

SENSITITRE® QUALITY CONTROL RESULTS

FORMAT: **CMV1AMAF**

BATCH NO: **B3071**

DATE MANUFACTURED: 2013-02-11

EXPIRY DATE: 2015-02-11

SIGNED:



CERTIFICATE ISSUE DATE: 2013-02-28

J.A. Bridger  
(Quality Control Manager)

RESULTS SUMMARY

- |                            |      |
|----------------------------|------|
| 1. Contamination           | Pass |
| 2. Positive growth control | Pass |
| 3. Negative growth control | NA   |
| 4. Packaging               | Pass |
| 5. Performance.            | Pass |

Inoculum broth. Mueller hinton broth supplemented to divalent cation level of 12.5mg Mg<sup>++</sup> /L and 25mg Ca<sup>++</sup>/ L.

Inoculum - 1x10<sup>5</sup> cfu / ml.

\* Acceptable Quality Control Ranges of Minimum Inhibitory Concentrations ( MICs µg/ml ) for Reference Strains - CLSI M (M100)

\*\* Sensititre Development Range.

# Acceptable Quality Control Ranges of Minimum Inhibitory Concentrations ( MICs µg/ml ) for Reference Strains – Veterinary Pathogens M31.

ANTIMICROBIC	<i>S.aureus</i>		<i>E.faecalis</i>	
	ATCC 29213		ATCC 29212	
	Range*	Result	Range*	Result
	MIC (µg / ml)		MIC (µg / ml)	
AMPICILLIN	0.25 – 1 **	0.25, 0.25	0.5 – 2	1, 1
PENICILLIN	0.12 – 1 **	0.25, 0.25	1 – 4	2, 2
ERYTHROMYCIN	0.25 – 1	≤ 0.25 – 0.5 ≤ 0.25 – 0.5	1 – 4	1 – 2 1
OXACILLIN + 2% NaCl	0.12 – 0.5	≤ 2, ≤ 2	8 – 32	>4, >4
PIRLIMYCIN	0.12 – 0.5 **	≤ 0.5, ≤ 0.5	1 – 4 **	2, 2
PENICILLIN/ NOVOBIOCIN	0.015 / 0.03 – 0.06 / 0.12 #	≤ 1 / 2 ≤ 1 / 2	0.25 / 0.5 – 2 / 4 #	≤ 1 / 2 ≤ 1 / 2
TETRACYCLINE	0.12 – 1	≤ 1, ≤ 1	8 – 32	>8, >8
CEPHALOTHIN	0.12 – 0.5	≤ 2, ≤ 2		
CEFTIOFUR	0.25 – 1 #	1, 1		
SULPHADIMETHOXINE			> 256	>256, >256

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	<i>E.coli</i>		<i>P.aeruginosa</i>	
	ATCC 25922		ATCC 27853	
	Range*	Result	Range*	Result
	MIC (µg / ml)		MIC (µg / ml)	
AMPICILLIN	2 – 8	4, 4		
PIRLIMYCIN	> 16 #	>4, >4	> 16 #	>4, >4
PENICILLIN/ NOVOBIOCIN	8 / 16 - > 8 / 16#	8 / 16 - >8 / 16 8 / 16 - >8 / 16	> 8 / 16 #	>8 / 16 >8 / 16
TETRACYCLINE	0.5 – 2	≤ 1, ≤ 1	8 – 32	>8, >8
CEPHALOTHIN	4 – 16	8, 8		
CEFTIOFUR	0.25 – 1 #	≤ 0.5, ≤ 0.5	16 – 64 #	>4, >4
SULPHADIMETHOXINE			> 256	>256, >256

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)
OXACILLIN + 2% NaCl	<i>S.aureus</i>	29213	0.12 – 0.5	0.12 – 0.25 0.12 – 0.25
PIRLIMYCIN	<i>S.aureus</i>	25923	0.25 – 1 **	0.5, 0.5
PENICILLIN/ NOVOBIOCIN	<i>E.faecalis</i>	29212	0.25 / 0.5 – 2 / 4 #	1 / 2 1 / 2
TETRACYCLINE	<i>E.coli</i>	25922	0.5 – 2	1, 1
CEFTIOFUR	<i>E.coli</i>	25922	0.25 – 1 #	0.25 – 0.5 0.5
SULPHADIMETHOXINE	<i>P.aeruginosa</i>	25619	64 – 256 **	128 – 256 128 – 256