Thermo SCIENTIFIC

SENSITITRE® QUALITY CONTROL RESULTS

FORMAT: **EUVENC** BATCH NO: **B5443**

DATE MANUFACTURED: 2025-10-29 EXPIRY DATE: 2027-10-29

SIGNED: CERTIFICATE ISSUE DATE: 2025-11-07

P. Goncearov
(Quality Control Manager)

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)**	
VANCOMYCIN	0.5 – 2	≤ 1	1 – 4	2
TEICOPLANIN	0.25 – 1	≤ 0.5	0.12 – 0.5 **	≤ 0.5
QUINUPRISTIN / DALFOPRISTIN	0.25 – 1	≤ 0.5	2 – 8	8
TETRACYCLINE	0.12 – 1	≤ 1	8 – 32	16
DAPTOMYCIN	0.12 – 1	≤ 0.25 – 0.5	1 – 4	1 – 2
CIPROFLOXACIN	0.12 – 0.5	0.5	0.25 – 2	0.5 – 1
ERYTHROMYCIN	0.25 – 1	≤ 1	1 – 4	2 – 4
TIGECYCLINE	0.03 – 0.25	0.06 – 0.12	0.03 – 0.12	≤ 0.03 – 0.12
LINEZOLID	1 – 4	2	1 – 4	1 – 2
GENTAMICIN	0.12 – 1	≤ 8	4 – 16	≤ 8
AMPICILLIN	0.25 – 1 **	≤ 0.5	0.5 – 2	1
CHLORAMPHENICOL	2 – 16	8	4 – 16	≤ 4

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ANTIMICROBIC	*E. coli*		*P. aeruginosa*	
	ATCC 25922		ATCC 27853	
	Range *	Result	Range *	Result
	MIC (µg / ml)		MIC (µg / ml)	
TETRACYCLINE	0.5 – 2	≤ 1	8 – 32	16
CIPROFLOXACIN	0.004 – 0.015	≤ 0.12	0.12 – 1	0.25
TIGECYCLINE	0.03 – 0.25	0.06 – 0.12		
GENTAMICIN	0.25 – 1	≤ 8	0.5 – 2	≤ 8
AMPICILLIN	2 – 8	4 – 8		
CHLORAMPHENICOL	2 – 8	≤ 4		

ANTIMICROBIC	*E. faecalis*		*E. faecalis*	
	ATCC 29212		ATCC 51299	
	Expected Result	Result	Expected Result	Result
GENTAMICIN	Sensitive ≤ 500	Sensitive ≤ 500	Resistant > 500	Resistant > 500

ANTIMICROBIC	*E. coli*	
	ATCC 35218	
	Range *	Result
	MIC (µg / ml)	
AMPICILLIN	> 32	> 64

5. Performance. (Continued)

On scale MIC obtained by varying inoculum volume and performing off-line dilutions.

ANTIMICROBIC	STRAIN	ATCC NO:	ACCEPTABLE QC RANGE * (µg/ml)	MIC (µg/ml)
VANCOMYCIN	*E. faecalis*	29212	1 – 4	2 – 4
TEICOPLANIN	*S. aureus*	29213	0.25 – 1	0.5
ERYTHROMYCIN	*E. faecalis*	29212	1 – 4	2 – 4
TIGECYCLINE	*E. coli*	25922	0.03 – 0.25	0.06 – 0.12
GENTAMICIN	*E. faecalis*	29212	4 – 16	8 – 16
CHLORAMPHENICOL	*E. faecalis*	29212	4 – 16	4 – 8