

Stability study: thermal stress validation



Product: Mueller Hinton II Ref: UM-MH-020

Objective:

Limits of storage and shipping conditions for the Mueller Hinton II 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 its expiration date.

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

Study:

Performances of the vials of Mueller Hinton II kit were assessed with the quality control strains recommended by EUCAST.

Performances were assessed at regular period 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. Vials stored at recommended conditions (2-8°C or 15-25°C avoiding light exposure) were used as reference (Table 1: conditions 4 and 5).

Table 1: Thermal stress conditions

Conditions	Temperature	Period
1	37°C	5 days
2	50°C	1 day
3	-20°C	1 day
4	2-8°C	Storage condition
5	15-25°C	Storage condition

Evaluated parameters are displayed in Table 2: for each condition, results obtained are conform, in accordance with expected values.

Table 2: Evaluated parameters

Evaluated parameter	Results	
Appearance: Clear, pale to light yellow	Pass	
pH : 7.3 ± 0.2	Pass	
Performances: Broth microdilution ; Inoculum : 5x10 ⁵ CFU/mL ; Incubation : 35 ± 1 °C, 18-24h		
E. coli ATCC 25922	Colistin Piperacillin-tazobactam	Pass
P. aeruginosa ATCC 27853		Pass
E. coli DSM 105182 (mcr-1)	Colistin	Pass
E. coli ATCC 35218 (bla _{TEM-1})	Piperacilin-tazobactam	Pass
S. aureus ATCC 29213	Vancomycin, Teicoplanin, Daptomycin, Linezolid	Pass
E. faecalis ATCC 29212		Pass

Note:

This document does not authorize:

- The storage of the Mueller Hinton II kit at any other storage conditions than mentioned on the label and in the instructions for use (+2/+25°C avoiding light exposure),
- The use of the Mueller Hinton II kit after its expiration date.

Quality Manager

Effective date and visa

25.05.2022