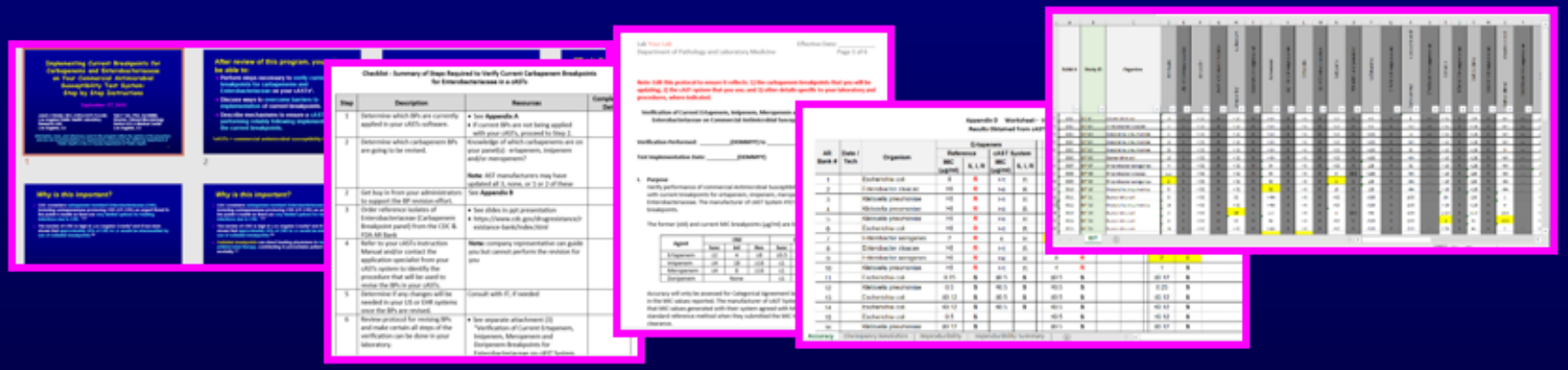
Implementing Current Breakpoints for Carbapenems and Enterobacteriaceae on Your Commercial Antimicrobial Susceptibility Test System

Step by Step Instructions!

Resources Provided to "Guide" You (Editable; Use is Optional!)

1. CBP Enterobacteriaceae BP Verif_D PPT slides
2. Checklist CBP Enterobacteriaceae BP Verif_D
3. Protocol CBP Enterobacteriaceae BP Verif_D
4. App D Worksheet CBP Enterobacteriaceae BP Verif_D
5. BIT ARBANK Updated MJM07302018_D – Spreadsheet w/ AR Bank Results (from CDC)

