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Allouis E., Renault-Mahieux M., Malluile E., Veillard V., Saeed W., Marque S., Paul M., Carvalho M. - Hospital Henri Mondor, 51 avenue du maréchal de Lattre de Tassigny, Créteil

## Introduction & objective

Cytotoxic preparations require transportation adapted to their conservation temperature in order to guarantee stability, efficacy and safety. Respecting the cold chain is essential, especially with longer transport times when subcontracting. Isothermal cases qualified by the suppliers are commonly used for the transport of cytotoxic preparations, are they really usable?

**OBJECTIVE :** Qualify the 2-hour routing of heat-sensitive cytotoxic preparations for the implementation of a subcontract

## Materials & methods

➤ **Operational qualification** to compare the performance of 3 models of isothermal cases



➤ Temperature measurements with :

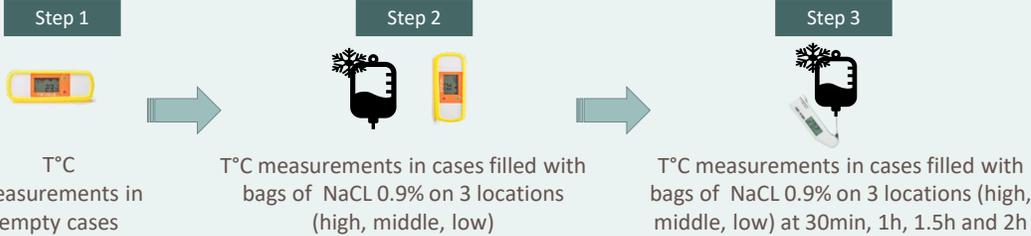
- **Temperature recorder** : measurement in cases every minute during 8.5h
  - **Probe thermometer** : visual measurement in bags at 30min, 1h, 1.5h and 2h
- Eutectics are placed at the top and bottom for models 1 and 3 and only at the top for model 2. Eutectics were conditioned at -20°C during 48h.

➤ Cases were placed in a climatic chamber (25±2°C ; Hygrometry 60±5%) → **controlled storage conditions.**

➤ Bags were conditioned at à 5±3°C. Same filling volume for each cases.

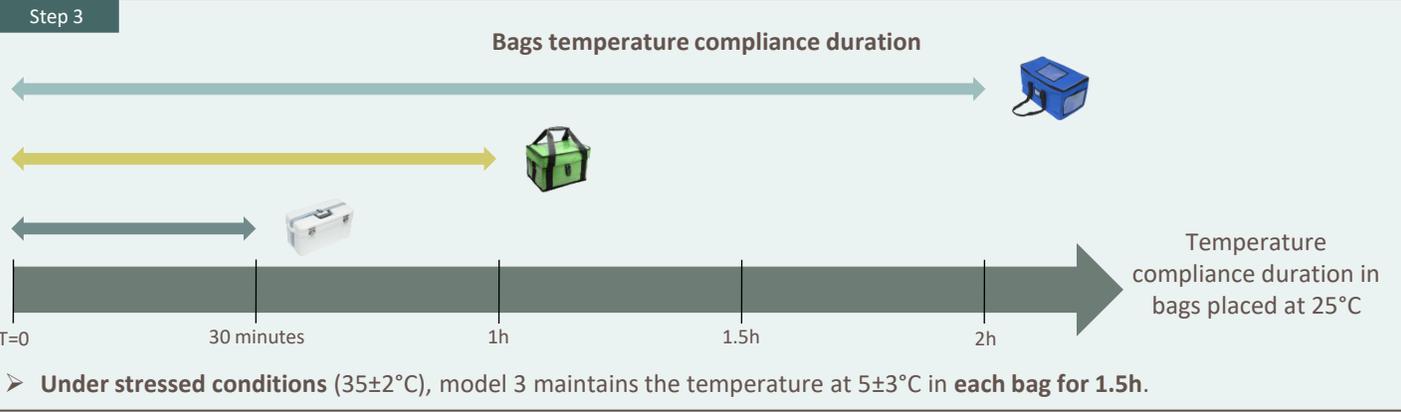
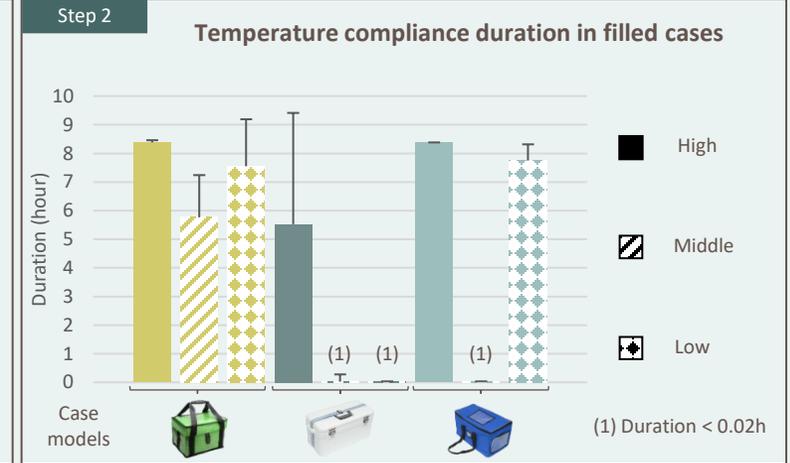
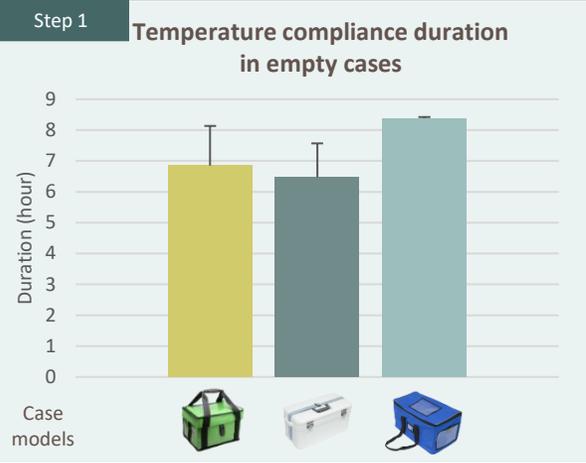
➤ Temperatures measured considered **compliant between 2 and 8°C.**

➤ Qualification in 3 steps :



- For the best performing cases → test under **stressed conditions** (35±2°C) with step 3 settings.
- Test carried out in triplicate.

## Results



## Discussion & Conclusion

No-load tests showed that the temperature was maintained for much less time than announced by the suppliers (model 1: 6.85h against 18h announced by the supplier; model 2: 6.5h against 8h). The cases are actually designed for the transport of biological samples. Tests with bags show that temperature retention is better when the bag is placed as close as possible to the eutectics. The results of the measurements inside the bags show that model 3 has a better conservation time at 5±3°C compatible with the estimated transport time for subcontracting and acceptable for high temperatures (35±2°C). Nevertheless, the tests should be continued to validate the circuit for intra-hospital transport with repeated openings.