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# Validation of cooler boxes for storage and transportation of drugs within and outside of Tan Tock Seng Hospital (TTSH), including use for civil emergency

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## Introduction

Cold chain is crucial in maintaining product quality from time of manufacture to administration, by ensuring that temperature-sensitive products are kept within proper storage temperatures, including during transportation to end users.

TTSH encountered following challenges with maintaining cold chain:

- Unable to source for in-use models of cooler boxes and ice packs for replacement.
- Current method is cumbersome as it involves wrapping ice packs with bubble wrap before use (to avoid direct contact with product).
- Unknown if current protocol is able to maintain 2-8°C throughout period of use for delivery to areas outside TTSH and out-of-fridge storage during civil emergency.

## Objectives

To perform validation of cooler boxes to establish a standardized cold chain protocol for:

1. Transportation of drugs to areas within and outside TTSH, with consideration for portability and improved convenience.
2. Out-of-fridge storage in cooler boxes, with sufficiently long interval between ice packs replacement, during civil emergency.

## Methodology

### Prepare

Refrigerate: test products + 2 temperature loggers (in each product retail box)  
Freeze: ice packs

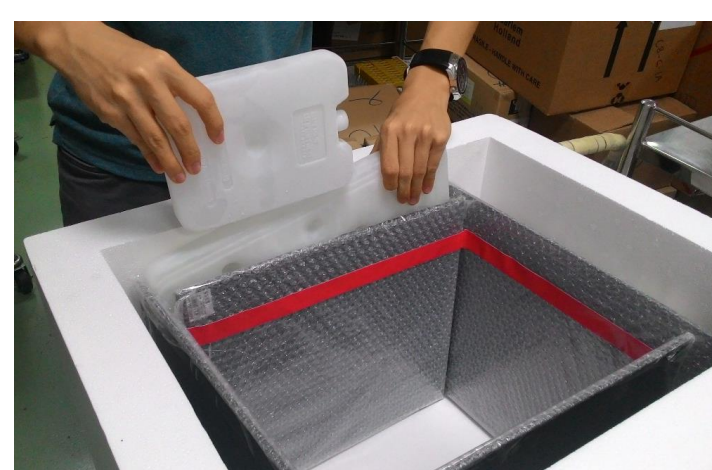
#### Test variables

Ice packs: freezing time, size & number

### Pre-condition

Transfer frozen ice packs to pre-conditioning location, for specific duration

Preconditioning: duration, ice packs placement, opened/closed cooler box



### Pack

Load refrigerated products into cooler box with ice packs. Place the 2 temperature loggers at 2 points<sup>†</sup> in cooler box.

Cooler box: modification design (e.g. partition thickness)  
Ice packs: packing configuration  
Temperature loggers: location

### Environment

- A. In a vehicle (ambient temperature tracked by a logger).  
B. Air-conditioned location with temperature setpoint of 23±1°C

### Measure

<sup>†</sup> 2 points in cooler box, to simulate the highest and lowest temperature points experienced by the product in the cooler box.

