

Stability study: thermal stress validation



Product: UMIC CEFIDEROCOL Ref: UM-CID-040

Objective:

Limits of storage and shipping conditions for the UMIC CEFIDEROCOL kit 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 the strips of UMIC CEFIDEROCOL kit were assessed with the quality control strains recommended by EUCAST.

Performances were assessed at regular period on product stressed by 6 months of incubation at 40°C. Obtained results are compliant, in accordance with the expected MIC values.

QC strains	Expected 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 the UMIC CEFIDEROCOL kit at any other storage conditions than mentioned on the label and in the instructions for use (+15/+25°C).
- The use of these devices after their expiration date.

R&D representative

S. Frisch

Effective date

Bornheim, 02-08-2022