

# VITEK®2

**CARDS FOR ANTIMICROBIAL SUSCEPTIBILITY TESTING (AST) IN THE CARIBBEAN**

*Microbiology with Reliability*



# When a patient has a bacterial infection, establishing the best treatment option requires a comprehensive antimicrobial susceptibility report.

Antimicrobial Susceptibility Testing (AST) and detection of Antimicrobial Resistance (AMR) mechanisms are critical to make informed therapeutic decisions and to implement infection prevention and control interventions, given the accelerated increase and diversity of emerging antimicrobial resistance worldwide.

Designed for **VITEK®2** automated instruments, **VITEK®2 AST** cards allow you to easily adapt your diagnostic strategy with more actionable antimicrobial susceptibility testing information through fast and accurate results:

- Strategic antibiotic composition for different clinical scenarios (urinary vs systemic infections, community and hospital acquired infections, etc.) supporting antimicrobial stewardship and infection control interventions.

- Updated expert rules for accurate clinical reports.

- Improved detection of antimicrobial resistance mechanisms: Updated versions of antibiotic formulations and lower calling ranges ( lower MICs ).

- Updated breakpoints according to CLSI and EUCAST standards.

- New antibiotics for testing multidrug-resistant microorganisms (MDRO) and to detect emerging resistance according to local epidemiology.

- Standardized antibiotics for local epidemiology reports.

- Developed in consultation with regional experts in clinical microbiology and infectious diseases, as well as bioMérieux medical affairs team.





**VITEK®2 AST** cards results are interpreted using an **ADVANCED EXPERT SYSTEM (AES)** that analyzes MIC patterns and detects AMR phenotypes for organisms tested. Rapid and comprehensive results allow clinicians to adjust empiric therapy and to prescribe targeted therapy, resulting in improved patient outcomes and enhanced **antimicrobial stewardship (AMS) practices**.

**NOTE:** To use these cards, make sure that your **VITEK®2 AST** software is upgraded to version **9.04**. Consult with your local bioMérieux representative.



**DISCLAIMER.**

Recommendations and suggestions provided in this booklet should be reviewed by each laboratory in consultation with the antimicrobial stewardship team and other relevant institutional stakeholders.



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# VITEK®2 AST-N450

The **VITEK®2 AST-N450** card is indicated for primary antimicrobial susceptibility testing of infections caused by **Enterobacterales** isolated from urine, stool, wounds and other samples according to local guidelines. It also provides oral alternatives for patients with chronic infections (e.g. Osteomyelitis) or patients discharged for outpatient therapy. Ampicillin/sulbactam susceptible results can be used to infer susceptible results to amoxicillin/clavulanic acid and can be displayed automatically using an expert rule. This rule applies to ceftriaxone susceptible or non-ESBL producing *E. coli*, *K. pneumoniae* and *P. mirabilis*.

Lower ciprofloxacin dilutions match the current CLSI-EUCAST recommendations for testing *Salmonella spp* and this card is also suitable for testing *Shigella spp* and *S. maltophilia*.

**Vitek®2 AST-N450**, incorporates lower dilutions for cefazolin, a first-generation cephalosporin used as “step-down therapy” for infections caused by *E. coli*, *K. pneumoniae* and *P. mirabilis*. Cefazolin is also a surrogate to predict the *in vitro* activity of oral cephalosporins like cephalexin for the treatment of uncomplicated urinary tract infections.

This card also includes cefuroxime, a 2nd generation cephalosporin suitable for sequential therapy (IV to oral) for selected infections caused by *E. coli*, *K. pneumoniae* and *P. mirabilis*

## VITEK®2 AST-N450 REF 424733

### ANTIBIOTICS INCLUDED

Amikacin  
Ampicillin/Sulbactam  
Cefazolin  
Cefepime  
Ceftazidime  
Ceftriaxone  
Cefuroxime  
Ciprofloxacin  
Ertapenem  
\*ESBL  
Fosfomycin  
Gentamicin  
Meropenem  
Nitrofurantoin  
Trimethoprim/sulfamethoxazole

