VITEK 2™ — technology

AST-XN08

IVD

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

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Amikacin	AN	8, 16, 64	2	64	CSAGNB**
Aztreonam	ATM	2, 8, 32	1	64	CSAGNB**
Cefalotin	CF	2, 8, 32	2	64	CSAGNB**
Cefotaxime	CTX	0.5, 2, 4, 8, 32	0.25	64	*Acinetobacter* spp., *Citrobacter* spp., *Enterobacter* spp., *E. coli*, KLEB(+K.pneumo)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. marcescens*, *Providencia* spp., SAL(+S.typhi)**
Cefotetan	CTT	2, 8, 32	4	64	CSAGNB**
Cefoxitin	FOX	8, 16, 32	4	64	CSAGNB**
Cefpodoxime	CPD	0.5, 1, 4	0.25	8	CSAGNB**
Ceftolozane/Tazobactam	CT	0.5/4, 1/4, 4/4, 8/4, 32/4	0.25	32	*E. cloacae*, *E. coli*, *K. oxytoca*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *C. freundii*, *C. koseri*, *E. aerogenes*, *P. vulgaris*, *Pv. stuartii*, *S. liquefaciens*
Cefuroxime	CXM	2, 8, 32	1	64	CSAGNB**
Doripenem NS	DOR	0.25, 0.5, 1, 4	0.12	8	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *C. freundii*, *E. cloacae*, *K. oxytoca*, *S. marcescens*
Meropenem	MEM❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Moxifloxacin	MXF	0.25, 1, 4	0.25	8	*K. pneumoniae*, *C. freundii*, *E. cloacae*, *E. coli*, *K. oxytoca*, *P. mirabilis*
Nalidixic Acid	NA	8, 16, 32	2	32	CSAGNB**
Tetracycline	TE	2, 4, 8	1	16	CSAGNB**
Ticarcillin/Clavulanic Acid	TCC	8/2, 32/2, 64/2	8/2	128/2	CSAGNB**
Tigecycline	TGC	1.5, 4, 8	0.5	8	*C. freundii*, *E. cloacae*, *E. coli*, *K. oxytoca*, *K. pneumoniae*, *C. koseri*, *E. aerogenes*, *S. marcescens*

Numerical values are expressed in µg/ml.

§ Equivalent standard method concentration by efficacy.
**CSAGNB = Clinically significant aerobic gram negative bacilli
✧ = Does not include the full CLSI/FDA-recommended dilution range for QC testing with this organism.
**KLEB(+K.pneumo) = *Klebsiella* spp. (including *K. pneumoniae*)
**SAL(+S.typhi) = *Salmonella* spp. (including *S. typhi*)
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.
❶,❷ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.

QUALITY CONTROL

		CLSI Quality Control Organisms VITEK 2 Results			
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp *pneumoniae* ATCC® 700603™
Amikacin	AN	≤2 – 4	≤2 – 4	-	-
Aztreonam	ATM	≤1	2 – 8	-	-
Cefalotin	CF	4 – 16	-	-	-
Cefotaxime	CTX	≤0.25* ✧ *(*FDA/CLSI Broth Microdilution expected QC range = 0.03 – 0.12 µg/ml)*	8 – 32	-	-
Cefotetan	CTT	≤4	-	-	-
Cefoxitin	FOX	≤4 – 8	-	-	-
Cefpodoxime	CPD	≤0.25 – 1	-	-	-
Ceftolozane/Tazobactam	CT	≤0.25 – 0.5* *(*FDA/CLSI Broth Microdilution expected QC range = 0.12/4 – 0.5/4 µg/ml)*	≤0.25 – 1	≤0.25* *(*FDA/CLSI Broth Microdilution expected QC range = 0.06/4 – 0.25/4 µg/ml)*	0.5 – 2
Cefuroxime	CXM	2 – 8	-	-	-
Doripenem[NS]	DOR	≤0.12	≤0.12 – 0.5	-	-
Meropenem	MEM	≤0.25	≤0.25 – 1	-	-
Moxifloxacin	MXF	≤0.25	1 – 8	-	-
Nalidixic Acid	NA	≤2 – 4	-	-	-
Tetracycline	TE	≤1 – 2	8 – ≥16	-	-
Ticarcillin/Clavulanic Acid	TCC	≤8/2 – 16/2	≤8/2 – 32/2	≤8/2 – 16/2 S/W ≤ VT2 4.01 & VT2compact 1.02 ≤8/2 – 32/2 S/W ≥ VT2 4.02 & VT2compact 2.01	-
Tigecycline	TGC	≤0.5* ✧ *(*FDA/CLSI Broth Microdilution expected QC range = 0.03 – 0.25 µg/ml)*	-	-	-

Numerical values are expressed in µg/ml.
✧ = Does not include the full CLSI/FDA-recommended dilution range for QC testing with this organism.
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.

LIMITATIONS

Ticarcillin/Clavulanic Acid has been approved for use only with *Pseudomonas aeruginosa*. An alternative method of testing must be performed prior to reporting of results for all other organisms.

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):
- Amikacin: *Acinetobacter baumannii*
- Aztreonam: *Pseudomonas* spp.
- Cefotaxime: *Pseudomonas fluorescens, Shigella* spp., *Hafnia alvei, Alcaligenes faecalis, Achromobacter denitrificans*
- Cefpodoxime: *Morganella morganii, Serratia* spp.
- Ceftolozane/Tazobactam: *Morganella morganii, Providencia rettgeri, Serratia marcescens*

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.

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:
- Tigecycline: *C. freundii, E. cloacae, E. coli, K. oxytoca, K. pneumoniae, C. koseri, E. aerogenes, S. marcescens*

The ability of the AST card to detect resistance with the following combination(s) is unknown because an insufficient number of resistant strains were available at the time of comparative testing. If such a strain is observed, it should be submitted to a reference laboratory for further testing.
- Ceftolozane/Tazobactam: *Citrobacter koseri, Proteus mirabilis, Proteus vulgaris, Serratia liquefacians*

Due to an insufficient number of on-scale isolates available for comparative testing, the performance of VITEK 2 Gram Negative **Cefotaxime** is unknown for this species with MICs in the range of 1 to 4 µg/mL. Isolates with MICs of 1 to 4 µg/mL should be tested using another method.
- Cefotaxime: *Proteus vulgaris*

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 A3104V0J---E

02 BAST-XN0811C

03 C---Z01080DU

04 D2V0R0K102-W

05 E0I2A2G1K0S6

06 F0-1334-O00Q

07 G1T-NS160IJE

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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