CBP, carbapenem; BP, breakpoint



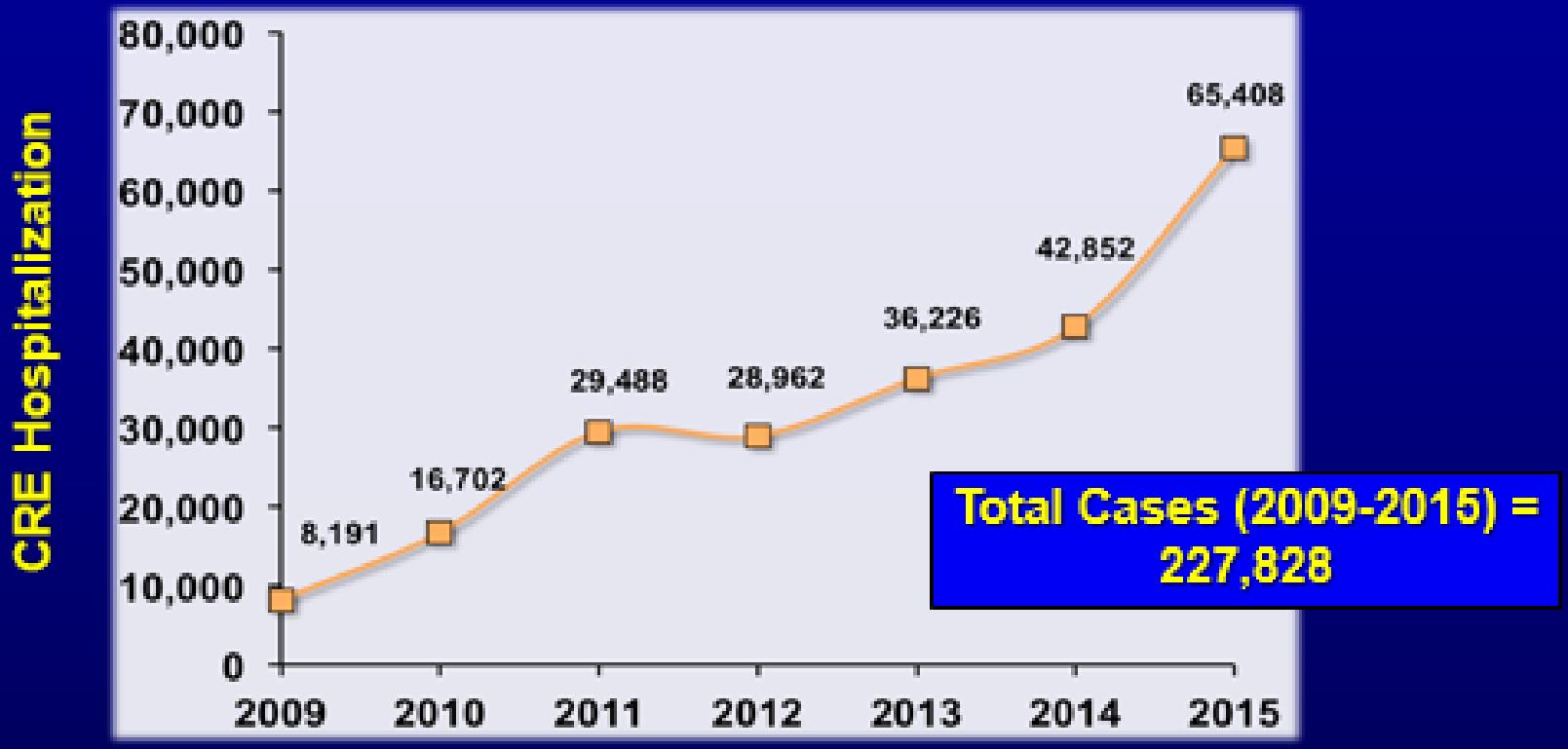
Why is this important?

- CDC considers carbapenem-resistant Enterobacteriaceae (CRE), including carbapenemase producing CRE (CP-CRE) an urgent threat to the public's health as there are very limited options for treating infections due to CRE.[1,2,3]
- The burden of CRE is high in Los Angeles County[4] and it has been shown that approximately 20% of CRE in LA would be misclassified by use of outdated breakpoints.[5,6]
- Outdated breakpoints can direct treating physicians to inappropriate antimicrobial therapy, contributing to preventable patient morbidity and mortality.[2,3]
- Outdated breakpoints hinder the ability to identify CRE, impairing" infection control initiatives and fueling the spread of CRE.[5]

See this webinar handout 2_Checklist CBP Enterobacteriaceae BP Verif; Appendix B.

Why is this important?

Steady Increase in CRE Cases in US



Schneider et al., SHEA 2017. Thaden et al. ICHE. 2014. Lodise et al., AAC 2017. Bartsch et al., Clin Microbiol Infect 2017.

Slide courtesy of Dr. James McKinnell

CARLA Survey (2015)

- California Antimicrobial Resistance Laboratory Network Assessment (CARLA)
- Joint project:
  - California Department of Public Health
  - Los Angeles County Department of Public Health
  - Survey of clinical laboratories re: AST practices
- Results:
  - 28% used outdated carbapenem breakpoints for Enterobacteriaceae
  - Many did not perform carbapenemase testing as required if old breakpoints used (CLSI M100 Table 3C)

Humphries RM et al. Clin Infect Dis. 2018;66:1061-1067.

