



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** |
| Aztreonam | ATM | 2, 8, 32 | 1 | 64 | CSAGNB** |
| Cefepime | FEP | 2, 8, 16, 32 | 1 | 64 | CSAGNB** |
| Ceftazidime | CAZ | 1, 2, 8, 32 | 1 | 64 | CSAGNB** |
| Ciprofloxacin | CIP | 0.5, 2, 4 | 0.25 | 4 | CSAGNB** |
| Colistin | CS | 4, 16, 32 | 0.5 | 16 | N/A** |
| Gentamicin | GM | 4, 16, 32 | 1 | 16 | CSAGNB** |
| Imipenem | IPM | 1, 2, 6, 12 | 0.25 | 16 | <i>Acinetobacter</i> spp., <i>Citrobacter</i> spp., <i>Enterobacter</i> spp., <i>E. coli</i> , <i>Klebsiella</i> spp., <i>M. morgani</i> , <i>P. vulgaris</i> , <i>Pv. rettgeri</i> , <i>P. aeruginosa</i> , <i>S. marcescens</i> , <i>Pv. stuartii</i> |
| 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</i> spp., <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</i> spp., <i>Shigella</i> spp. |
| Piperacillin | PIP [Ⓢ] | 4, 16, 32, 64 | 4 | 128 | <i>Acinetobacter</i> spp., <i>Enterobacter</i> spp., <i>E. coli</i> , <i>Klebsiella</i> spp., <i>M. morgani</i> , <i>Pv. rettgeri</i> , <i>P. mirabilis</i> , <i>P. vulgaris</i> , <i>P. aeruginosa</i> , <i>Serratia</i> spp., <i>B. cepacia</i> , <i>C. koseri</i> , <i>C. freundii</i> , <i>P. fluorescens</i> , <i>C. sakazakii</i> |
| Piperacillin/Tazobactam | 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> |
| Rifampicin | RA | 2, 4, 16 | 2 | 32 | N/A** |
| Ticarcillin | TIC | 16, 32, 64 | 8 | 128 | CSAGNB** |

| | | | | | |
|-------------------------------|-------|--------------------|-----------|--------------|---|
| Ticarcillin/Clavulanic Acid | TCC | 8/2, 32/2, 64/2 | 8/2 | 128/2 | CSAGNB** |
| Tobramycin | TM | 8, 16, 64 | 1 | 16 | CSAGNB** |
| Trimethoprim/Sulfamethoxazole | SXT ② | 1/19, 4/76, 16/304 | 20 (1/19) | 320 (16/304) | <i>Klebsiella</i> spp., <i>Enterobacter</i> spp., <i>M. morgani</i> , <i>P. vulgaris</i> , <i>P. mirabilis</i> , <i>S. sonnei</i> , <i>S. flexneri</i> , Eco(+ETEC)**, <i>C. sakazakii</i> |

Numerical values are expressed in µg/ml.

§ Equivalent standard method concentration by efficacy.

**CSAGNB = Clinically significant aerobic gram negative bacilli

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

①, ② etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.

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

QUALITY CONTROL

| Antimicrobial | Code | CLSI® Quality Control Organisms VITEK 2 Results | | |
|-------------------------------|------|---|--------------------------------------|--|
| | | <i>E. coli</i> ATCC® 25922™ | <i>P. aeruginosa</i> ATCC® 27853™ | <i>E. coli</i> ATCC® 35218™ |
| Amikacin | AN | ≤2 – 4 | ≤2 – 4 | - |
| Aztreonam | ATM | ≤1 | 2 – 8 | - |
| Cefepime | FEP | ≤1 | ≤1 – 8 | - |
| Ceftazidime | CAZ | ≤1 | ≤1 – 4 | - |
| Ciprofloxacin | CIP | ≤0.25 | ≤0.25 – 1 | - |
| Colistin | CS | ≤0.5 – 1 | ≤0.5 – 2 | - |
| Gentamicin | GM | ≤1 | ≤1 – 2 | - |
| Imipenem | IPM | ≤0.25 | 1 – 4 | - |
| Levofloxacin | LEV | ≤0.12 | 0.5 – 4 | - |
| Meropenem | MEM | ≤0.25 | ≤0.25 – 1 | - |
| Piperacillin | PIP | ≤4 | ≤4 – 8 | - |
| Piperacillin/Tazobactam | TZP | ≤4/4 | ≤4/4 – 8/4 | ≤4/4 |
| Rifampicin | RA | 4 – 16 | 16 – ≥32 | - |
| Ticarcillin | TIC | ≤8 – 16 | ≤8 – 32 | - |
| 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 |
| Tobramycin | TM | ≤1 | ≤1 | - |
| Trimethoprim/Sulfamethoxazole | SXT | ≤20 (1/19) | 160 (8/152) – ≥320 (16/304) | - |

Numerical values are expressed in µg/ml.

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

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 |  A 3 1 0 H B 0 J - - - X |
| 02 |  B A S T - N 2 4 0 0 1 E |
| 03 |  C - - - Z 0 1 0 8 1 C T |
| 04 |  D 0 G 0 L 1 8 0 3 2 0 L |
| 05 |  E 1 W 2 G 2 0 2 P 1 M 2 |
| 06 |  F 0 N 1 3 0 5 2 3 0 0 X |

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 |
|  | 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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 **bioMérieux, Inc.**
 100 Rodolphe Street
 Durham, North Carolina
 27712 USA

EC REP **bioMérieux SA**
 Chemin de l'Orme
 RCS LYON 673 620 399
 69280 Marcy-l'Etoile / France
 Tel. 33 (0)4 78 87 20 00
 Fax 33 (0)4 78 87 20 90
 www.biomerieux.com

