

CRO Breakpoint Implementation Toolkit

APPENDIX B — IMPLEMENTATION WORKSHEETS

This document contains worksheets to assist laboratories with the implementation of the updated Clinical Laboratory Standards Institute (CLSI) breakpoint values for use in antibiotic resistance (AR) testing. The worksheets are to be used in conjunction with isolates ordered from the [AR Isolate Bank](#), a collaborative program between the US Centers for Disease Control and Prevention (CDC) and the US Food and Drug Administration (FDA) that provides curated panels to laboratories, manufacturers and researchers to advance the fight against AR.

Please review and receive approval on the verification plan from the CLIA Director or appropriate designee prior to proceeding.

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Enterobacterales	Carbapenems	Doripenem
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Test Date/Tech	Isolate No.	Organism	Doripenem			
			S, I, R		MIC	
			Reference	Observed	Reference	Observed
	0001	<i>Escherichia coli</i>	R		4	
	0002	<i>Enterobacter cloacae</i>	R		>8	
	0003	<i>Klebsiella pneumoniae</i>	R		8	
	0004	<i>Klebsiella pneumoniae</i>	R		>8	
	0005	<i>Klebsiella pneumoniae</i>	R		8	
	0006	<i>Escherichia coli</i>	R		4	
	0007	<i>Klebsiella aerogenes</i>	S		0.5	
	0008	<i>Enterobacter cloacae</i>	I		2	
	0009	<i>Klebsiella aerogenes</i>	R		4	
	0010	<i>Klebsiella pneumoniae</i>	S		1	
	0011	<i>Escherichia coli</i>	S		≤0.12	
	0012	<i>Klebsiella pneumoniae</i>	S		≤0.12	
	0013	<i>Escherichia coli</i>	S		≤0.12	
	0014	<i>Escherichia coli</i>	S		≤0.12	
	0015	<i>Escherichia coli</i>	S		≤0.12	
	0016	<i>Klebsiella pneumoniae</i>	S		≤0.12	
	0017	<i>Escherichia coli</i>	S		0.25	
	0018	<i>Klebsiella aerogenes</i>	S		≤0.12	
	0019	<i>Escherichia coli</i>	S		≤0.12	
	0020	<i>Escherichia coli</i>	S		≤0.12	
	0021	<i>Citrobacter freundii</i>	S		≤0.12	
	0022	<i>Citrobacter freundii</i>	S		≤0.12	
	0023	<i>Citrobacter freundii</i>	S		≤0.12	
	0024	<i>Citrobacter koseri</i>	S		≤0.12	
	0025	<i>Citrobacter koseri</i>	S		≤0.12	
	0026	<i>Providencia stuartii</i>	S		0.25	
	0027	<i>Serratia marcescens</i>	S		≤0.12	
	0028	<i>Klebsiella oxytoca</i>	S		≤0.12	
	0029	<i>Proteus mirabilis</i>	S		1	
	0030	<i>Shigella sonnei</i>	S		≤0.12	
	0031	<i>Salmonella typhimurium</i>	S		≤0.12	

		Number	%
Date:	Categorical Agreement		
	Very Major Errors		
Tech:	Major Errors		
	Minor Errors		

Breakpoints for doripenem and *Enterobacterales* used are:

S _____ (mcg/ml)
 I _____ (mcg/ml)
 R _____ (mcg/ml)

which are found in CLSI M100, _____ edition (year/fillable text)