LA County CRE Initiative

- **Goal:** get labs to use current carbapenem breakpoints for Enterobacteriaceae
- "Visited" **41 laboratories** that were using outdated breakpoints (identified from CARLA)
- **Status** of breakpoint updates:
  - 7 updated
  - 27 thought they were updated
  - 17 did not know how to update
  - 10 insufficient resources (staffing, etc)

34 labs

OUR HEALTH · OUR COMMUNITY · OUR LOS ANGELES COUNTY
LOS ANGELES COUNTY HEALTH AGENCY

Thanks to Dr. James McKinnell, Dr. Dawn Terashita and team for helping many labs update breakpoints in LA County over the past 2 years!

LA County CRE Initiative (continued)

- Follow up after initial "visits" to 34 labs (labs were given information to assist with the breakpoint update)
  - 16 updated
  - 12 have isolates to perform update
  - 6 planning to obtain isolates

Thanks to Dr. James McKinnell, Dr. Dawn Terashita and team for helping many labs update breakpoints in LA County over the past 2 years!

Breakpoints

Where are the current CLSI breakpoints for carbapenems and Enterobacteriaceae?

M100S 28th ed Table 2A (January 2018)

Table 2A
Enterobacteriaceae
M02 and M07

Table 2A. Zone Diameter and MIC Breakpoints for *Enterobacteriaceae*

Testing Conditions

Medium: Disk diffusion: MHA
Broth dilution: CAMHB
Agar dilution: MHA

Inoculum: **Broth culture** method or colony suspension, equivalent to a 0.5 McFarland standard

Incubation: 35°C ± 2°C; ambient air
Disk diffusion: 16–18 hours
Dilution methods: 16–20 hours

Routine QC Recommendations (see Tables 4A-1 and 5A-1 for acceptable QC ranges)

Escherichia coli ATCC®* 25922
Pseudomonas aeruginosa ATCC® 27853 (for carbapenems)

Refer to Tables 4A-2 and 5A-2 to select strains for routine QC of β-lactam combination agents.

When a commercial test system is used for susceptibility testing, refer to the manufacturer's instructions for QC test recommendations and QC ranges.

* ATCC® is a registered trademark of the American Type Culture Collection.

Refer to Tables 3A, 3B, and 3C for additional testing, reporting, and QC for *Enterobacteriaceae*.

General Comments

(1) For disk diffusion, test a maximum of 12 disks on a 150-mm plate and no more than 6 disks on a 100-mm plate; disks should be placed no less than 24 mm apart, center to center (see M02,[1] Subchapter 3.6). Each zone diameter should be clearly measurable; overlapping zones prevent accurate measurement.

B	Doripenem	10 µg	≥23	–	20–22	≤19	≤1	–	2	≥4	**(28)** Breakpoints are based on a dosage regimen of 500 mg every 8 h.
B	Ertapenem	10 µg	≥22	–	19–21	≤18	≤0.5	–	1	≥2	**(29)** Breakpoints are based on a dosage regimen of 1 g every 24 h.
B	Imipenem	10 µg	≥23	–	20–22	≤19	≤1	–	2	≥4	**(30)** Breakpoints are based on a dosage regimen of 500 mg every 6 h or 1 g every 8 h.
B	Meropenem	10 µg	≥23	–	20–22	≤19	≤1	–	2	≥4	**(31)** Breakpoints are based on a dosage regimen of 1 g every 8 h.

S I R S I R

Page 34.

www.clsi.org

1. Click "Resources"

2. Click "Free Resources"

3. Click Access M100 (on screen use only)

Enterobacteriaceae - Carbapenem Breakpoints (MIC µg/ml)[1]

Agent	Old			Current		
	Susc	Int	Res	Susc	Int	Res
Ertapenem	≤2	4	≥8	≤0.5	1	≥2
Imipenem	≤4	8	≥16	≤1	2	≥4
Meropenem	≤4	8	≥16	≤1	2	≥4
Doripenem	none			≤1	2	≥4