\*ESBL= Extended-Spectrum  
Beta-Lactamase

### RECOMMENDATIONS:

- This card replaces VITEK®2 AST-N401.
- N450 is not intended for antimicrobial susceptibility testing of *P. aeruginosa*.
- Ampicillin/sulbactam should be reported as R when ceftriaxone is R or the ESBL test is positive.
- Antimicrobial susceptibility testing is not recommended for *B. cepacia complex* by any method.
- Enterobacterales resistant to any carbapenem tested (e.g. Ertapenem and/or meropenem), should be tested for a carbapenemase using phenotypic and/or molecular assays.
- For *E. coli* and *K. pneumoniae* testing intermediate or resistant to any carbapenem, the ESBL result should be deleted from the report. Enterobacterales intermediate or resistant to ertapenem and/or meropenem or positive for carbapenemases, should be tested using VITEK®2 AST-N403 to provide additional therapeutic options.
- Cefepime should be reported as R or deleted from the report if the isolate is resistant to carbapenems, or is confirmed to produce a carbapenemase.
- Nitrofurantoin should not be reported from sources other than urinary tract. *Proteus*, *Morganella*, *Providencia*, *Serratia* and *P. aeruginosa* are intrinsically resistant to nitrofurantoin.
- Fosfomycin should be reported only for *E. coli*.
- For *Stenotrophomonas maltophilia*, report only trimethoprim/sulfa.
- Isolates resistant to ciprofloxacin may develop resistance to other fluoroquinolones. We recommend to include a note to avoid using other quinolones if ciprofloxacin is resistant.



# VITEK®2 AST-N402

The **VITEK®2 AST-N402** card is indicated for antimicrobial susceptibility testing of Gram-negative bacilli (e.g. Enterobacterales other than *Salmonella* and *Shigella*, *P. aeruginosa* & *A. baumannii* complex) isolated from hospital services like ICUs, general wards and emergency rooms. It could be applied for isolates from urine, blood cultures, body fluids, skin and soft tissues and bone and joint infections.

The antibiotic composition of VITEK®2 AST-N402 is suitable for services where carbapenem resistant isolates are unusual. Ampicillin/sulbactam susceptible results can be used to infer susceptible results to amoxicillin/clavulanic acid and can be displayed automatically using an expert rule. This rule applies to ceftriaxone susceptible or non-ESBL producing *E. coli*, *K. pneumoniae*, and *P. mirabilis*.

Lower concentrations for cephalosporins (e.g. ceftriaxone, cefepime, ceftazidime) and carbapenems (e.g. ertapenem, imipenem, meropenem), allow for better detection of extended spectrum betalactamases (ESBLs) and carbapenemases. Reporting lower Minimum Inhibitory Concentrations (MICs), using VITEK®2 AST-N402 correlates better with clinical outcomes and contribute to Antimicrobial Stewardship (AMS) and infection control and prevention interventions. Tigecycline is active against *Acinetobacter baumannii* complex, and is also active against ESBL and carbapenemase-producing Enterobacterales and may be a therapeutic option for intraabdominal and skin and soft tissue infections.

## VITEK®2 AST-N402 REF 423644

### ANTIBIOTICS INCLUDED

Amikacin  
Ampicillin/Sulbactam  
Cefazolin  
Cefepime  
Ceftazidime  
Ceftriaxone  
Ciprofloxacin  
Ertapenem  
\*ESBL  
Gentamicin  
Imipenem  
Meropenem  
Piperacillin/tazobactam  
Tigecycline

\*ESBL = Extended-Spectrum  
Beta-Lactamase

### RECOMMENDATIONS:

- Enterobacterales resistant to any carbapenem tested (e.g. Ertapenem, imipenem and meropenem), should be tested for a carbapenemase using phenotypic and/or molecular assays. As an exception to this recommendation is *Proteus*, *Providencia* and *Morganella* that are only resistant to imipenem because of intrinsic resistance.
- Enterobacterales intermediate or resistant to ertapenem and/or meropenem or positive for carbapenemases, can be tested using Vitek®2 AST-N403 to provide additional therapeutic options.
- For Enterobacterales, cefepime should be reported as R or deleted from the report if the isolate is resistant to carbapenems, or is confirmed to produce a carbapenemase.
- For *E. coli* and *K. pneumoniae* testing intermediate or resistant to any carbapenem, the ESBL result should be deleted from the report.
- Ampicillin/sulbactam should be reported as R when ceftriaxone is R or the ESBL test is positive.
- If cefazolin is considered for IV therapy in systemic infections, it should be tested using VITEK®2 AST-N450 or VITEK®2 AST-N806.
- Tigecycline should not be reported on organisms isolated from the urinary tract. *Proteus*, *Morganella*, *Providencia* and *Pseudomonas* spp. are intrinsically resistant to tigecycline.
- *P. aeruginosa* resistant to imipenem and meropenem and ceftazidime should be tested for a carbapenemase using phenotypic and/or molecular assays.
- *P. aeruginosa* resistant to carbapenems and/or producing a carbapenemase can be tested using VITEK®2 AST-N403 to provide additional therapeutic options.
- Isolates resistant to ciprofloxacin may develop resistance to other fluoroquinolones. We recommend to include a note to avoid using other quinolones if ciprofloxacin is resistant.





