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|  MC 6.01 AST-GN95 Susceptibility Reporting Guidelines |
| **Purpose** | This procedure provides instruction and guidance for routine testing and reporting of Antimicrobial Agents / organism groupings for the AST-GN95 Vitek card for patient testing. This procedure also provides instructions for a rolling validation for lowering breakpoints to be consistent with CLSI M100 edition 29 published in 2019. Organisms with intrinsic resistance to antimicrobial agents will not be reported. ***Stenotrophomonas maltophilia*** and ***Burkholderia cepacia*** ***complex*** are not approved for use on the AST-GN95 card.  |
| **Principal and Clinical Significance** | The decisions for the most appropriate antimicrobial agents to test and report are made with input from Pharmacy, Infectious Disease and the Clinical Laboratory. The goal is to provide clinically relevant information that will decrease the chance of developing antibiotic resistance, harmful effects of inappropriate antimicrobial use and avoid reporting results that could adversely affect patient care. |
| **Policy Statements** | This procedure applies to Microbiologists who perform culture set-up and plate reading. |
| **Special Safety Precautions** | Microbiologists are subject to occupational risks associated with specimen handling.1. [*Biohazard Containment*](file:///%5C%5Ckidsnet.childrenshc.org%5Cchcdfs%5Cdept%5CLab%20Procedures%5CMicro%20Procedure%20Manuals%5CMC%20200%20%20%20%20Safety%5CMC%20201%20%20%20Biohazard%20Containment.doc)
2. [*Biohazardous Spills*](file:///%5C%5Ckidsnet.childrenshc.org%5Cchcdfs%5Cdept%5CLab%20Procedures%5CMicro%20Procedure%20Manuals%5CMC%20200%20%20%20%20Safety%5CMC%20204%20%20%20Biohazardous%20spills.doc)
3. [*Safety in the Microbiology/Virology Laboratory*](file:///%5C%5Ckidsnet.childrenshc.org%5Cchcdfs%5Cdept%5CLab%20Procedures%5CMicro%20Procedure%20Manuals%5CMC%20200%20%20%20%20Safety%5CMC%20202%20%20%20Safety%20in%20the%20Microbiology%20Lab%20Policy.doc)
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| **Procedure** | 1. The AST-GN95 card is approved for use on clinically significant Gram Negative Rods listed in organism tables below.
2. The AST-GN95 card has been validated following the FDA Indications for Use. Only report Vitek AST-GN95 results on patients following the FDA Indications for Use.
3. Perform and report KB or MicroScan results for antimicrobial agents that are not FDA approved or a card limitation for patient testing following organism tables below.
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| **Lowering Breakpoints Validation** | 1. CLSI M100 edition 29 has updated 2019 breakpoints for *Pseudomonas aeruginosa* and *Acinetobacter* spp. To validate the 2019 breakpoints, we will perform KB and enter results into Sunquest for patient testing. Vitek MIC results from un-validated antimicrobial agents will be visible on the Vitek printout but will not cross into Sunquest. **Do not manually enter results**.
2. Using the results from the AST-GN95 card and the KB results, we will performing a rolling validation. Enter Vitek and KB results into the spreadsheet to collect data to validate the lower breakpoints.[**GN95 rolling validation.**](file:///G%3A%5CLAB%5CMicrobiology%5CMicro%20Validations%5CGN95%20rolling%20validation.xlsx)
3. If results are discrepant, report the KB results. For validation purposes, repeat both KB and GN95, freeze organism and notify supervisor.
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| **Enterobacteriaceae** | *Enterobacteriaceae*

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| Antibiotic | FDA Indications for use (IFU) report from Vitek card GN95 | Perform KB  |
| Ampicillin | Approved for all clinically significant GNR  |  |
| Ampicillin/Sulbactam | Approved for all clinically significant GNR  |  |
| Cefazolin | Report only on EC, PRMI, KLPN from urine | KB for all other organismsand non-urine sources |
| Cefepime | *Enterobacter* spp*, EC, KLPN, PMIR, CITD, CITF, ENAG, KLOX, PRVU, PROR, PROS, SMAR* | KB for all other organisms  |
| Ceftazidime | Approved for all clinically significant GNR |  |
| Ceftriaxone | *ENAE, EC, KLOX, KLPN, PMIR, PROV, PROR, SMAR, CITD, CITF, SHIG* spp*,*  | KB for all other organisms KB with resistant *Shigella* spp., *Providencia rettgeri*  |
| Ciprofloxacin | Approved for all clinically significant GNR |  |
| Ertapenem | *EC, KLPN, CITF, CITD, ENAR, ENCL, KLOX(-ESBL) MORG, PMIR, PRVU, PROR, PROS, SMAR* | KB for all other organisms and KB for all IFU organisms with MIC of 0.25-0.5  |
| ESBL | *EC, KLPN, KLOX* |  |
| Gentamicin | Approved for all clinically significant GNR |  |
| Imipenem | *CITR, Enterobacter spp, EC, KLEB* spp*, MORG, PVUL, PROR, PROS* | KB for all other organisms  |
| Nitrofurantoin (urine) | Approved for all clinically significant GNR |  |
| Levofloxacin | *ENCL, EC, KLPN, PMIR, SMAR, CITD, CITF, ENAE, KLOX, MORG, ENSA, PRVU, PROR, PROS, ENAG* | KB for all other organisms |
| Piperacillin /Tazobactam | *EC, KLPN, CITD, MORG, PMIR, PRVU, PROR, PROS, SAENT* | KB for all other organisms  |
| Tobramycin | Approved for all clinically significant GNR |  |
| Trimeth/Sulfa |  *KLEB spp, Enterobacter* spp*, MORG,* *PRVU, PMIR, SHSO, SHFL, EC, ENSA* | KB for all other organisms |