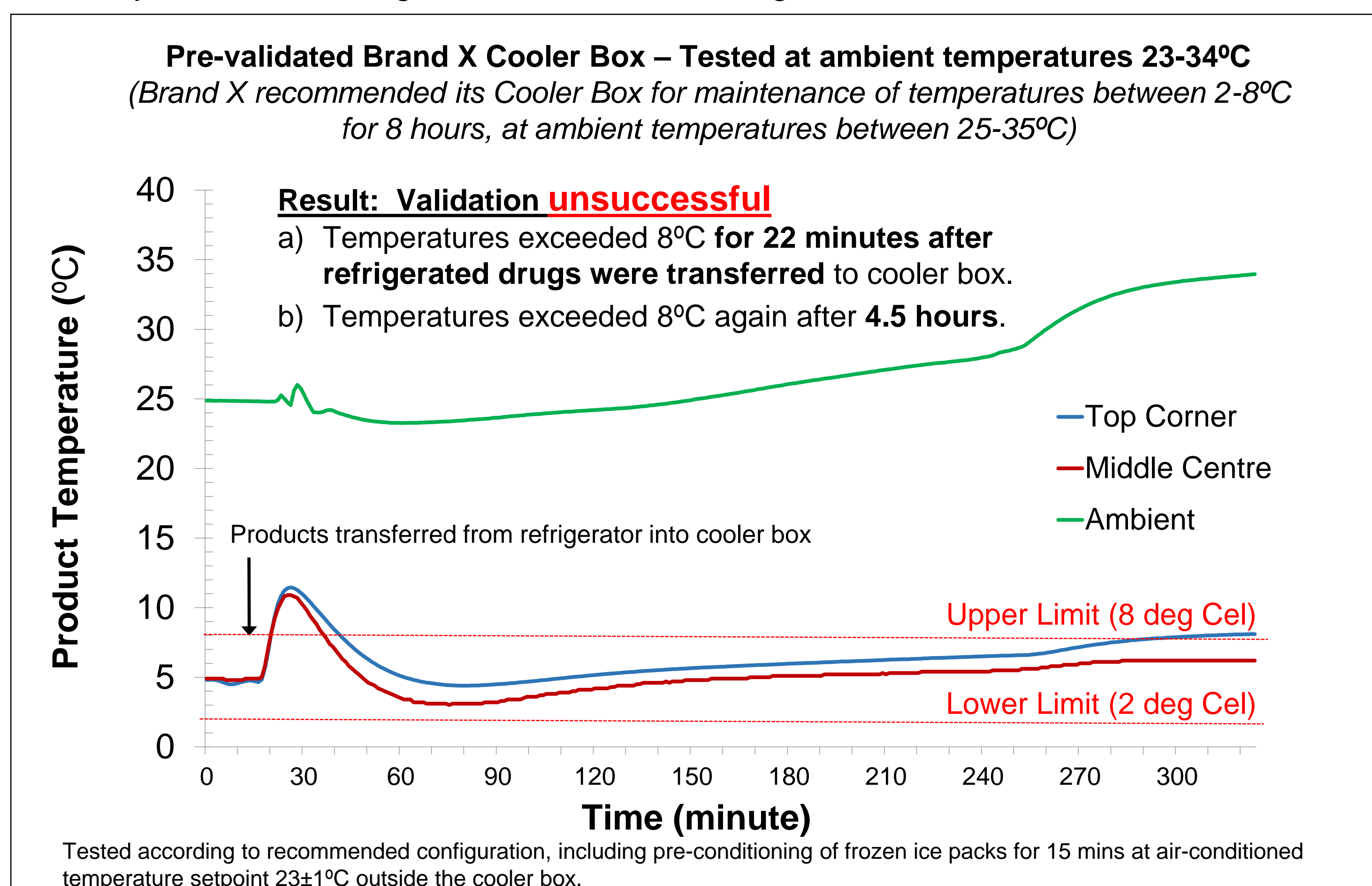
### Validate

**Success = Temperatures at the 2 points<sup>†</sup> maintained between 2-8°C for twice the intended duration of use\***  
(to allow for opening and closing of the box e.g. during civil emergency.)

\*WHO Department of Immunization, Vaccines and Biologicals (PQS devices catalogue, version date: 5<sup>th</sup> July 2018) recommendation: "to take account of cold box opening and transport delays, double the estimated cold/ warm life requirement."