# VITEK®2 AST-N403

The **VITEK®2 AST-N403** card is indicated for antimicrobial susceptibility testing of Gram-negative bacilli (e.g. Enterobacterales, *P. aeruginosa* & *A. baumannii* complex) from any source, isolated from hospital services with high endemicity of multidrug resistant isolates, especially carbapenem resistant and/or carbapenemase producers, where testing for new  $\beta$ -lactam/ $\beta$ -lactamase inhibitor combinations is required.

Ampicillin/sulbactam susceptible results can be used to infer susceptible results to amoxicillin/clavulanic acid and can be displayed automatically using an expert rule. This rule applies to ceftriaxone susceptible or non-ESBL producing *E. coli*, *K. pneumoniae* y *P. mirabilis*.

Lower concentrations for cephalosporins (e.g. ceftriaxone, cefepime, ceftazidime) and carbapenems (e.g. ertapenem, imipenem, meropenem), allow for better detection of extended spectrum betalactamases (ESBLs) and carbapenemases. Ceftazidime/avibactam is active in class A carbapenemase producers (e.g. KPC, GES) and class D carbapenemase producers (e.g. OXA-48) for both Enterobacterales and *P. aeruginosa*.

Ceftolozane/tazobactam is active in difficult-to-treat resistant (DTR) *P. aeruginosa* (e.g. Carbapenem-resistant) but is inactive against carbapenemase-producing Enterobacterales or *P. aeruginosa*.

- Aztreonam is used for Enterobacterales and *P. aeruginosa* producing metallo-carbapenemases (e.g. VIM, NDM, IMP) when combined with ceftazidime/avibactam. Aztreonam susceptible results can be used to infer susceptibility to aztreonam/avibactam.

## VITEK®2 AST-N403 REF 423645

### ANTIBIOTICS

Amikacin  
Ampicillin/Sulbactam  
Aztreonam  
Cefepime  
Ceftazidime  
Ceftazidime/avibactam  
Ceftolozane/tazobactam  
Ciprofloxacin  
Ertapenem  
\*ESBL  
Imipenem  
Meropenem  
Piperacillin/tazobactam  
Tigecycline

\*ESBL= Extended-Spectrum  
Beta-Lactamase

### RECOMMENDATIONS:

- Enterobacterales resistant to any carbapenem tested (e.g. Ertapenem, imipenem and meropenem), should be tested for a carbapenemase using phenotypic and/or molecular assays. As an exception to this recommendation is *Proteus*, *Providencia* and *Morganella* that are only resistant to imipenem because of intrinsic resistance.
- For *E. coli* and *K. pneumoniae* testing intermediate or resistant to any carbapenem, the ESBL result should be deleted from the report.
- Tigecycline should not be reported on organisms isolated from the urinary tract. *Proteus*, *Morganella*, *Providencia* and *Pseudomonas spp.* are intrinsically resistant to tigecycline.
- Ampicillin/sulbactam should be reported as R when ceftriaxone is R or the ESBL test is positive.
- For *E. coli* and *K. pneumoniae* testing intermediate or resistant to any carbapenem, the ESBL result should be deleted from the report.
- For Enterobacterales, cefepime should be reported as R or deleted from the report if the isolate is resistant to carbapenems, or is confirmed to produce a carbapenemase.
- Ceftazidime/avibactam should be deleted from the report or reported as R if the isolate produces a metallo-carbapenemase.
- Aztreonam should be deleted from the report or reported as R if the isolate produces a KPC.
- *P. aeruginosa* resistant to carbapenems (e.g. Imipenem and meropenem) and ceftazidime can be tested for a carbapenemase using phenotypic and/or molecular assays.
- Ceftolozane/tazobactam should be deleted from the report or reported as R if isolates of Enterobacterales or *Pseudomonas aeruginosa* produces any carbapenemase.
- Isolates resistant to ciprofloxacin may develop resistance to other fluoroquinolones. We recommend to include a note to avoid using other quinolones if ciprofloxacin is resistant.
- Aztreonam, ceftazidime/avibactam and ceftolozane/tazobactam are not active against *Acinetobacter baumannii* complex.