[1]CLSI M100 28[h] ed; corresponding disk diffusion breakpoints also provided

Breakpoint Reminders

- CLSI and FDA set / update breakpoints in USA
- Carbapenem breakpoints for Enterobacteriaceae were updated by:
  - CLSI in 2010
  - FDA in 2012 (ertapenem, imipenem); 2013 (meropenem); 2017 (doripenem)
- Not all cAST systems are updated with current CLSI / FDA breakpoints
  - No regulatory mandate for cAST manufacturers to do this
  - Not a priority for some cAST system manufacturers

*cAST = commercial antimicrobial susceptibility test

Breakpoint Reminders (cont')

- Clinical laboratories must perform a **verification** for a cAST system if using breakpoints other than those that are FDA-cleared on that system

Check with manufacturer of your cAST system for breakpoint status!

Verification

CLIA Regulations re: Verification of tests

User must demonstrate performance specifications when using a test that is not FDA-cleared or using a modification of an FDA-cleared test BEFORE use for patient testing…

- Accuracy
- Precision (reproducibility)

- Reportable range of patient test results
- Reference range(s)
- Any characteristic required for test performance or interpretation of results

CLIA 493.1253

Applying current carbapenem breakpoints for Enterobacteriaceae in a cAST system….

Is a "modification of an FDA-cleared test"

IF….

the cAST system does not have the current breakpoints in its software!

Must "verify"!

Agent	Old			Current		
	Susc	Int	Res	Susc	Int	Res
Ertapenem	≤2	4	≥8	≤0.5	1	≥2
Imipenem	≤4	8	≥16	≤1	2	≥4
Meropenem	≤4	8	≥16	≤1	2	≥4
Doripenem	none			≤1	2	≥4

CLIA rules very general….

The verification of method performance should provide evidence that the accuracy, precision, and reportable range of the procedure are adequate to meet the clients' needs, as determined by the laboratory director and clinical consultant. A laboratory may use the manufacturer's performance specifications as a guideline, but is responsible for verifying the manufacturer's analytical claims before initiating patient testing.

Does not specify:

- Number of specimens to test
- Comparator method
- Criteria for acceptability

CLIA Surveyor Guidelines.

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_c_lab.pdf

User Lab Verification vs. Routine QC

Verification

- Complete before reporting patient results
- Make sure results from the cAST system are reliable (accurate, reproducible)

"Routine" QC

- Ongoing

Reminder….

- Can "reduce" amount required by CLIA:
  - AST – "Daily" to "Weekly"
  - Need Individual Quality Control Plan (IQCP)!

