VITEK 2™ — technology

AST-GP75

IVD

Staphylococcus spp., *Enterococcus* spp. and *S. agalactiae* Susceptibility

SUMMARY AND EXPLANATION

The VITEK® 2 Gram Positive Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of ***Staphylococcus* spp., *Enterococcus* spp., and *S. agalactiae*** 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**

See the Product Information manual for additional Instructions for Use.

STORAGE CONDITIONS

Store at 2° to 8° C.

CONTENTS OF THE CARD

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Ampicillin *Enterococcus* spp. *S. agalactiae*	AM	0.5, 4, 8, 32	- 2 0.25	- 32 16	*Enterococcus* spp., *S. agalactiae*
Cefoxitin Screen	OXSF	6	NEG	POS	*Staphylococcus* spp.
Ciprofloxacin	CIP	1, 2, 4	0.5	8	*Staphylococcus* spp., *Enterococcus* spp.
Clindamycin	CM	0.06, 0.25, 1	0.125	4	MSSA**, MSSE**
Daptomycin [NS]	DAP	0.5, 1, 2, 4, 16	0.12	8	*S. aureus*, VSEfaeca**
Doxycycline	DO	0.25, 1, 2, 4	0.5	16	*S. aureus*
Erythromycin	E❶	0.25, 0.5, 2	0.25	8	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Gentamicin	GM	8, 16, 64	0.5	16	*Staphylococcus* spp.
Gentamicin High Level (synergy)	HLG	500	S	R	*Enterococcus* spp.
Inducible Clindamycin Resistance	ICR❷	CM 0.5, CM/E 0.25/0.5	NEG	POS	*Staphylococcus* spp.
Levofloxacin	LEV	0.25, 2, 8	0.12	8	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Linezolid	LNZ	0.5, 1, 2	0.5	8	*S. agalactiae*, *E. faecalis*, *E. faecium*, *S. aureus*, *S. epidermidis*, *S. haemolyticus*
Moxifloxacin	MXF	0.25, 2, 8	0.25	8	MSSA**
Nitrofurantoin	FT	16, 32, 64	16	512	*Staphylococcus* spp., *Enterococcus* spp.
Oxacillin	OX1	0.5, 1, 2	0.25	4	*Staphylococcus* spp.
Rifampicin	RA	0.25, 0.5, 2	0.5	32	*Staphylococcus* spp.
Streptomycin High Level (synergy)	HLS	1000	S	R	*Enterococcus* spp.
Tetracycline	TE	0.5, 1, 2	1	16	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Tigecycline [NS]	TGC	0.25, 0.5, 1	0.12	2	*E. faecalis*, *E. faecium*, *S. aureus*, *S. epidermidis*, *S. haemolyticus*, *S. agalactiae*, *E. casseliflavus*
Trimethoprim/Sulfamethoxazole [c]	SXT❶	2/38, 8/152, 16/304	10 (0.5/9.5)	320 (16/304)	*S. aureus*
Vancomycin	VA❷	1, 2, 4, 8, 16	0.5	32	*Enterococcus* spp., *Staphylococcus* spp., *S. agalactiae*

Numerical values are expressed in µg/ml.
§ Equivalent standard method concentration by efficacy.
NEG = Negative
POS = Positive

**MSSA = Methicillin-susceptible *S. aureus*
**MSSE = Methicillin-susceptible *S. epidermidis*
NS = 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.
**VSEfaeca = *E. faecalis* (vancomycin susceptible strains)
❶,❷ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.
c = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.

QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results					
Antimicrobic	Code	*E. faecalis* ATCC® 29212™	*S. aureus* ATCC® 29213™	*E. faecalis* ATCC® 51299™	*S. aureus* ATCC® BAA-1026™	*S. aureus* ATCC® BAA-976™	*S. aureus* ATCC® BAA-977™
Ampicillin *Enterococcus* spp. *S. agalactiae*	AM	≤2	0.5 – 2	-	-	-	-
Cefoxitin Screen	OXSF	-	NEG	-	POS	-	-
Ciprofloxacin	CIP	≤0.5 – 2	≤0.5	-	-	-	-
Clindamycin	CM	≥4	≤0.12 – 0.25* *(*FDA/CLSI Broth Microdilution expected QC range = 0.06 – 0.25 µg/ml)*	-	-	-	-
Daptomycin[NS]	DAP	1 – 4	0.25 – 1	-	-	-	-
Doxycycline	DO	2 – 8	≤0.5	-	-	-	-
Erythromycin	E	1 – 4	≤0.25 – 1	-	-	-	-
Gentamicin	GM	-	≤0.5 – 1	-	-	-	-
Gentamicin High Level (synergy)	HLG	S	-	R	-	-	-
Inducible Clindamycin Resistance	ICR	-	-	-	-	NEG	POS
Levofloxacin	LEV	0.25 – 2	≤0.12 – 0.5	-	-	-	-
Linezolid	LNZ	1 – 4	1 – 4	-	-	-	-
Moxifloxacin	MXF	≤0.25 – 0.5	≤0.25	-	-	-	-
Nitrofurantoin	FT	≤16	≤16 – 32	-	-	-	-
Oxacillin	OX1	-	≤0.25 – 0.5	-	-	-	-
Rifampicin	RA	-	≤0.5	-	-	-	-
Streptomycin High Level (synergy)	HLS	S	-	R	-	-	-
Tetracycline	TE	8 – ≥16	≤1	-	-	-	-
Tigecycline[NS]	TGC	≤0.12	≤0.12 – 0.25	-	-	-	-
Trimethoprim/Sulfamethoxazole[c]	SXT	-	≤10 (0.5/9.5)	-	-	-	-
Vancomycin	VA	1 – 4	≤0.5 – 2	-	-	-	-

Numerical values are expressed in µg/ml.
NEG = Negative
POS = Positive
NS = 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.
c = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.

LIMITATIONS

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):
- Daptomycin: *Streptococcus agalactiae*
- Erythromycin: *Streptococcus agalactiae*

Perform an alternative method of testing prior to reporting of results when a Positive (+) result is obtained with the following antibiotic/organism combination(s):
- Cefoxitin Screen: *Staphylococcus saprophyticus*

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:
- Ampicillin: *Streptococcus agalactiae*
- Linezolid: *Enterococcus* spp., *Staphylococcus* spp., *Streptococcus agalactiae*
- Tigecycline: *Enterococcus* spp., *Staphylococcus* spp., *Streptococcus* spp.

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.

01 A3207G0P---R

02 BAST-GP7501H

03 C---Z0D370HP

04 D473X3Y0I196

05 E183I132N2R6

06 F0V200X1E1HC

07 G3K343L-S-FC

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
Σ	Contains sufficient for <n> tests
EC REP	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.

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