# VITEK®2 AST-N806

The VITEK®2 AST-N806 card is indicated for primary antimicrobial susceptibility testing of community-acquired and hospital acquired infections caused by Enterobacterales, and non-fermentative Gram-negative bacilli (e.g. *P. aeruginosa* and *A. baumannii* complex).

Lower ciprofloxacin dilutions match the current CLSI-EUCAST recommendations for testing *Salmonella* spp and this card is also suitable to test *Shigella* spp and *S. maltophilia*.

Vitek®2 AST-N806, incorporates lower concentrations for cefazolin, a first-generation cephalosporin used as “step-down therapy” for infections caused by *E. coli*, *K. pneumoniae* and *P. mirabilis*. Cefazolin is also a surrogate to predict *in vitro* activity of oral cephalosporins like cephalexin for the treatment of uncomplicated urinary tract infections.

Ampicillin/sulbactam susceptible results can be used to infer susceptible results to amoxicillin/clavulanic acid and can be automated using an expert rule. This rule applies to ceftriaxone susceptible or non-ESBL producing *E. coli*, *K. pneumoniae*, and *P. mirabilis*.

Lower concentrations for cephalosporins (e.g. ceftriaxone, cefepime, ceftazidime) and carbapenems (e.g. ertapenem, meropenem), allow for better detection of extended spectrum betalactamases (ESBLs) and carbapenemases.

Vitek®2 AST-N806 could be considered as a routine AST card, especially in wards with low endemicity of multidrug resistant Gram-negative bacilli or following local antimicrobial stewardship policies.

## VITEK®2 AST-N806 REF 424709

### ANTIBIOTICS

Ampicillin  
Ampicillin/Sulbactam  
Cefazolin  
Cefepime  
Ceftazidime  
Ceftriaxone  
Ciprofloxacin  
Ertapenem  
\*ESBL  
Gentamicin  
Levofloxacin  
Meropenem  
Nitrofurantoin  
Piperacillin/tazobactam  
Trimethoprim/sulfamethoxazole

\*ESBL= Extended-Spectrum  
Beta-Lactamase

### RECOMMENDATIONS:

- Enterobacterales resistant to any carbapenem tested (e.g. Ertapenem and/or meropenem), should be tested for a carbapenemase using phenotypic and/or molecular assays.
- Ampicillin/sulbactam should be reported as R when ceftriaxone is R or the ESBL test is positive.
- For Enterobacterales, cefepime should be reported as R or deleted from the report if the isolate is resistant to carbapenems, or is confirmed to produce a carbapenemase.
- *P. aeruginosa* resistant to meropenem and ceftazidime should be tested for a carbapenemase using phenotypic and/or molecular assays.
- Enterobacterales intermediate or resistant to ertapenem and/or meropenem or positive for carbapenemases, should be tested using VITEK®2 AST XN30 to provide additional therapeutic options.
- For *E. coli* and *K. pneumoniae* testing intermediate or resistant to any carbapenem, the ESBL result should be deleted from the report.
- *P. aeruginosa* resistant to ceftazidime and meropenem and/or producing a carbapenemase should be tested using VITEK®2 AST XN30 to provide additional therapeutic options.
- *Proteus*, *Morganella*, *Providencia*, *Serratia* and *P. aeruginosa* are intrinsically resistant to nitrofurantoin.
- Nitrofurantoin should not be reported for sources other than urinary tract.
- Antimicrobial susceptibility testing is not recommended for *B. cepacia* complex by any method.
- For *Stenotrophomonas maltophilia*, report only trimethoprim/sulfa.
- Isolates resistant to ciprofloxacin may develop resistance to other fluoroquinolones. We recommend to include a note to avoid using other quinolones if ciprofloxacin is resistant.
- If amikacin and imipenem are considered as first treatment option for *P. aeruginosa* infections, primary testing can be made with AST N402 or ASTN403.