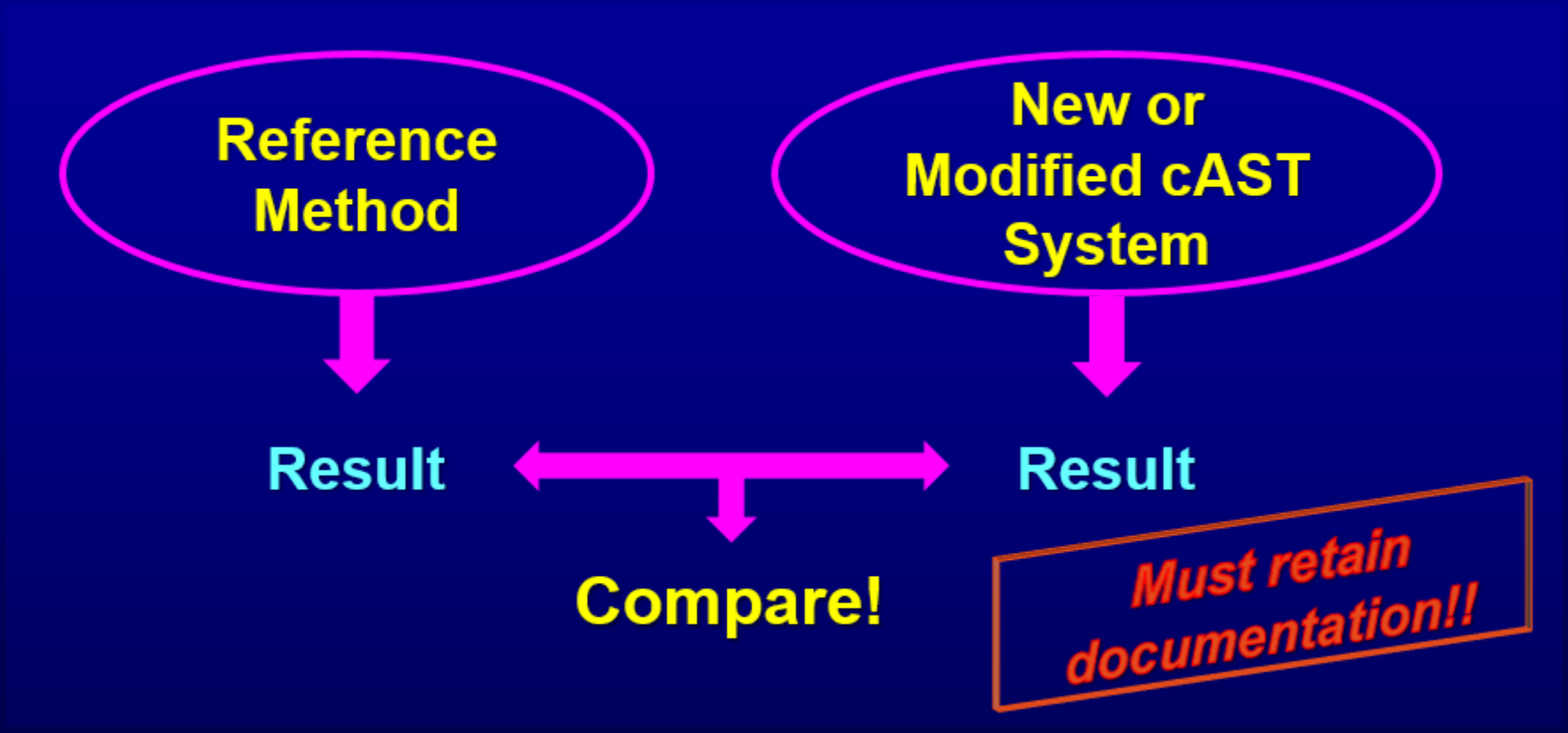
Where can I find information about "verification of cAST systems?

CLSI M52 (2015) describes verification of:

- **New cAST system in your lab (Full verification)**
- **Adding new drugs to your cAST system (Limited Verification)**

- **Updating breakpoints not FDA cleared in cAST system (Limited Verification)**
  see CLSI M52 page 51 App B

For verification, test each isolate by….



How do we get REF results for isolates used in a cAST system verification?

1. Test isolates with CLSI standard reference method
   - Broth microdilution or agar dilution MICs
   - Disk diffusion
2. Test isolates with commercial FDA-cleared AST method that was previously verified
3. Obtain isolates with known AST results from verified AST system (from outside source)
   - e.g. CDC & FDA AR Bank Isolates

For #1 and #2, testing of cAST system to be verified often done at same time as REF testing.

Summary of Recommendations for Meeting CLIA-Required Performance Specifications for Verification of cAST System

CLIA Performance Specifications	Recommendation
Accuracy	Categoric Agreement (S, I*, R) (see 3.8.5) Essential Agreement (MIC) when applicable (see 3.8.5)
Precision (Reproducibility)	S, I, or R interpretation reproducible MIC value reproducible with an accepted variation of +/- 1 doubling dilution for bacteria and +/- 2 doubling dilutions for yeast (see 3.8.4)

*"I" includes SDD (susceptible does dependent)

CLSI M52 page 10 Table 1.

What criteria are used to determine if cAST system results are acceptable?

Criteria	Defined as…	Acceptable limits
Category Agreement (CA)	S, I, and R results agree	≥90%
Essential Agreement (EA)	MIC within +/- 1 doubling dilution of the REF MIC	≥90%

Accuracy!