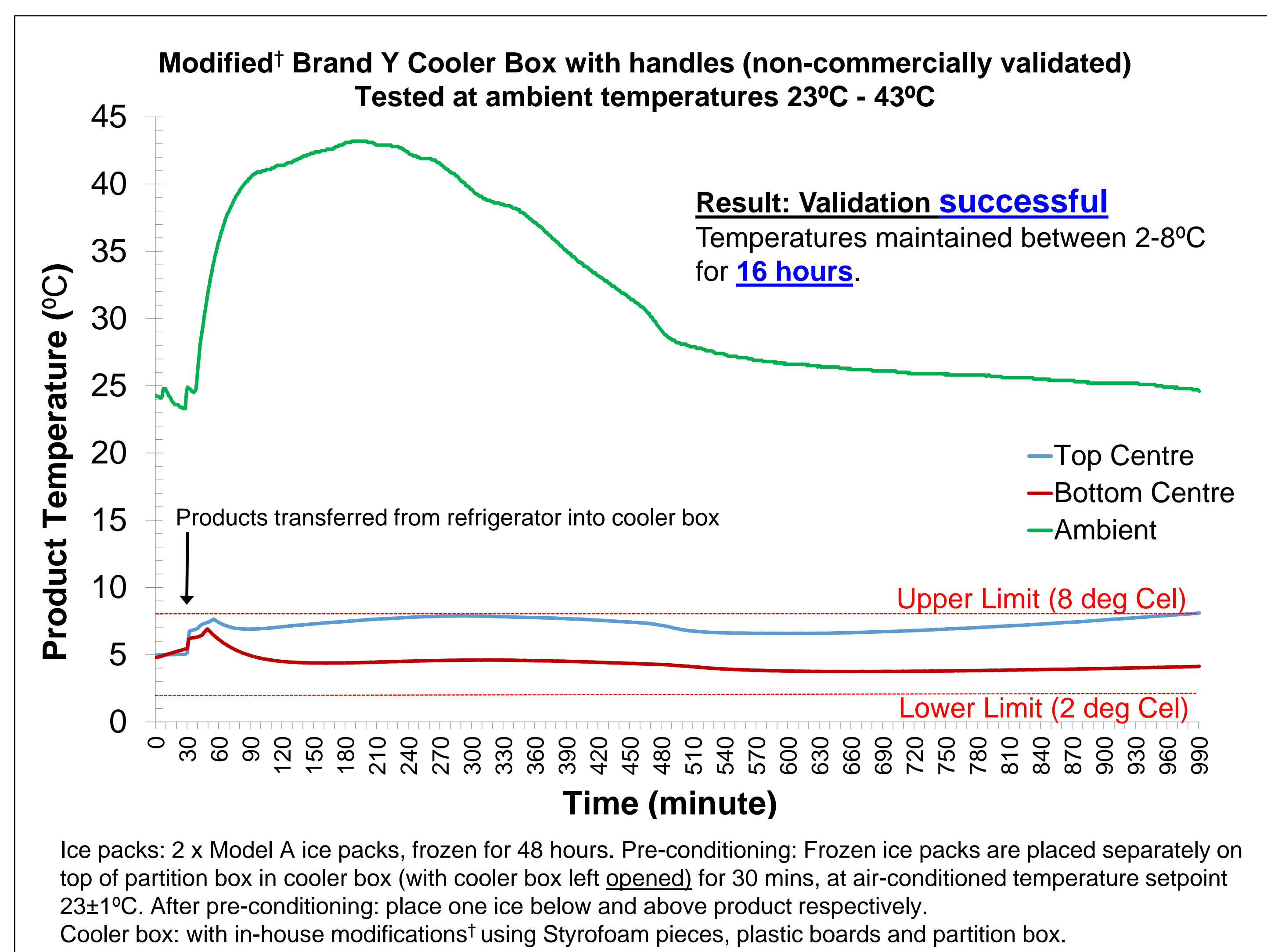
## Results

Validation of a commercially available pre-validated cooler box was unsuccessful when tested by TTSH according to recommended configuration.