# VITEK®2 AST-XN 30

The **VITEK®2 AST-XN30** card is indicated as an extension card for VITEK® 2 AST-N806. This card is intended to be used for complementary AST of Gram-negative bacilli (e.g. Enterobacterales other than *Salmonella* and *Shigella*, *Pseudomonas aeruginosa* & *Acinetobacter baumannii* complex) from any source, isolated from hospital services with high endemicity of multidrug resistant isolates, especially carbapenem resistant and/or carbapenemase producers, where testing for new  $\beta$ -lactam/  $\beta$ -lactamase inhibitor combinations and supplementary antibiotics is required.

New generation  $\beta$ -lactamase inhibitors are active against carbapenemase-producing Enterobacterales. Ceftazidime/avibactam inhibits KPC and OXA-48 like enzymes, whereas meropenem/vaborbactam and imipenem/relebactam inhibit KPC including ceftazidime/avibactam resistant variants. Imipenem/relebactam and ceftolozane/tazobactam are active against difficult-to-treat *P. aeruginosa*. Minocycline, tigecycline and eravacycline are active against carbapenem-resistant *A. baumannii* complex. Aztreonam is used for Enterobacterales and *P. aeruginosa* producing metallo-carbapenemases (e.g. VIM, NDM, IMP) when combined with ceftazidime/avibactam. Aztreonam susceptible results can be used to infer susceptibility to aztreonam/avibactam.

Polymyxin B is a therapeutic alternative in combination therapy for MDR Gram-negative bacilli when new drugs are not available. Tobramycin is the most potent aminoglycoside for *P. aeruginosa* infections.

## VITEK®2 AST-XN30 REF 424639

### ANTIBIOTICS

Amikacin  
Amoxicillin/clavulanic acid  
Aztreonam  
Cefotaxime  
Cefpodoxime  
Ceftazidime/avibactam  
Ceftolozane/tazobactam  
Doxycycline  
Eravacycline  
Imipenem  
Imipenem/relebactam  
Meropenem/vaborbactam  
Minocycline  
Polymyxin B  
Tigecycline  
Tobramycin

### RECOMMENDATIONS:

- Enterobacterales resistant to any carbapenem tested (e.g. Ertapenem, imipenem and meropenem), should be tested for a carbapenemase using phenotypic and/or molecular assays. As an exception to this recommendation is *Proteus*, *Providencia* and *Morganella* that are only resistant to imipenem because of intrinsic resistance.
- For Enterobacterales, cefepime should be reported as R or deleted from the report if the isolate is resistant to carbapenems, or is confirmed to produce a carbapenemase.
- Meropenem/vaborbactam should not be reported in *P. aeruginosa*.
- Imipenem/relebactam should not be reported in *Proteus*, *Morganella* and *Providencia*.
- Ceftazidime/avibactam, imipenem/relebactam and meropenem/vaborbactam should be deleted from the report or reported as R if the isolate produces a metallo-carbapenemase.
- Aztreonam should be deleted from the report or reported as R if the isolate produces a KPC.
- Ceftolozane/tazobactam should be deleted from the report or reported as R if isolates of Enterobacterales or *P. aeruginosa* produces any carbapenemase.
- Aztreonam, imipenem/relebactam, meropenem/vaborbactam, ceftazidime/avibactam and ceftolozane/tazobactam are not active against *A. baumannii* complex.
- Tigecycline, minocycline and eravacycline should not be reported in *Proteus*, *Morganella*, *Providencia* and *Pseudomonas spp.* because of intrinsic resistance. Additionally this drugs should not be reported in organisms isolated from the urinary tract.
- Polymyxin B results, either intermediate or resistant can be extrapolated to colistin.
- Polymyxin B should be reported as colistin on organisms isolated from the urinary tract.
- Polymyxin B should not be reported in *Proteus*, *Morganella*, *Providencia* and *Serratia* because of intrinsic resistance. Additionally this drug should not be reported in organisms isolated from the urinary tract. For UTIs, report colistin instead.
- Resistance rates for new antibiotics may be included in the local epidemiology according with antimicrobial stewardship policies.