Table 1In summary: perform KB for CEFE, CAX, ERTA, IMP, LEVO, PIPT and TS when applicable. |
| **PSAR**  | *Pseudomonas aeruginosa*

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| Antibiotic | FDA Indications for use report from Vitek card GN95 | Validation for lowering breakpoints- perform KB |
| Cefepime | Approved for *PSAR* |   |
| Ceftazidime | Approved for *PSAR* |  |
| Ciprofloxacin | Approved for *PSAR* | Perform KB for validation of breakpoints |
| Gentamicin | Approved for *PSAR* |  |
| Imipenem | Approved for *PSAR* | Perform KB for validation of breakpoints |
| Levofloxacin | Approved for *PSAR* | Perform KB for validation of breakpoints |
| Piper/Tazobactam | Not approved for *PSAR* | Perform KB |
| Tobramycin | Approved for *PSAR* |  |

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|  | Table 2 |
| **Non-Enterobacteriaceae** | *Non-Enterobacteriaceae*

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| Antibiotic | FDA Indications for use report from Vitek card GN95 | Perform MicroScan |
| Cefepime | Not approved |  NC68 |
| Ceftazidime | Approved for all clinically significant GNR |  |
| Ceftriaxone | Not approved | NC68 |
| Ciprofloxacin | Approved for all clinically significant GNR |  |
| Gentamicin | Approved for all clinically significant GNR |  |
| Imipenem | Not approved | NC68 |
| Piper/Tazobactam | Not approved | NC68 |
| Tobramycin | Approved for all clinically significant GNR |  |
| Trimeth/Sulfa | Not approved | NC68 |
| Levofloxacin | Not approved | NC68 |

Table 3For Non-Enterobacteriaceae, perform AST-GN95 and MicroScan. There are no CLSI guidelines for KB with Non-Enterobacteriaceae. |
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| **Acinetobacter spp.**  | *Acinetobacter*

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| Antibiotic | FDA Indications for use report from Vitek card GN95 | For Validation for lowering breakpoints- perform KB |
| Ampicillin-Sulbactam | Approved for all clinically significant GNR |  |
| Cefepime | Not approved |  Perform KB |
| Ceftazidime | Approved for all clinically significant GNR |  |
| Ceftriaxone | Not approved | Perform KB |
| Ciprofloxacin | Approved for all clinically significant GNR |  |
| Gentamicin | Approved for all clinically significant GNR |  |
| Imipenem | Approved for *Acinetobacter* spp. | Perform KB for validation of breakpoints |
| Levofloxacin | Approved for *ABAU* and *ALWO* | If not *ABAU* and *ALWO*, perform KB |
| Piper/Tazobactam | Approved for *ABAU* | If not *ABAU,* perform KB  |
| Trimeth/Sulfa | Not approved | Perform KB |
| Tobramycin | Approved for all clinically significant GNR |  |

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|  | Table 4 In summary, perform KB for CEFE, CAX and TS. |
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| **References** | Vitek AST-GN95 Gram Negative Susceptibility Card bioMerieux 2017/11CLSI M100 edition 29 Performance Standards for Antimicrobial Susceptibility Testing 1/2019 |
| **Training Plan/ Competency Assessment** | **Training Plan** | **Initial Competency Assessment** |
| 1. Employee must read the procedure.
2. Employee will observe trainer performing the procedure.
3. Employee will demonstrate the ability to perform procedure, record results and document corrective action after instruction by the trainer.
 | 1. Direct observation.
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| **Historical Record** |  |  |  |  |
|  | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | Susan DeMeyere | 11/5/2019 | Initial version |
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