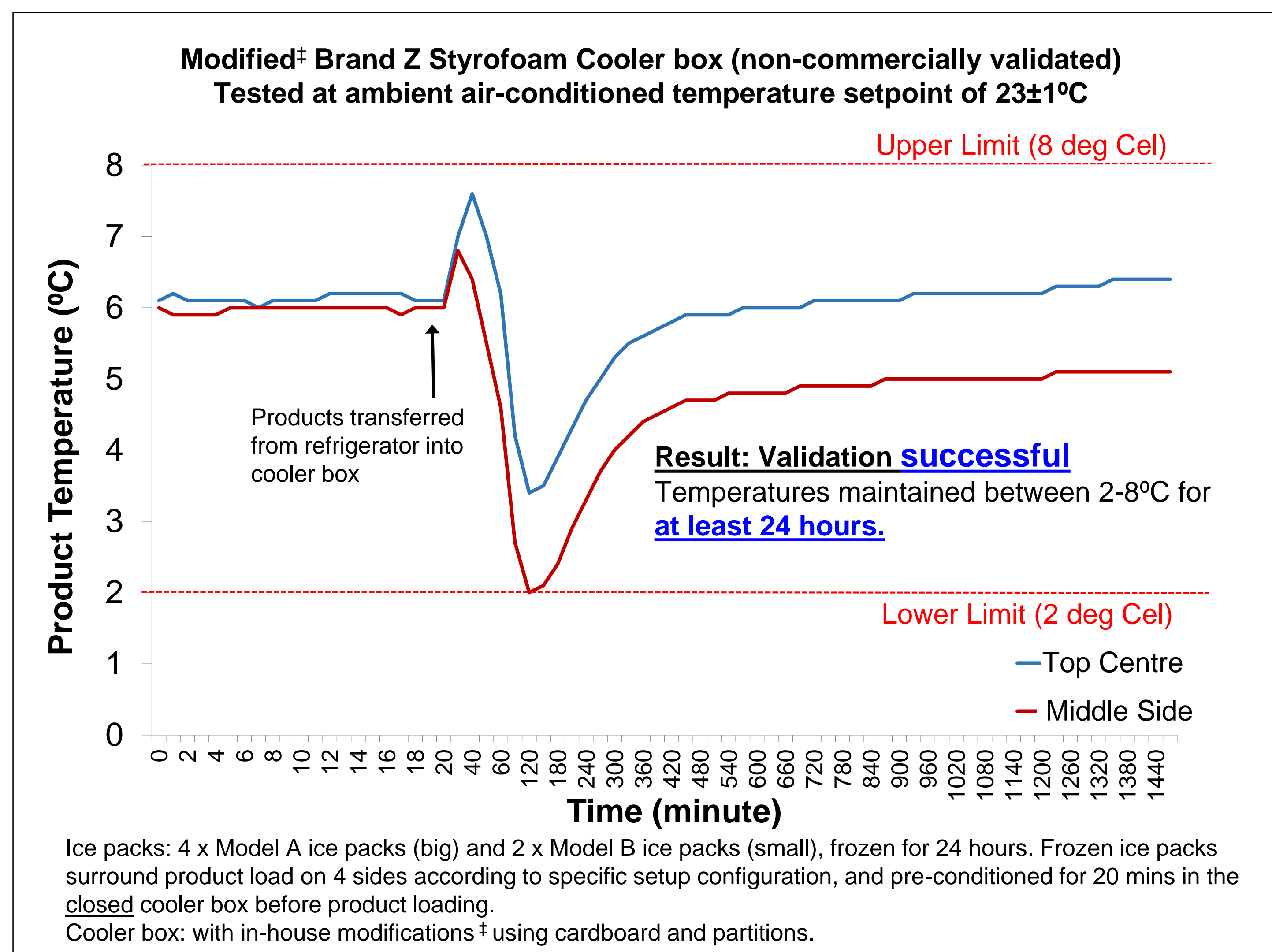


After exploring other non-commercially validated cooler boxes and multiple modifications, TTSH established the method of using cooler boxes to maintain 2-8°C at:

- A. **In-vehicle temperatures** ranging from 23°C - 43°C, to allow for **maximum 8 hours use**, for each delivery to areas **outside TTSH**.



- B. **Air-conditioned temperature** setpoint of 23±1°C, to allow for **maximum 12 hours use** per delivery/ storage **within TTSH**.



The TTSH-validated Styrofoam cooler box is favourable for use for:

1. Civil emergency, as the relatively long duration of 12 hours storage means ice pack replacement will be infrequent during this period when manpower is likely to be limited.
2. Delivery within TTSH, as styrofoam boxes are lightweight and of high capacity, hence suitable for high product loads typical of deliveries within TTSH (e.g. between Pharmacy sections).

The protocol, including the actual detailed steps for preconditioning and packing, was uploaded into the TTSH intranet for standardization of use.

## Conclusion

TTSH Pharmacy established standardised protocols for cold chain transportation within and outside the hospital, and storage of drugs during civil emergency using cooler boxes.

There is improved convenience with use of partitions to segregate products from ice packs, in replacement of wrapping bubble wraps around ice packs.

It is recommended that users validate cooler boxes before use, including commercially available pre-validated ones, to ensure cold chain is maintained throughout storage and transportation.