

Stability study: thermal stress validation

Product: UMIC COLISTIN Ref: UM-COL-040

Objective:

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

Performances were assessed at regular period on product stressed by 10 days of incubation at 45°C and then stored at room temperature, until their expiry date. Strips stored at recommended conditions were used as reference.

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

QC strains	Expected MIC values	Results
- <i>E. coli</i> ATCC 25922	0.25-2 µg/mL	Pass
- <i>P. aeruginosa</i> ATCC 27853	0.5-4 µg/mL	
- <i>E. coli</i> DSM 105182 (<i>mcr-1</i>)	2-8 µg/mL*	

*MIC target value is 4 mg/L and should only on occasion be 2 or 8 µg/mL.

Note:

This document does not authorize:

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

Responsable Qualité / Quality Manager

Date d'application et visa / Effective date and visa

25.05.2022

