

SECURIZING OF TISAGENLECLEUCEL (KYMRIAH®)

STORAGE

Background and Importance

Tisagenlecleucel is available in frozen bags stored and shipped under -120 °C. The SPC allowed storage in a cryogenic freezer (vapor phase of nitrogen (LN2) is cited only as an example). As the pharmacy has not LN2 storage facilities, Tisagenlecleucel bags are stored in a freezer set at -150 °C. With only one freezer, another, located in the biological hematology laboratory, was chosen as back up in case of failure.

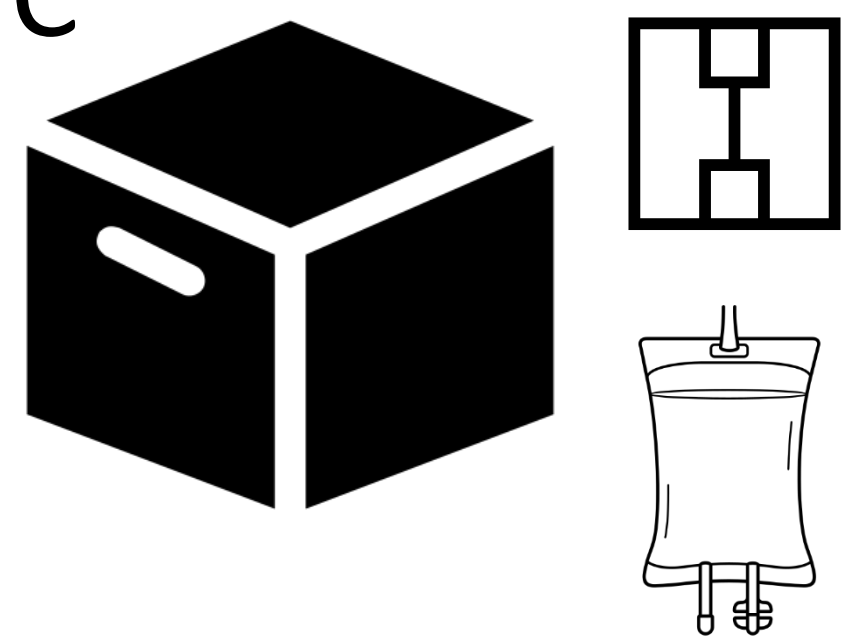
Aim and objectives

The aim of this work is to validate the thermal performance of container transfer system between our facility and our back-up ones.

Material and methods


Polystyrene transport container Cryoexpress®

Placed in freezer set at -150°C

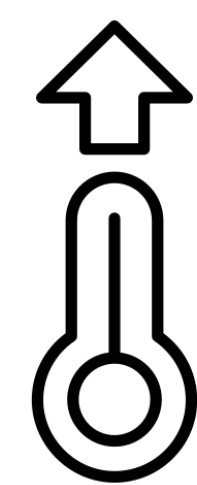


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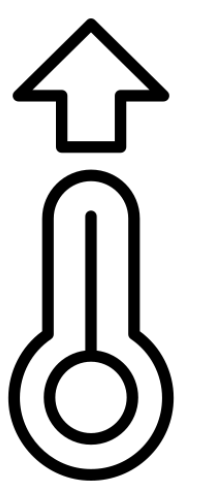
- Sodium chloride bags
- Aluminium cassette used for tisagenlecleucel

 Emerald® sensor, Oceaview® software

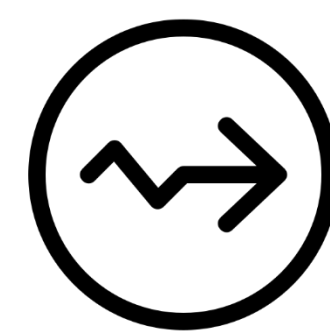
Real time monitoring temperature inside it



Mimic a temperature excursion
Freezer set on -140°C

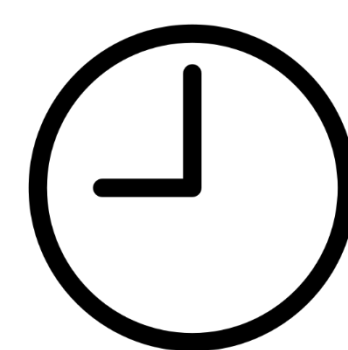


After temperature stabilization, freezer was opened, container hermetically closed, container left in room