What criteria are used to determine if cAST system results are acceptable? (con't)

Error	Results		Acceptable Error Rate
	REF	cAST system	
Very major	R[1]	S	≤1.5 %
Major	S[2]	R	≤3.0 %
Minor	S	I	Not specified
	R	I	
	I	S	
	I	R	

[1] only isolates R by REF included in calculating error rate
[2] only isolates S by REF included in calculating error rate

Accuracy!

Calculating EA / CA

Category agreement (CA) =

$$\frac{\text{\# with same S, I, or R result as REF MIC}}{\text{Total \# isolates tested}} \times 100$$

Essential agreement (EA) =

$$\frac{\text{\# within +/- 1 two-fold dilution of REF MIC}}{\text{Total \# isolates tested}} \times 100$$

Calculating % Errors

Very major error (VME) =

$$\frac{\text{\# with VME error (false R)}}{\text{Total \# "R" isolates tested}} \times 100$$

Major error (ME) =

$$\frac{\text{\# with ME error (false S)}}{\text{Total \# "S" isolates tested}} \times 100$$

Minor error (miE) =

$$\frac{\text{\# with miE error}}{\text{Total \# isolates tested}} \times 100$$

How do we examine reproducibility of a cAST system?

Reproducibility- CLSI M52 page 29.

- **Test isolates:**
  - **Routine ATCC QC strains and/or clinical isolates**
  - **Preferably isolate(s) with on-scale endpoints if available**
  - **Test 3 times (3 separate inocula)**
  - **Test over 1-3 days on cAST system**
- **Acceptable results:**
  - **95% within +/- 1 dilution (essential agreement)**
  - **For ATCC QC strains; 95% must be within +/- 1 dilution and within acceptable QC range (CLSI M100)**
  - **No limit described for S, I, R reproducibility**

What to do for reproducibility for breakpoint update?

Reproducibility

Up to the laboratory director! Suggestions:

- **Review results from reproducibility studies previously done**
  - **What MIC and S I R ranges were "covered" (if current BPs applied)?**
  - **Is there a need to examine additional isolates to confirm S I R reproducibility?**
- **Isolate selection options:**
  - **Isolate from Enterobacteriaceae Breakpoint Panel (e.g. #3 *Klebsiella pneumoniae*)**
  - **QC strain *P. aeruginosa* ATCC 27853**
  - **2 – 3 isolates sufficient**

The Carbapenem Enterobacteriaceae Verification Study!

Checklist

- Step by step instructions with resources to support various steps

Checklist - Summary of Steps Required to Verify Current Carbapenem Breakpoints for Enterobacteriaceae in a cAST System (9/27/18)

Step	Description	Resources / Comments	Completion Date
1	Determine which BPs are currently applied in your cAST system software.	• See **Appendix A** below • If current BPs are not being applied with your cAST system, proceed to Step 2.	
2	Determine which carbapenem BPs are going to be updated.	Knowledge of which carbapenems are on your panel(s): ertapenem, imipenem and/or meropenem? **Note:** AST manufacturers may have updated all 3, none, or 1 or 2 of these	
2	Get buy in from your administrators to support the BP update effort.	See **Appendix B** below	
3	Order reference isolates of Enterobacteriaceae (Carbapenem Breakpoint panel) from the CDC & FDA AR Bank.	• See slides in ppt presentation • https://www.cdc.gov/drugresistance/resistance-bank/index.html	
4	Refer to your cAST System Instruction Manual and/or contact the application specialist from your cAST system to identify the procedure that will be used to update the BPs in your cAST system.	**Note:** company representative can guide you but cannot perform the update for you	
5	Determine if any changes will be needed in your LIS or EHR systems once the BPs are updated.	Consult with IT, if needed.	
6	Review protocol for updating BPs and make certain all steps of the verification can be done in your laboratory.	• See separate attachment (3) "Verification of Current Ertapenem, Imipenem, Meropenem and Doripenem Breakpoints for Enterobacteriaceae on cAST System XYZ".	

Verification Protocol

- Customize to your laboratory:
- cAST system
- Drugs to be verified
- When cAST system was originally verified
- Concentrations of drugs on your cAST system panel
- Other

- Write protocol before verification begins!

