

SENSITITRE® QUALITY CONTROL RESULTS

FORMAT:

BOPO6F

BATCH NO: **B3152**

DATE MANUFACTURED: 2013-04-09

EXPIRY DATE: 2015-04-09

SIGNED:



J.A. Bridger
(Quality Control Manager)

CERTIFICATE ISSUE DATE: 2013-04-25

RESULTS SUMMARY

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

Non Fastidious isolates.

Inoculum broth. Sensititre Mueller hinton broth supplemented to divalent cation level of
12.5mg Mg⁺⁺ /L and 25mg Ca⁺⁺ / L.
Inoculum- 1x10⁵ cfu / ml

S.pneumoniae

Inoculum broth. Sensititre Mueller hinton broth supplemented to divalent cation level of
12.5mg Mg⁺⁺ /L and 25mg Ca⁺⁺ / L.+ Lysed Horse Blood.

Inoculum- 5x10⁵ cfu / ml

Inoculum volume 100µl, results quoted have been corrected to allow for panel reconstitution of 50µl.

H.somni and A.pleuropneumoniae

Inoculum broth Sensititre Veterinary fastidious Media (VFM)

Inoculum - 5x10⁵ cfu / ml.

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

** Sensititre® Development Range.

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

SENSITITRE® QUALITY CONTROL RESULTS

FORMAT:

BOPO6F

BATCH NO: B3152

SIGNED:



CERTIFICATE ISSUE DATE: 2013-04-25

J.A. Bridger

(Quality Control Manager)

ANTIMICROBIC	<i>S.aureus</i>		<i>E.faecalis</i>	
	ATCC 29213		ATCC 29212	
	Range*	Result	Range*	Result
	MIC (µg / ml)		MIC (µg / ml)	
CEFTIOFUR	0.25 – 1 #	1		
GENTAMICIN	0.12 – 1	≤ 1	4 – 16	16
FLORFENICOL	2 – 8 #	4	2 – 8 #	2 – 4
TIAMULIN	0.5 – 2 #	1		
CHLORTETRACYCLINE	0.12 – 0.5 **	≤ 0.5	2 – 8 **	4
PENICILLIN	0.12 – 1 **	0.25 – 0.5	1 – 4	2
AMPICILLIN	0.25 – 1 **	0.25 – 0.5	0.5 – 2	1
DANOFLOXACIN	0.06 – 0.25 #	≤ 0.12 – 0.25	0.25 – 1 #	1
TRIMETHOPRIM / SULFAMETHOXAZOLE	≤ 0.5 / 9.5	≤ 2 / 38	≤ 0.5 / 9.5	≤ 2 / 38
SPECTINOMYCIN	64 – 256 #	>64	32 – 128 **	64
TYLOSIN TARTRATE	0.5 – 4 #	2	0.5 – 4 #	2
TULATHROMYCIN	2 – 8 #	8	4 – 32 #	16
TILMICOSIN	0.5 – 2 **	≤ 4	8 – 32 #	16
CLINDAMYCIN	0.06 – 0.25	≤ 0.25	4 – 16	8 – 16
SULPHADIMETHOXINE			> 256 **	>256
ENROFLOXACIN	0.06 – 0.25 **	≤ 0.12	0.12 – 1 #	0.5

	<i>E.coli</i>		<i>P.aeruginosa</i>	
	ATCC 25922		ATCC 27853	
	Range *	Result	Range *	Result
	MIC (µg / ml)		MIC (µg / ml)	
CEFTIOFUR	0.25 – 1 #	0.5	16 – 64 #	>8
GENTAMICIN	0.25 – 1	≤ 1	0.5 – 2	≤ 1
FLORFENICOL	2 – 8 #	4	> 16 #	>8
CHLORTETRACYCLINE	1 – 4 **	1	4 – 16 **	8
OXYTETRACYCLINE	0.5 – 2 **	1 – 2		
AMPICILLIN	2 – 8	4		
DANOFLOXACIN	0.008 – 0.06 #	≤ 0.12	0.5 – 2 #	1
NEOMYCIN	0.5 – 2 **	≤ 4		
TRIMETHOPRIM / SULFAMETHOXAZOLE	≤ 0.5 / 9.5	≤ 2 / 38	8 / 152 – 32 / 608	>2 / 38
SPECTINOMYCIN	8 – 64 #	16	256 - > 512 #	>64
TYLOSIN TARTRATE	> 32 #	>32	> 32 #	>32
TILMICOSIN	≥ 64 **	>64	> 64 **	>64
SULPHADIMETHOXINE			> 256 **	>256
ENROFLOXACIN	0.008 – 0.03 #	≤ 0.12	1 – 4 #	1


SENSITITRE® QUALITY CONTROL RESULTS

FORMAT:

BOPO6F

BATCH NO: B3152

SIGNED:



CERTIFICATE ISSUE DATE: 2013-04-25

J.A. Bridger
(Quality Control Manager)

ANTIMICROBIC	<i>H.somni</i>		<i>A.pleuropneumoniae</i>	
	ATCC 70025		ATCC 27090	
	Range#	Result	Range#	Result
	MIC (µg / ml)		MIC (µg / ml)	
CEFTIOFUR	0.0005 – 0.004	≤ 0.25	0.004 – 0.015	≤ 0.25
GENTAMICIN	4 – 16 **	4 – 8	8 – 32	8 – 16
FLORFENICOL	0.12 – 0.5	≤ 0.25	0.25 – 1	≤ 0.25
TIAMULIN			8 – 32	16
PENICILLIN	0.015 – 0.06	≤ 0.12	0.12 – 1	0.5
DANOFLOXACIN	0.015 – 0.12	≤ 0.12	0.008 – 0.06 **	≤ 0.12
TRIMETHOPRIM / SULFAMETHOXAZOLE	0.03 / 0.57 – 0.12 / 2.38	≤ 2 / 38	0.015 / 0.28 – 0.06 / 1.14	≤ 2 / 38
TULATHROMYCIN	4 – 32	4	8 – 32 **	16
TILMICOSIN	2 – 16	≤ 4	4 – 32	8
ENROFLOXACIN	0.015 – 0.06	≤ 0.12	0.015 – 0.06	≤ 0.12

ANTIMICROBIC	<i>S.pneumoniae</i>	
	ATCC 49619	
	Range *	Result
	MIC (µg/ml)	
FLORFENICOL	1 – 4 #	1 – 2
TIAMULIN	0.5 – 4 #	0.5
PENICILLIN	0.25 – 1	0.25 – 0.5
AMPICILLIN	0.06 – 0.25	≤ 0.12
TRIMETHOPRIM / SULFAMETHOXAZOLE	0.12 / 2.4 – 1 / 19	≤ 1 / 19
TULATHROMYCIN	0.12 – 1 #	≤ 0.5
CLINDAMYCIN	0.03 – 0.12	≤ 0.12

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)
NEOMYCIN	<i>E.coli</i>	25922	0.5 – 2 **	1 – 2
TRIMETHOPRIM / SULFAMETHOXAZOLE	<i>E.coli</i>	35218	0.25 / 4.75 – 1 / 19 **	>0.12 / 2.38 ≤ 0.5 / 9.5
SULPHADIMETHOXINE	<i>P.aeruginosa</i>	25619	64 – 256 **	>64 ≤ 256