

# Stability study: thermal stress validation

**Product:** Iron-depleted CAMHB, Ref: E2-333-020

**Objective:**

Limits of storage and shipping conditions for Iron-depleted CAMHB were determined by thermal stress validity studies in accordance with EN ISO 23640:2015 standard.

These studies confirm that product performances are maintained until the expiration date.

These studies consist in simulation of extreme storage and shipping conditions that may occur during delivery and/or storage.

**Study:**

Performances of Iron-depleted CAMHB were assessed with the quality control strains recommended by EUCAST for cefiderocol MIC by using the UMIC Cefiderocol strips.

Performances were assessed at regular periods on product stressed after incubation at different temperatures (Table 1: conditions 1,2 and 3) and then stored at room temperature avoiding light exposure until their expiry date (Table 1: condition 4).

Table 1: Thermal stress and storage conditions

| Condition | Temperature | Duration                              |
|-----------|-------------|---------------------------------------|
| 1         | 40 °C       | 1 day                                 |
| 2         | 25 °C       | 1 day                                 |
| 3         | 40 °C       | 1 day                                 |
| 4         | 2-25 °C     | Until expiry date and 3 months beyond |

Obtained results are compliant, in accordance with the expected MIC values.

Table 2: Cefiderocol MIC results after thermal stress and subsequent storage

| QC strains                        | Expected cefiderocol MIC values | Results |
|-----------------------------------|---------------------------------|---------|
| - <i>E. coli</i> ATCC 25922       | 0.06 - 0.5 µg/mL                | Pass    |
| - <i>P. aeruginosa</i> ATCC 27853 | 0.06 - 0.5 µg/mL                |         |

**Note:**

This document does not authorize:

- The storage of Iron-depleted CAMHB at any other storage conditions than mentioned on the label and in the instructions for use (2 - 25 °C in the dark),
- The use of these devices after their expiration date.

R&D representative

*S. Frisch*

Effective date

*2022-08-05, Bamheim*