# VITEK®2 AST-P663

The **VITEK®2 AST-P663** card is indicated for routine antimicrobial susceptibility testing of *Staphylococcus spp*, *Enterococcus spp* and *Streptococcus agalactiae* isolated from any source for both community-acquired and hospital acquired infections.

This card contains the most used antibiotics to treat Gram-positive infections. For *S. aureus* this card includes oxacillin and the ceftioxin screening to detect MRSA and the inducible clindamycin resistance test for isolates displaying erythromycin resistant and clindamycin susceptible results. For *Enterococcus spp* this card includes ampicillin, and high-level resistance for gentamicin and streptomycin, to evaluate the possibility of synergy with cell wall active agents like betalactams and vancomycin. For *S. agalactiae* this card includes benzyl penicillin and ampicillin, as well as levofloxacin and vancomycin.

VITEK®2 AST-P663 includes both systemic (e.g. linezolid, daptomycin, ceftaroline, vancomycin etc.) and urinary antibiotics (e.g. nitrofurantoin). Predictive rules can be created to expand susceptibility reports. For example, *Staphylococcus spp* susceptible to erythromycin are considered susceptible to clarithromycin and azithromycin, as well as isolates susceptible to tetracycline are considered susceptible to doxycycline and minocycline.

## VITEK®2 AST-P663 REF 423646

### ANTIBIOTICS

Ampicillin  
Benzyl Penicillin  
Ceftioxin Screening  
Ceftaroline  
Ciprofloxacin  
Clindamycin  
Daptomycin  
Erythromycin  
\*HL gentamicin  
Inducible clindamycin resistance  
Levofloxacin  
Linezolid  
Nitrofurantoin  
Oxacillin  
Rifampin  
\*HL Streptomycin  
Tetracycline  
Trimethoprim/sulfa  
Vancomycin  
\*HL= High level resistance.

### RECOMMENDATIONS:

- *Staphylococcus spp* resistant to vancomycin and linezolid are unusual and should be confirmed and sent to a local reference laboratory.
- *Staphylococcus spp* non-susceptible to daptomycin are unusual. Repeat testing if MICs are  $\geq 2\mu\text{g/mL}$ .
- *Enterococcus faecalis* should be susceptible to both ampicillin and benzyl penicillin. Discordant results should be confirmed before reporting ampicillin.
- Clindamycin, erythromycin and rifampin should not be reported on organisms isolated from the urinary tract.
- Daptomycin should not be reported on organisms isolated from the lower respiratory tract.
- Rifampin should not be used alone for antimicrobial therapy.
- Isolates resistant to ciprofloxacin may develop resistance to other fluoroquinolones. We recommend to include a note to avoid using other quinolones if ciprofloxacin is resistant.

# SUGGESTED PROTOCOLIZATION OF VITEK® 2 AST CARDS

GROUP OF PATHOGENS	SOURCE*	PRIMARY/ROUTINE VITEK® 2 AST CARDS	ANCILLARY VITEK2® AST CARDS FOR CARBAPENEM RESISTANT ISOLATES	RECOMMENDATIONS
<i>Enterobacterales other than Salmonella and Shigella</i>	Urine	AST- N450	AST-N403	Test for carbapenemases using phenotypic or molecular methods.
	Systemic	AST- N402	AST-N403	
	Urine & systemic	AST- N806	AST-XN30	
<i>Salmonella and Shigella</i>	Any	AST- N450	AST-N403	For isolates resistant to ceftriaxone, report ertapenem and meropenem
		AST- N806	AST-XN30	
<i>Pseudomonas aeruginosa</i>	Any	AST- N402	AST- N403	For isolates resistant to ceftazidime and meropenem, test for carbapenemases using phenotypic or molecular methods.
		AST- N403	N/A	
		AST- N806	AST-XN30	
<i>Acinetobacter baumannii complex</i>	Any	AST- N402	N/A	For isolates resistant to ampicillin/sulbactam and meropenem, test for carbapenemases using phenotypic or molecular methods.
		AST- N403	N/A	
		AST- N806	AST-XN30	
<i>Stenotrophomonas maltophilia</i>	Any	AST- N450	N/A	For <i>Stenotrophomonas maltophilia</i> , report only trimethoprim/sulfa.
		AST- N806	N/A	

N/A= Not applicable. \* Local epidemiology and institutional AMS policies should be taken into consideration to establish a tailored protocol.

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