Note: Edit this protocol to ensure it reflects: 1) the carbapenem breakpoints that you will be updating; 2) the cAST system that you use; and 3) other details specific to your laboratory and procedures, where indicated.

Verification of Current Ertapenem, Imipenem, Meropenem and Doripenem Breakpoints for Enterobacteriaceae on Commercial Antimicrobial Susceptibility Testing System XYZ

Verification Performed: _____(DDMMYY) to _____(DDMMYY)

Test Implementation Date: _____(DDMMYY)

I. Purpose

Verify performance of commercial Antimicrobial Susceptibility Testing (cAST) System XYZ with current breakpoints for ertapenem, imipenem, meropenem and doripenem, for the Enterobacteriaceae. The manufacturer of cAST System XYZ has not yet updated these breakpoints.

The former (old) and current MIC breakpoints (µg/ml) are listed below:

Agent	Old			Current		
	Susc	Int	Res	Susc	Int	Res
Ertapenem	≤2	4	≥8	≤0.5	1	≥2
Imipenem	≤4	18	≥16	≤1	2	≥4
Meropenem	≤4	8	≥16	≤1	2	≥4
Doripenem	None			≤1	2	≥4

Accuracy will only be assessed for Categorical Agreement because there will be no changes in the MIC values reported. The manufacturer of cAST System XYZ previously demonstrated that MIC values generated with their system agreed with MIC values obtained from a standard reference method when they submitted the MIC test data for these drugs for FDA clearance.

CDC & FDA Antibiotic Resistance (AR) Isolate Bank
Enterobacteriaceae Carbapenem Breakpoint Panel

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

SEARCH

CDC A-Z INDEX

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- Protect Yourself and Your Family
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- U.S. Action +
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CDC & FDA Antibiotic Resistance (AR) Isolate Bank

AR ISOLATE BANK

On This Page

- Advancing the Fight against Antibiotic Resistance
- Why the AR Isolate Bank is Unique
- Order Isolates
- Isolates Available from Other Resources

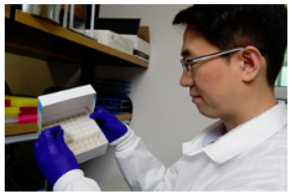
The CDC and FDA AR Isolate Bank provides information on resistance to support innovation in diagnostics and drug development. CDC provides isolates (pure samples of a germ) to approved institutions. Access the AR Isolate Bank.

> "The isolates helped us challenge our diagnostic tests to ensure they can detect a variety of resistance targets,"
> -Biotechnology company"

Advancing the Fight against Antibiotic Resistance

As of January 2018, the AR Isolate Bank shipped more than 2,000 isolate panels. The AR Isolate Bank helps:

- Strengthen diagnostics by validating lab tests
- Inform research and development to
  - develop drugs like antibiotics and antifungals
  - develop diagnostic devices, tests, or assays
  - satisfy a request or support an application to FDA
- Perform testing to ensure drug effectiveness
- Study biology and pathogenic mechanisms
- Detect new and unusual public health resistance threats



The AR Isolate Bank shipped more than 2,000 isolate panels as of January 2018.

This work ultimately improves patient care and builds solutions against resistance threats.

Why the AR Isolate Bank is Unique

What is the CDC & FDA AR Bank?

- **Repository of organisms with a variety of resistance mechanisms and MIC values to be used by industry, researchers, clinical labs and others**
  - **Develop new tests / drugs**
  - **Validate current tests**
- **Provided in "sets" or panels (frozen), e.g.,**
  - **Enterobacteriaceae carbapenem breakpoint panel**
  - **Gram negative carbapenemase detection panel**
  - **Ceftazidime – avibactam panel**
- **Accompanied with MIC and S, I, R results, sometimes molecular characterization**