Date: _____ Initials: _____

Enterobacterales	Carbapenems	Ertapenem
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Test Date/Tech	Isolate No.	Organism	Ertapenem			
			S, I, R		MIC	
			Reference	Observed	Reference	Observed
	0001	<i>Escherichia coli</i>	R		8	
	0002	<i>Enterobacter cloacae</i>	R		>8	
	0003	<i>Klebsiella pneumoniae</i>	R		>8	
	0004	<i>Klebsiella pneumoniae</i>	R		>8	
	0005	<i>Klebsiella pneumoniae</i>	R		>8	
	0006	<i>Escherichia coli</i>	R		>8	
	0007	<i>Klebsiella aerogenes</i>	R		2	
	0008	<i>Enterobacter cloacae</i>	R		>8	
	0009	<i>Klebsiella aerogenes</i>	R		>8	
	0010	<i>Klebsiella pneumoniae</i>	R		>8	
	0011	<i>Escherichia coli</i>	S		0.25	
	0012	<i>Klebsiella pneumoniae</i>	S		0.5	
	0013	<i>Escherichia coli</i>	S		<=0.12	
	0014	<i>Escherichia coli</i>	S		<=0.12	
	0015	<i>Escherichia coli</i>	S		0.5	
	0016	<i>Klebsiella pneumoniae</i>	S		<=0.12	
	0017	<i>Escherichia coli</i>	S		<=0.12	
	0018	<i>Klebsiella aerogenes</i>	S		<=0.12	
	0019	<i>Escherichia coli</i>	S		<=0.12	
	0020	<i>Escherichia coli</i>	S		<=0.12	
	0021	<i>Citrobacter freundii</i>	S		<=0.12	
	0022	<i>Citrobacter freundii</i>	S		<=0.12	
	0023	<i>Citrobacter freundii</i>	S		<=0.12	
	0024	<i>Citrobacter koseri</i>	S		<=0.12	
	0025	<i>Citrobacter koseri</i>	S		<=0.12	
	0026	<i>Providencia stuartii</i>	S		<=0.12	
	0027	<i>Serratia marcescens</i>	S		<=0.12	
	0028	<i>Klebsiella oxytoca</i>	S		<=0.12	
	0029	<i>Proteus mirabilis</i>	S		0.25	
	0030	<i>Shigella sonnei</i>	S		<=0.12	
	0031	<i>Salmonella typhimurium</i>	S		<=0.12	

		Number	%
Date:	Categorical Agreement		
	Very Major Errors		
Tech:	Major Errors		
	Minor Errors		

Breakpoints for ertapenem and *Enterobacterales* used are:

S _____ (mcg/ml)
 I _____ (mcg/ml)
 R _____ (mcg/ml)

which are found in CLSI M100, _____ edition (year/fillable text)

Date: _____ Initials: _____

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Enterobacterales	Carbapenems	Imipenem
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Test Date/Tech	Isolate No.	Organism	Imipenem			
			S, I, R		MIC	
			Reference	Observed	Reference	Observed
	0001	<i>Escherichia coli</i>	R		4	
	0002	<i>Enterobacter cloacae</i>	R		16	
	0003	<i>Klebsiella pneumoniae</i>	R		8	
	0004	<i>Klebsiella pneumoniae</i>	R		16	
	0005	<i>Klebsiella pneumoniae</i>	R		16	
	0006	<i>Escherichia coli</i>	R		16	
	0007	<i>Klebsiella aerogenes</i>	S		1	
	0008	<i>Enterobacter cloacae</i>	S		1	
	0009	<i>Klebsiella aerogenes</i>	R		8	
	0010	<i>Klebsiella pneumoniae</i>	R		4	
	0011	<i>Escherichia coli</i>	S		<=0.5	
	0012	<i>Klebsiella pneumoniae</i>	S		<=0.5	
	0013	<i>Escherichia coli</i>	S		<=0.5	
	0014	<i>Escherichia coli</i>	S		<=0.5	
	0015	<i>Escherichia coli</i>	S		<=0.5	
	0016	<i>Klebsiella pneumoniae</i>	S		<=0.5	
	0017	<i>Escherichia coli</i>	S		<=0.5	
	0018	<i>Klebsiella aerogenes</i>	S		1	
	0019	<i>Escherichia coli</i>	S		<=0.5	
	0020	<i>Escherichia coli</i>	S		1	
	0021	<i>Citrobacter freundii</i>	S		<=0.5	
	0022	<i>Citrobacter freundii</i>	S		1	
	0023	<i>Citrobacter freundii</i>	S		<=0.5	
	0024	<i>Citrobacter koseri</i>	S		<=0.5	
	0025	<i>Citrobacter koseri</i>	S		<=0.5	
	0026	<i>Providencia stuartii</i>	S		<=0.5	
	0027	<i>Serratia marcescens</i>	S		<=0.5	
	0028	<i>Klebsiella oxytoca</i>	S		<=0.5	
	0029	<i>Proteus mirabilis</i>	R		8	
	0030	<i>Shigella sonnei</i>	S		<=0.5	
	0031	<i>Salmonella typhimurium</i>	S		<=0.5	

