



Streptococcus Susceptibility Card

### SUMMARY AND EXPLANATION

The VITEK® 2 Streptococcus Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of ***S. pneumoniae***, **beta-hemolytic Streptococcus**, and **Viridans Streptococcus** to antimicrobial agents when used as instructed in the Product Information manual.

### INSTRUCTIONS FOR USE

A package insert is provided in the kit or downloadable from [www.biomerieux.com/techlib](http://www.biomerieux.com/techlib)

See the Product Information manual for additional Instructions for Use.

### STORAGE CONDITIONS

Store at 2° to 8° C.

### CONTENTS OF THE CARD

Antimicrobial	Code	Concentration §	Calling Range		FDA Indications for Use
			≤	≥	
Ampicillin <sup>NS2</sup>	AM	0.5, 1, 4, 8	0.25	16	grpBetaHS**, grpVIR**
Benzylpenicillin <sup>NS2</sup>	P	0.06, 0.12, 0.5, 2	0.06	8	grpC/G**, <i>S. pyogenes</i> , <i>S. agalactiae</i> , <i>S. pneumoniae</i> , grpVIR**
Cefotaxime	CTX	0.25, 0.5, 1, 2	0.12	8	<i>S. pneumoniae</i> , SpyA**, <i>Streptococcus</i> spp.
Ceftriaxone <sup>NS2</sup>	CRO	0.12, 0.25, 1, 4	0.12	8	grpVIR**, <i>S. agalactiae</i> , <i>S. pneumoniae</i> , <i>S. pyogenes</i>
Chloramphenicol	C	1, 4, 8	1	16	N/A**
Clindamycin <sup>c</sup>	CM	CM 0.12, CM 0.25, CM 0.5, CM/E 0.5/0.1	0.25	1	SP(Pen(S))**, <i>S. pyogenes</i> , <i>S. agalactiae</i> , <i>S. mitis</i> , <i>S. oralis</i>
Erythromycin	E	1, 2, 4, 16	0.12	8	<i>S. pneumoniae</i> , <i>S. pyogenes</i> , grpVIR**
Gentamicin	GM	512, 1024	64	512	N/A**
Inducible Clindamycin Resistance <i>S. agalactiae</i> , <i>S. pyogenes</i>	ICR	CM 0.5, CM/E 0.25/0.5	- NEG	- POS	<i>S. agalactiae</i> , <i>S. pyogenes</i>
Levofloxacin	LEV	1, 2, 4, 16	0.25	16	SP+MDRSP**, <i>S. pyogenes</i> , grpC/F**, grpG**, <i>S. agalactiae</i> , grpVIR**, <i>S. milleri</i>
Linezolid <sup>NS</sup>	LNZ	2, 4	2	8	SP+MDRSP**, <i>S. agalactiae</i> , <i>S. pyogenes</i>
Moxifloxacin	MXF	0.5, 1, 4, 8	0.06	4	<i>S. anginosus</i> , <i>S. constellatus</i> , SP+MDRSP**, <i>S. pyogenes</i> , <i>S. agalactiae</i> , grpVIR**
Rifampicin	RA	0.015, 0.03, 0.12, 0.5	0.06	4	N/A**
Teicoplanin	TEC	0.5, 1, 4	0.12	4	N/A**
Tetracycline	TE	0.12, 0.5, 1, 4	0.25	16	<i>S. pneumoniae</i> , <i>S. pyogenes</i> , grpVIR**
Tigecycline <sup>NS</sup>	TGC	0.12, 0.25, 0.5	0.06	1	SP(Pen(S))**, <i>S. anginosus</i> grp. (includes <i>S. anginosus</i> , <i>S. intermedius</i> , and <i>S. constellatus</i> ), <i>S. agalactiae</i> , <i>S. pyogenes</i>
Trimethoprim/Sulfamethoxazole <sup>c</sup>	SXT	8/152, 16/304, 64/1216	10 (0.5/9.5)	320 (16/304)	<i>S. pneumoniae</i>
Vancomycin <sup>NS</sup>	VA	0.5, 1, 2, 4	0.12	8	grpVIR**, <i>S. pyogenes</i> , <i>S. agalactiae</i>

Numerical values are expressed in µg/ml.

§ Equivalent standard method concentration by efficacy.

<sup>NS2</sup> = Beta-hemolytic Streptococci: The current absence of resistant isolates precludes defining any results other than susceptible. Isolates yielding MIC results suggestive of Nonsusceptible category should be submitted to a reference laboratory for further testing.

