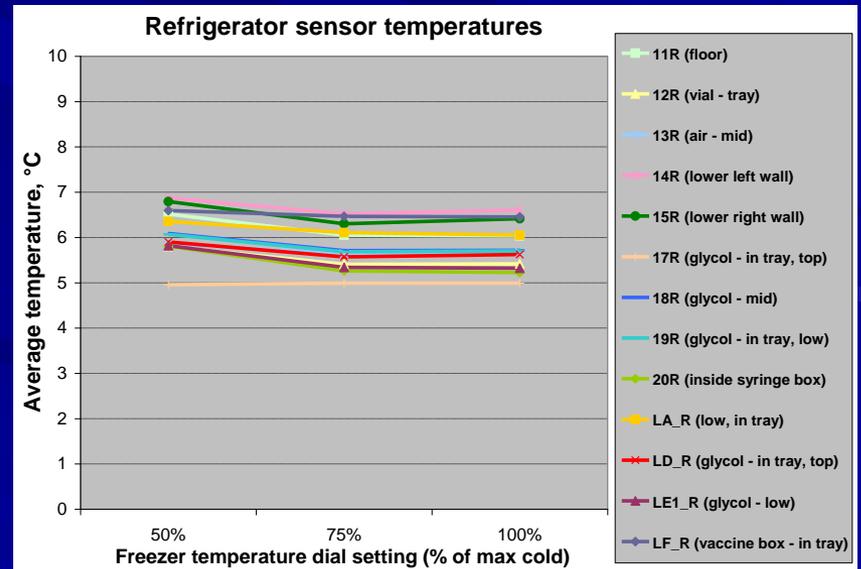
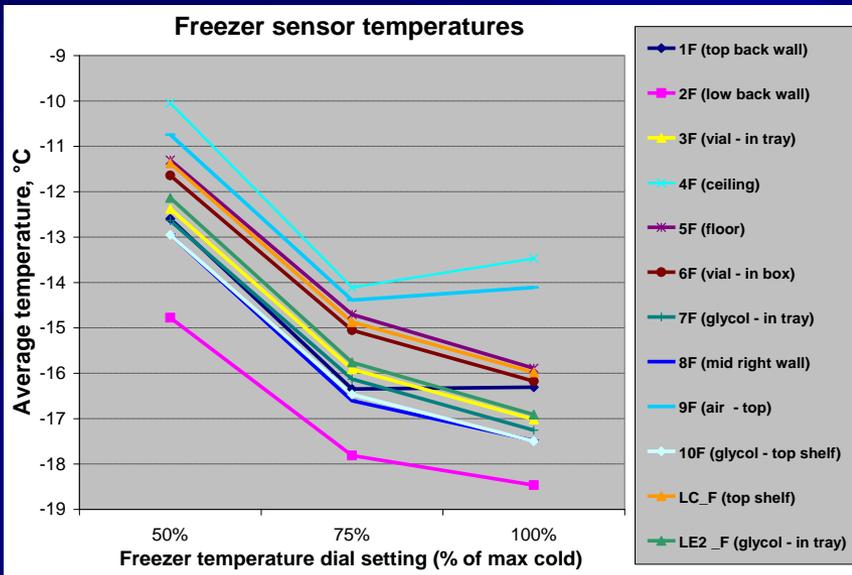
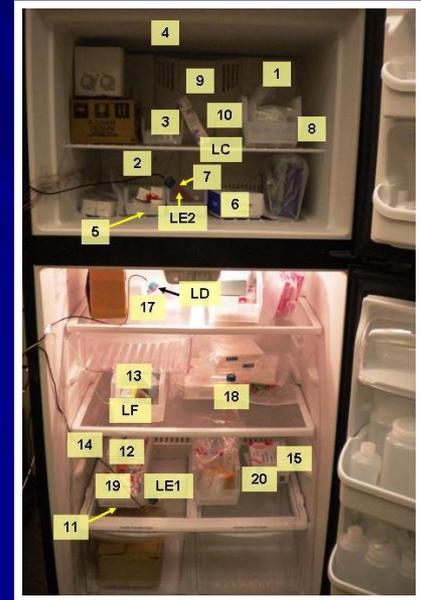
Sensors arranged throughout freezer and refrigerator compartments →

Varied freezer set point dial, refrigerator temp setting left unchanged

- 50%, 75%, and 100% (maximum cold setting)
- Recorded temperature effects in both compartments

Results: change in refrigerator sensor temperatures ~10% temperature drop recorded by freezer sensors

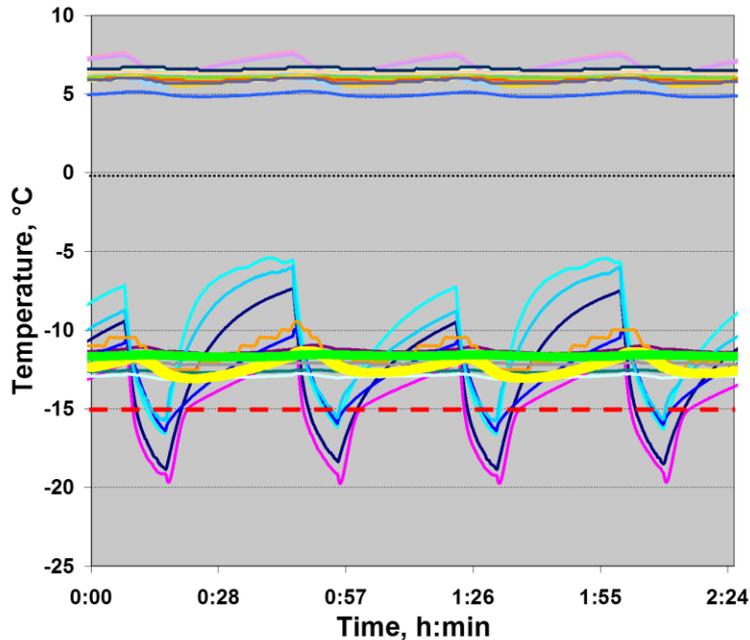
- In order to change the refrigerator compartment temperature by 1°C, the freezer compartment must be adjusted by 10 °C
- In our test unit, adjusting the freezer temperature is **unlikely to negatively impact vaccines stored in refrigerator compartment**



