Thermo SCIENTIFIC

SENSITITRE® QUALITY CONTROL RESULTS

FORMAT: **EUVSEC2** BATCH NO: **B5392**

DATE MANUFACTURED: 2025-09-23 EXPIRY DATE: 2027-09-23

SIGNED: CERTIFICATE ISSUE DATE: 2025-10-07

K.Moore, P. Goncearov
(Quality Control Shift Lead)

RESULTS SUMMARY

1. Contamination	Pass
2. Positive growth control	Pass
3. Negative growth control	N/A
4. Packaging	Pass
5. Performance.	Pass

Inoculum broth. Mueller hinton broth supplemented to divalent cation level of 12.5mg Mg^{++} / L and 25mg Ca^{++}/ L.
Inoculum – $1x10^5$ cfu / ml.

* Acceptable Quality Control Ranges of Minimum Inhibitory Concentrations (MICs µg/ml) for Reference Strains – CLSI M7 (M100).

** Sensititre® Development Range.

ANTIMICROBIC	***S. aureus***		***E. faecalis***	
	ATCC 29213		**ATCC 29212**	
	Range*	**Result**	**Range***	**Result**
	MIC (µg / ml)		**MIC (µg / ml)**	
CEFOXITIN	1 – 4	4		
CEFOTAXIME	1 – 4	2		
ERTAPENEM	0.06 – 0.25	0.12	4 – 16	> 2
TEMOCILLIN	128 – 512 **	> 128		
IMIPENEM	0.015 – 0.06	≤ 0.12	0.5 – 2	0.5 – 1
MEROPENEM	0.03 – 0.12	0.06 – 0.12	2 – 8	2 – 4
CEFTAZIDIME	4 – 16	8		
CEFEPIME	1 – 4	2		

ANTIMICROBIC	***E. coli***		***P. aeruginosa***	
	ATCC 25922		**ATCC 27853**	
	Range *	**Result**	**Range ***	**Result**
	MIC (µg / ml)		**MIC (µg / ml)**	
CEFOXITIN	2 – 8	4		
CEFOTAXIME	0.03 – 0.12	≤ 0.25	8 – 32	16
ERTAPENEM	0.004 – 0.015	≤ 0.015	2 – 8	> 2
TEMOCILLIN	8 – 32 **	8 – 16	128 – 512 **	128
IMIPENEM	0.06 – 0.5	≤ 0.12	1 – 4	1 – 2
MEROPENEM	0.008 – 0.06	≤ 0.03	0.12 – 1	0.25 – 0.5
CEFTAZIDIME	0.06 – 0.5	≤ 0.25	1 – 4	1 – 2
CEFEPIME	0.015 – 0.12	≤ 0.06	0.5 – 4	1

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ANTIMICROBIC	***K. pneumoniae***
	ATCC 700603
	Result
	MIC (µg / ml)
CEFOTAXIME	2
CEFOTAXIME / CLAVULANIC ACID	0.25 / 4
CEFTAZIDIME	16 – 32
CEFTAZIDIME / CLAVULANIC ACID	0.5 / 4

Pass criteria is where the presence of 4µg/ml of clavulanic acid results in a decrease in MIC of 3 or more doubling dilutions.

Cefotaxime and Ceftazidime must give MICs of ≥ 2µg/ml.