



Gram Negative Susceptibility Card

SUMMARY AND EXPLANATION

The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of **clinically significant aerobic gram-negative bacilli** 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

Antimicrobial	Code	Concentration §	Calling Range		FDA Indications for Use
			≤	≥	
Amikacin	AN	8, 16, 64	2	64	CSAGNB**
Amoxicillin/Clavulanic Acid	AMC	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Ampicillin	AM	4, 8, 32	2	32	CSAGNB**
Cefazolin	CZ	4, 16, 64	4	64	CSAGNB**
Cefepime	FEP	2, 8, 16, 32	1	64	CSAGNB**
Cefoxitin	FOX	8, 16, 32	4	64	CSAGNB**
Ceftazidime	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Ceftriaxone	CRO	1, 2, 8, 32	1	64	CSAGNB**
Ciprofloxacin	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Ertapenem ^c	ETP	0.5, 1, 6	0.5	8	<i>E. coli</i> , <i>K. pneumoniae</i> , <i>C. freundii</i> , <i>C. koseri</i> , <i>E. aerogenes</i> , <i>E. cloacae</i> , Kox(-ESBL)** , <i>M. morgani</i> , <i>P. mirabilis</i> , <i>P. vulgaris</i> , <i>S. marcescens</i>
Gentamicin	GM	4, 16, 32	1	16	CSAGNB**
Levofloxacin	LEV	0.25, 0.5, 2, 8	0.12	8	<i>E. cloacae</i> , <i>E. coli</i> , <i>K. pneumoniae</i> , <i>P. mirabilis</i> , <i>P. aeruginosa</i> , <i>S. marcescens</i> , <i>A. baumannii</i> , <i>A. lwoffii</i> , <i>C. koseri</i> , <i>C. freundii</i> , <i>E. aerogenes</i> , <i>E. sakazakii</i> , <i>K. oxytoca</i> , <i>M. morgani</i> , <i>P. agglomerans</i> , <i>P. vulgaris</i> , <i>Pv. rettgeri</i> , <i>Pv. stuartii</i> , <i>P. fluorescens</i> , <i>C. sakazakii</i>
Meropenem	MEM	0.5, 2, 6, 12	0.25	16	<i>E. coli</i> , <i>K. pneumoniae</i> , <i>P. aeruginosa</i> , <i>P. mirabilis</i> , <i>Acinetobacter spp.</i> , <i>C. freundii</i> , <i>E. cloacae</i> , <i>K. oxytoca</i> , <i>M. morgani</i> , <i>P. vulgaris</i> , <i>S. marcescens</i> , <i>A. hydrophila</i> , <i>C. diversus</i> , <i>H. alvei</i> , <i>P. multocida</i> , <i>Salmonella spp.</i> , <i>Shigella spp.</i>
Nitrofurantoin	FT	16, 32, 64	16	512	CSAGNB**
Piperacillin/Tazobactam ^c	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	<i>A. baumannii</i> , <i>E. coli</i> , <i>K. pneumoniae</i> , <i>P. aeruginosa</i> , <i>C. koseri</i> , <i>M. morgani</i> , <i>P. mirabilis</i> , <i>P. vulgaris</i> , <i>Pv. rettgeri</i> , <i>Pv. stuartii</i> , <i>S. enterica</i>
Tetracycline	TE	2, 4, 8	1	16	CSAGNB**
Tobramycin	TM	8, 16, 64	1	16	CSAGNB**

Trimethoprim/Sulfamethoxazole	SXT [Ⓢ]	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	<i>Klebsiella</i> spp., <i>Enterobacter</i> spp., <i>M.morganii</i> , <i>P. vulgaris</i> , <i>P. mirabilis</i> , <i>S. sonnei</i> , <i>S. flexneri</i> , Eco(+ETEC)**, <i>C. sakazakii</i>
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Numerical values are expressed in µg/ml.

§ Equivalent standard method concentration by efficacy.

**CSAGNB = Clinically significant aerobic gram negative bacilli

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

**Kox(-ESBL) = *K. oxytoca* (excluding ESBL producing strains)

Ⓢ, Ⓣ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.

**Eco(+ETEC) = *E. coli* (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results		
Antimicrobial	Code	<i>E. coli</i> ATCC® 25922™	<i>P. aeruginosa</i> ATCC® 27853™	<i>E. coli</i> ATCC® 35218™
Amikacin	AN	≤2 – 4	≤2 – 4	-
Amoxicillin/Clavulanic Acid	AMC	≤2/1 – 8/4	-	4/2 – 16/8
Ampicillin	AM	≤2 – 8	-	-
Cefazolin	CZ	≤4	-	-
Cefepime	FEP	≤1	≤1 – 8	-
Cefoxitin	FOX	≤4 – 8	-	-
Ceftazidime	CAZ	≤1	≤1 – 4	-
Ceftriaxone	CRO	≤1	8 – ≥64	-
Ciprofloxacin	CIP	≤0.25	≤0.25 – 1	-
Ertapenem ^c	ETP	≤0.5	2 – ≥8	-
Gentamicin	GM	≤1	≤1 – 2	-
Levofloxacin	LEV	≤0.12	0.5 – 4	-
Meropenem	MEM	≤0.25	≤0.25 – 1	-
Nitrofurantoin	FT	≤16	-	-
Piperacillin/Tazobactam ^c	TZP	≤4/4* (*FDA/CLSI Broth Microdilution expected QC range = 1/4 – 4/4 µg/ml)	≤4/4 – 8/4* (*FDA/CLSI Broth Microdilution expected QC range = 1/4 – 8/4 µg/ml)	≤4/4* (*FDA/CLSI Broth Microdilution expected QC range = 0.5/4 – 2/4 µg/ml)
Tetracycline	TE	≤1 – 2	8 – ≥16	-
Tobramycin	TM	≤1	≤1	-
Trimethoprim/Sulfamethoxazole	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-

Numerical values are expressed in µg/ml.

^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):

- Amikacin: *Acinetobacter baumannii*
- Amoxicillin/Clavulanic Acid: *Providencia* spp.
- Ampicillin: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Piperacillin/Tazobactam: *Serratia marcescens*

Perform an alternative method of testing prior to reporting of results when an intermediate or resistant result is obtained with the following antibiotic/organism combination(s):

- Amoxicillin/Clavulanic Acid: *Proteus* spp.

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):

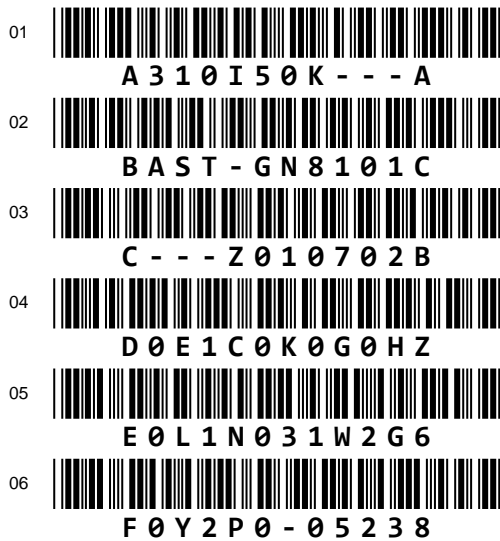
- Meropenem: *Aeromonas* spp.
- Piperacillin/Tazobactam: *Pseudomonas aeruginosa*

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:











- Ertapenem: *E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, *K. oxytoca* (excluding ESBL producing strains), *M. morgani*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*

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.


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