Dual Zone Case Study:

Is this refrigerator model suitable for frozen vaccine storage?

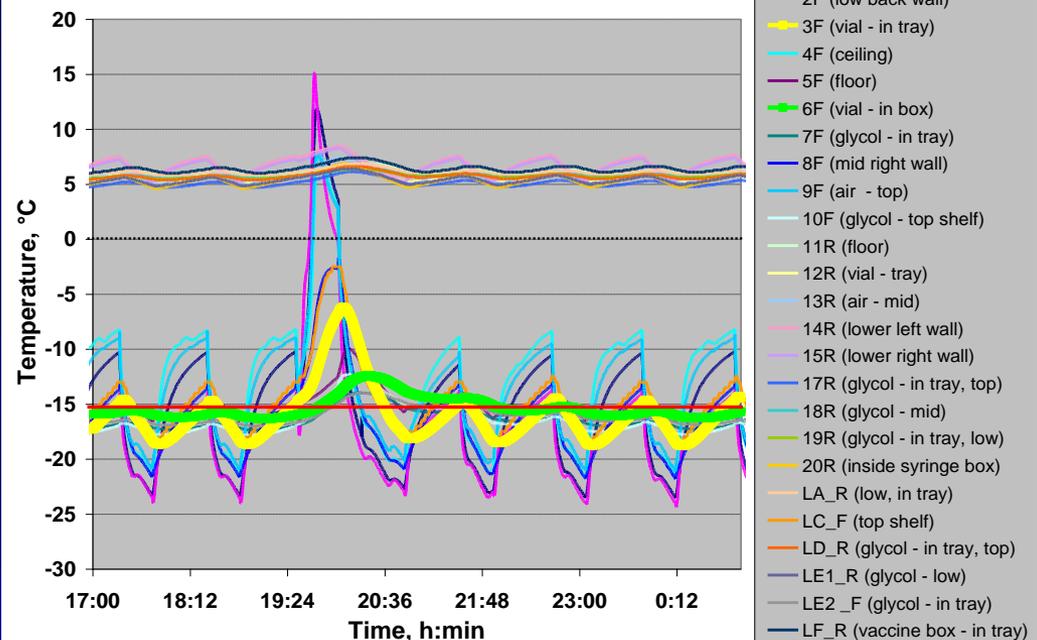
Midpoint Freezer Setting



Freezer thermostat dial set to midpoint position: vaccine vial temperatures between -13 °C and -11 °C

Upper temperature limit for frozen vaccine storage = -15 °C

Coldest Freezer Setting



Maximum cold setting: vial temperatures fluctuate between -19 °C and -13 °C

- Upper limit exceeded
- 5 °C fluctuation due to freezer control is large – no room for set point error

Defrost cycle temperature spike

- 2+ hr thermal excursion > -15 °C, every 24 hrs
- Possible significant impact on vaccine quality

Summary of Results

- **Dual-zone units are suitable for refrigerated vaccine storage**
 - Adjusting the freezer temperature control dial on a unit featuring separate controls did not significantly impact the temperature of refrigerated vaccines
 - Refrigerated vaccines remained within prescribed 2 °C to 8 °C during the case study and throughout our in-depth evaluation of refrigerated vaccine storage
- **Dual-zone units may be unacceptable for frozen vaccine storage**
 - Our test unit was UNABLE to maintain frozen vaccine storage temperatures < -15 °C
 - Even with freezer control set to “COLDEST,” vaccines stored inside the freezer experienced thermal excursions above -15 °C
 - Defrost cycle causes major thermal excursions – some freezer locations exceed 0 °C
 - The tested unit was brand new. Older units currently used in the field may be even more problematic.
- **Continuous temperature monitoring is an integral part of effective vaccine storage management – and is a REQUIREMENT for providers using dual-zone units for frozen vaccine storage**
 - This study raises serious questions about the suitability of these units.. and the effectiveness of vaccines stored in their freezers
 - Continuous temperature monitoring of BOTH freezer and refrigerator compartments is the only way to ensure that vaccines are stored properly
 - Sensor placement should match locations/ methods in which vaccine vials are stored
 - If monitoring shows a unit does not maintain temperatures within -50 °C and -15 °C, the unit is **NOT ACCEPTABLE FOR FROZEN VACCINE STORAGE**

Next Steps

- **Case study results highlight the need for a more in-depth study of frozen vaccine storage**
- **We hope to evaluate various freezer types and storage methods for effective frozen vaccine storage in a future NIST-CDC study**
- **To verify that correct storage temperatures are consistently maintained for both refrigerated and frozen vaccines, providers must use continuous temperature monitoring devices**
- **Without continuous temperature monitoring of ALL stored vaccines... there is no way to tell if delivered vaccines are SAFE and EFFECTIVE.**

Thank You!

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