Temperature each 30 seconds till overrun of -120°C

- Room temperature +20°C
- Worst case > +30°C



Transfer time to back-up freezer

Two different operators in triplicate

Results



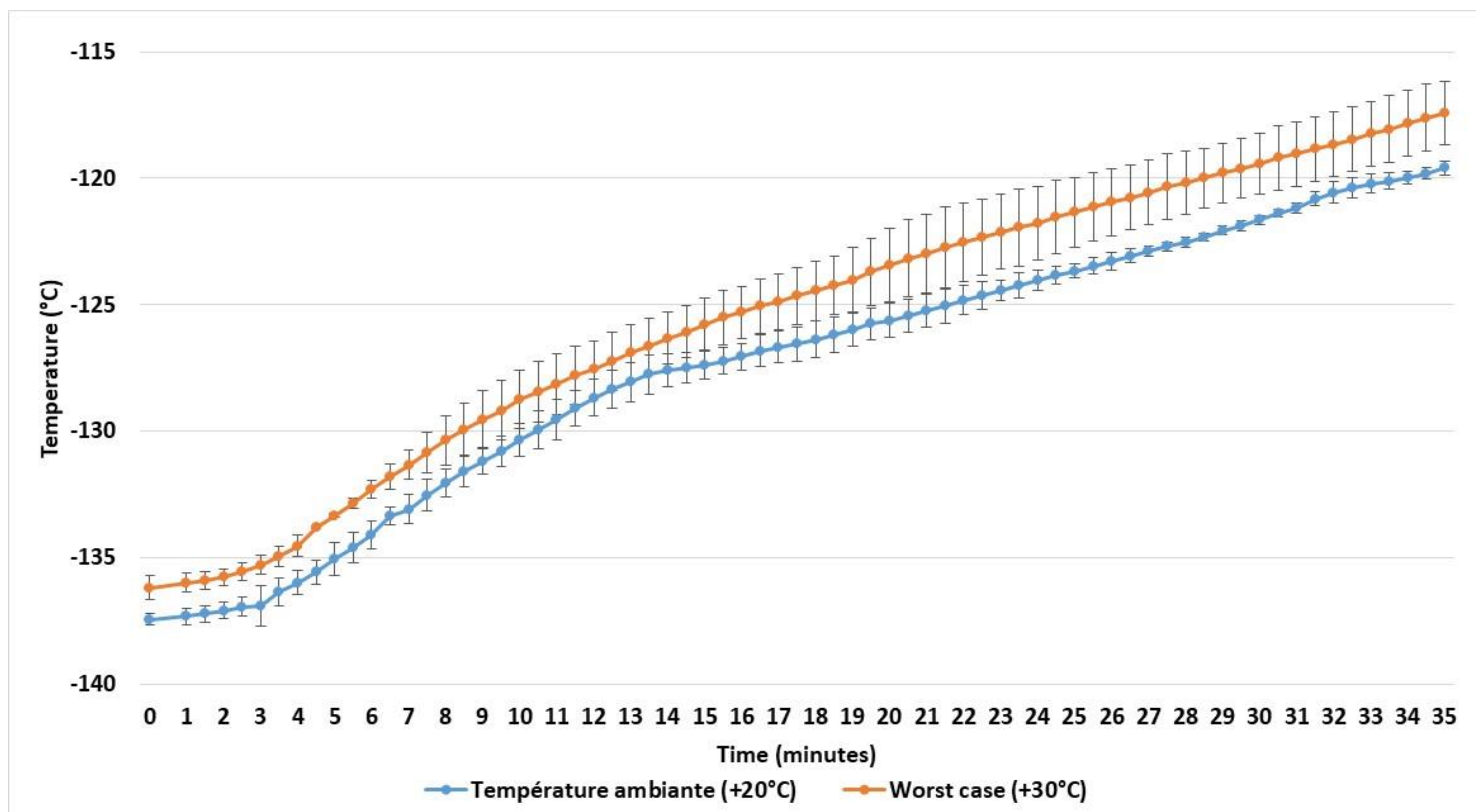
Température maintenue < -120°C

Room +20°C

Room +30°C

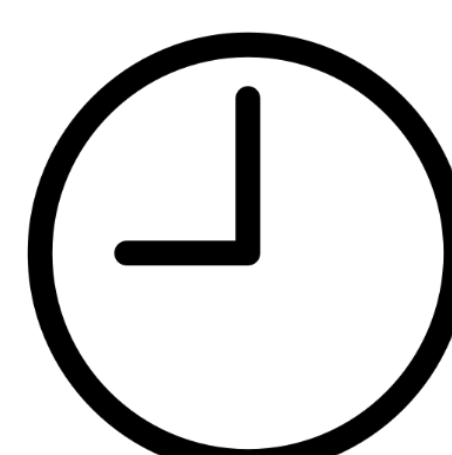
33'30''

28'



Conclusion and relevance

Transfer duration to back up installation is far lower than time during which an optimum storage temperature for tisagenlecleucel is maintained with our transport system



Transfer from pharmacy to back-up

03'15'' ± 0,25