\*\*grpBetaHS = Beta-hemolytic group Streptococcus species

\*\*grpVIR = Viridans group Streptococcus

\*\*grpC/G = Beta-hemolytic Streptococcus groups C and G

\*\*SpyA = *S. pyogenes* (Group A beta-hemolytic streptococci)

\*\*N/A = No specific FDA Indications for Use available

<sup>c</sup> = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.

\*\*SP(Pen(S)) = *S. pneumoniae* (penicillin-susceptible strains)

NEG = Negative

POS = Positive

\*\*SP+MDRSP = *S. pneumoniae* (including multi-drug resistant strains (MDRSP))

\*\*grpC/F = Beta-hemolytic Streptococcus groups C and F

\*\*grpG = Beta-hemolytic Streptococcus group G

<sup>NS</sup> = The current absence of resistant isolates precludes defining any results other than susceptible. Isolates yielding MIC results suggestive of Nonsusceptible category should be submitted to a reference laboratory for further testing.

## QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results		
Antimicrobial	Code	<i>S. pneumoniae</i> ATCC® 49619™	<i>S. aureus</i> ATCC® 29213™	<i>S. aureus</i> ATCC® BAA-977™
Ampicillin <sup>NS2</sup>	AM	≤0.25	-	-
Benzylpenicillin <sup>NS2</sup>	P	0.25 – 1	-	-
Cefotaxime	CTX	≤0.12* <i>(*Broth Microdilution for FDA expected QC range is 0.06 – 0.25 and CLSI is 0.03 – 0.12 µg/ml)</i>	-	-
Ceftriaxone <sup>NS2</sup>	CRO	≤0.12* <i>(*Broth Microdilution for FDA and CLSI expected QC range = 0.03 – 0.12 µg/ml)</i>	-	-
Chloramphenicol	C	2 – 8	-	-
Clindamycin <sup>c</sup>	CM	≤0.25	-	-
Erythromycin	E	≤0.12	-	-
Gentamicin	GM	≤64	-	-
Inducible Clindamycin Resistance <i>S. agalactiae, S. pyogenes</i>	ICR	-	NEG	POS
Levofloxacin	LEV	0.5 – 2	-	-
Linezolid <sup>NS</sup>	LNZ	≤2	-	-
Moxifloxacin	MXF	≤0.06 – 0.25	-	-
Rifampicin	RA	≤0.06	-	-
Teicoplanin	TEC	≤0.12	-	-
Tetracycline	TE	≤0.25 – 0.5	-	-
Tigecycline <sup>NS</sup>	TGC	≤0.06 – 0.12	-	-
Trimethoprim/Sulfamethoxazole <sup>c</sup>	SXT	≤10 (0.5/9.5) – 20 (1/19)	-	-
Vancomycin <sup>NS</sup>	VA	≤0.12 – 0.5	-	-

Numerical values are expressed in µg/ml.

<sup>NS2</sup> = Beta-hemolytic Streptococci: The current absence of resistant isolates precludes defining any results other than susceptible. Isolates yielding MIC results suggestive of Nonsusceptible category should be submitted to a reference laboratory for further testing.

<sup>c</sup> = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.

NEG = Negative

POS = Positive

<sup>NS</sup> = The current absence of resistant isolates precludes defining any results other than susceptible. Isolates yielding MIC results suggestive of Nonsusceptible category should be submitted to a reference laboratory for further testing.

## LIMITATIONS

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Erythromycin: *Streptococcus mitis, S. oralis, S. parasanguinis*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:











- Benzylpenicillin: *S. pneumoniae* (based on the breakpoints for pneumonia)
- Linezolid: *S. pneumoniae*, *S. agalactiae*, *S. pyogenes*
- Tigecycline: *S. pneumoniae* (penicillin-susceptible strains), *S. anginosus*, *S. intermedius*, *S. constellatus*, *S. agalactiae*, *S. pyogenes*
- Vancomycin: *Streptococcus agalactiae*, *Streptococcus pyogenes*, *Viridans* group *Streptococcus*

**NOTE:** A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

↓ MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.



## INDEX OF SYMBOLS

Symbol	Meaning
	Catalogue number
	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
	Temperature limitation
	Use by
	Batch code
	Consult Instructions for Use
	Contains sufficient for <n> tests
	Authorized representative in the European Community

## PATENTS

Product covered by one or more of U.S. Patent Nos. D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 and 6,340,573; and Foreign Counterparts. Other Patents Pending.

## WARRANTY

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