VITEK 2™ — technology

AST-GN95

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
Ampicillin	AM	4, 8, 32	2	32	CSAGNB**
Ampicillin/Sulbactam	SAM	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Cefazolin	CZ	4, 16, 64	4	64	CSAGNB**
Cefepime	FEP	0.25, 1, 4, 16, 32	0.12	32	*Enterobacter* spp., *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *C. koseri*, *C. freundii*, *P. agglomerans*, *K. oxytoca*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. marcescens*
Ceftazidime	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Ceftriaxone	CRO	0.12, 0.25, 1, 4, 16	0.25	64	*E. aerogenes*, *E. coli*, *K. oxytoca*, *K. pneumoniae*, *P. mirabilis*, *S. marcescens*, *C. koseri*, *C. freundii*, *Shigella* spp., PROV(+Pv.rettgeri)**, SAL(+S.typhi)**
Ciprofloxacin	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Ertapenem	ETP	0.03, 0.12, 0.5, 2	0.12	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, Kox(-ESBL)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. marcescens*
ESBL	ESB	FEP 1, CTX 0.5, CAZ 0.5, FEP/CA 1/10, CTX/CA 0.5/4, CAZ/CA 0.5/4	NEG	POS	*E. coli*, *K. pneumoniae*, *K. oxytoca*
Gentamicin	GM	4, 16, 32	1	16	CSAGNB**
Imipenem	IPM	1, 2, 6, 12	0.25	16	*Acinetobacter* spp., *Citrobacter* spp., *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. vulgaris*, *Pv. rettgeri*, *P. aeruginosa*, *S. marcescens*, *Pv. stuartii*
Levofloxacin	LEV❷	0.25, 0.5, 2, 8	0.12	8	*E. cloacae*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *S. marcescens*, *A. baumannii*, *A. lwoffii*, *C. koseri*, *C. freundii*, *E. aerogenes*, *E. sakazakii*, *K. oxytoca*, *M. morganii*, *P. agglomerans*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *P. fluorescens*, *C. sakazakii*
Nitrofurantoin	FT	16, 32, 64	16	512	CSAGNB**

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Piperacillin/Tazobactam [c]	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*
Tobramycin	TM	8, 16, 64	1	16	CSAGNB**
Trimethoprim/Sulfamethoxazole	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Numerical values are expressed in µg/ml.
§ Equivalent standard method concentration by efficacy.
**CSAGNB = Clinically significant aerobic gram negative bacilli
**PROV(+Pv.rettgeri) = *Providencia* spp. (including *Pv. rettgeri*)
**SAL(+S.typhi) = *Salmonella* spp. (including *S. typhi*)
**Kox(-ESBL) = *K. oxytoca* (excluding ESBL producing strains)
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
POS = Positive
A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.
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.
**Eco(+ETEC) = *E. coli* (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

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™
Ampicillin	AM	≤2 – 8	-	-	-
Ampicillin/Sulbactam	SAM	≤2/1 – 8/4	-	8/4 – ≥32/16	-
Cefazolin	CZ	≤4	-	-	-
Cefepime	FEP	≤0.12* *(*FDA/CLSI Broth Microdilution expected QC range = 0.015 – 0.12 µg/ml)*	0.5 – 4	-	-
Ceftazidime	CAZ	≤1	≤1 – 4	-	-
Ceftriaxone	CRO	≤0.25* *(*FDA/CLSI Broth Microdilution expected QC range = 0.03 – 0.12 µg/ml)*	8 – ≥64	-	-
Ciprofloxacin	CIP	≤0.25	≤0.25 – 1	-	-
Ertapenem	ETP	≤0.12 ✧	-	-	-
ESBL	ESB	NEG	-	-	POS
Gentamicin	GM	≤1	≤1 – 2	-	-
Imipenem	IPM	≤0.25	1 – 4	-	-
Levofloxacin	LEV	≤0.12	0.5 – 4	-	-
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)*	-
Tobramycin	TM	≤1	≤1	-	-
Trimethoprim/Sulfamethoxazole	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-	-

Numerical values are expressed in µg/ml.
✧ = Does not include the full CLSI/FDA-recommended dilution range for QC testing with this organism.
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
POS = Positive
A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.
[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):
- Ampicillin: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Ampicillin/Sulbactam: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Cefepime: *Bordetella bronchiseptica, Hafnia alvei, Morganella* spp.
- Ceftriaxone: *Proteus vulgaris, Enterobacter cloacae, E. cloacae* complex, *Morganella* spp.
- Ertapenem: *Hafnia alvei*
- Imipenem: *Serratia marcescens*
- Piperacillin/Tazobactam: *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):
- Imipenem: *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:
- Ceftriaxone: *Shigella* spp., *Providencia rettgeri, Salmonella* spp.

Although within Essential Agreement, the lack of an intermediate category has shown major and very major discrepancies when compared to the reference method. Testing should be repeated using an alternative testing/reference method prior to reporting results when the VITEK 2 MIC is 8 µg/ml or 16 µg/ml for the following antibiotic/organism(s):

- Cefepime: *Pseudomonas aeruginosa*

Due to an insufficient number of on-scale isolates available for comparative testing, the performance of VITEK 2 Gram Negative **Ertapenem** is unknown for isolates with MICs in the range of 0.25 - 0.5 µg/mL. To avoid the occurrence of very major errors, isolates with MICs of 0.25 µg/mL and 0.5 µg/mL should be retested using another method.

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 
A310IJ0I---4

02 
BAST-GN9501J

03 
C---Z02000E7

04 
D2U0G2X0L2YE

05 
E1103201W0YX

06 
F2P0523000004

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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