		Number	%
Date:	Categorical Agreement		
	Very Major Errors		
Tech:	Major Errors		
	Minor Errors		

Breakpoints for imipenem and *Enterobacterales* used are:

S _____ (mcg/ml)
 I _____ (mcg/ml)
 R _____ (mcg/ml)

which are found in CLSI M100, _____ edition (year/fillable text)

Date: _____ Initials: _____

Enterobacterales

Carbapenems

Imipenem

Director/Designee Approval or Comments:	Meets criteria for verification?	Yes	No
	Additional Information:		
Date:			

Enterobacterales	Carbapenems	Meropenem
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Test Date/Tech	Isolate No.	Organism	Meropenem			
			S, I, R		MIC	
			Reference	Observed	Reference	Observed
	0001	<i>Escherichia coli</i>	R		4	
	0002	<i>Enterobacter cloacae</i>	R		>8	
	0003	<i>Klebsiella pneumoniae</i>	R		>8	
	0004	<i>Klebsiella pneumoniae</i>	R		>8	
	0005	<i>Klebsiella pneumoniae</i>	R		>8	
	0006	<i>Escherichia coli</i>	R		8	
	0007	<i>Klebsiella aerogenes</i>	I		2	
	0008	<i>Enterobacter cloacae</i>	I		2	
	0009	<i>Klebsiella aerogenes</i>	I		2	
	0010	<i>Klebsiella pneumoniae</i>	S		1	
	0011	<i>Escherichia coli</i>	S		≤0.12	
	0012	<i>Klebsiella pneumoniae</i>	S		0.25	
	0013	<i>Escherichia coli</i>	S		≤0.12	
	0014	<i>Escherichia coli</i>	S		≤0.12	
	0015	<i>Escherichia coli</i>	S		≤0.12	
	0016	<i>Klebsiella pneumoniae</i>	S		≤0.12	
	0017	<i>Escherichia coli</i>	S		≤0.12	
	0018	<i>Klebsiella aerogenes</i>	S		≤0.12	
	0019	<i>Escherichia coli</i>	S		≤0.12	
	0020	<i>Escherichia coli</i>	S		≤0.12	
	0021	<i>Citrobacter freundii</i>	S		≤0.12	
	0022	<i>Citrobacter freundii</i>	S		≤0.12	
	0023	<i>Citrobacter freundii</i>	S		≤0.12	
	0024	<i>Citrobacter koseri</i>	S		≤0.12	
	0025	<i>Citrobacter koseri</i>	S		≤0.12	
	0026	<i>Providencia stuartii</i>	S		≤0.12	
	0027	<i>Serratia marcescens</i>	S		≤0.12	
	0028	<i>Klebsiella oxytoca</i>	S		≤0.12	
	0029	<i>Proteus mirabilis</i>	S		0.5	
	0030	<i>Shigella sonnei</i>	S		≤0.12	
	0031	<i>Salmonella typhimurium</i>	S		≤0.12	

		Number	%
Date:	Categorical Agreement		
	Very Major Errors		
Tech:	Major Errors		
	Minor Errors		

Breakpoints for meropenem and *Enterobacterales* used are:

S _____ (mcg/ml)
 I _____ (mcg/ml)
 R _____ (mcg/ml)

which are found in CLSI M100, _____ edition (year/fillable text)

Date: _____ Initials: _____

Enterobacterales

Carbapenems

Meropenem

Director/Designee Approval or Comments:	Meets criteria for verification?	Yes	No
	Additional Information:		
Date:			