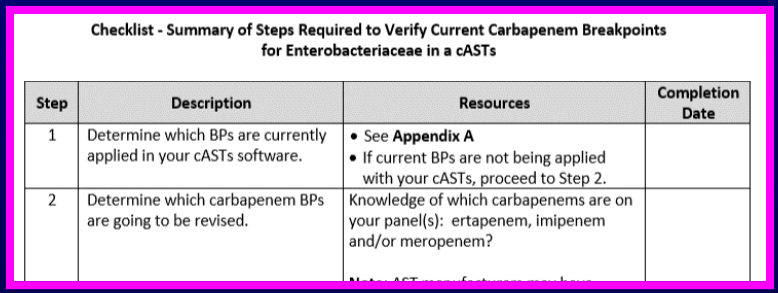
Getting isolates from the CDC & FDA AR Bank…

- **Register**
  - **Registration must be approved**
- **Submit order**
- **Complete forms (materials transfer and biosafety compliance)**
- **Free (but pay shipping)!**
- **1-2 weeks; arrive “frozen”**

See slides at end of this set for step by step ordering instructions

The Study in Brief!

- Test 31 isolates from AR Bank Enterobacteriaceae Carbapenem Breakpoint Panel on your cAST system
- Record MIC results (NOT S I R) results on Worksheet
- Interpret each MIC result as S, I (SDD), or R with current CLSI breakpoints
- Compare S, I, R result with CDC reference result for each isolate



Checklist - Summary of Steps Required to Verify Current Carbapenem Breakpoints for Enterobacteriaceae in a cASTs

Step	Description	Resources	Completion Date
1	Determine which BPs are currently applied in your cASTs software.	• See **Appendix A** • If current BPs are not being applied with your cASTs, proceed to Step 2.	
2	Determine which carbapenem BPs are going to be revised.	Knowledge of which carbapenems are on your panel(s): ertapenem, imipenem and/or meropenem?	

No need to compare MICs - manufacturer already demonstrated "Essential Agreement" with "MIC reference method" during initial FDA clearance of tests for these drugs.

The Study in Brief! (cont')

- Calculate:
  - Category Agreement - ≥90%
  - Very Major Errors - none allowed
  - Major Errors - only 1 acceptable
  - Minor Errors – up to laboratory director!
    - See CLSI M52 page 52
- Following satisfactory verification, update breakpoints in your cAST system
  - Contact application specialist for your cAST system, if you need advice on how to do this!
- Ensure results are accurately transmitted to patient charts (IT check)
- Inform stakeholders (Antibiotic Stewardship Team, etc) of the change

Worksheet (editable)

- Note CDC reference results
- Record MICs obtained from your testing
- Interpret MICs with current breakpoints
- (Ignore interpretation from cAST system)

Appendix D

Results Obtained from cAST System XYZ Compared to CDC FDA AR Bank Isolate Reference Results

AR Bank #	Date / Tech	Organism	Ertapenem				Imipenem				Meropenem			
			Reference		cAST System		Reference		cAST System		Reference		cAST System	
			MIC (µg/ml)	S, I, R	MIC (µg/ml)	S, I, R	MIC (µg/ml)	S, I, R	MIC (µg/ml)	S, I, R	MIC (µg/ml)	S, I, R	MIC (µg/ml)	S, I,
1		Escherichia coli	8	R	>4	R	4	R			4	R		
2		Enterobacter cloacae	>8	R	>4	R	16	R			>8	R		
3		Klebsiella pneumoniae	>8	R	>4	R	8	R			>8	R		
4		Klebsiella pneumoniae	>8	R	>4	R					>8	R		
5		Klebsiella pneumoniae	>8	R	>4	R					>8	R		
6		Escherichia coli	>8	R	>4	R					8	R		
7		Enterobacter aerogenes	2	R	4	R					1	S		
8		Enterobacter cloacae	>8	R	>4	R					2	I		
9		Enterobacter aerogenes	>8	R	>4	R					2	I		
10		Klebsiella pneumoniae	>8	R	>4	R					1	S		
11		Escherichia coli	0.25	S	≤0.5	S	≤0.5	S			≤0.12	S		
12		Klebsiella pneumoniae	0.5	S	≤0.5	S	≤0.5	S			0.25	S		
13		Escherichia coli	≤0.12	S	≤0.5	S	≤0.5	S			≤0.12	S		
14		Escherichia coli	≤0.12	S	≤0.5	S	≤0.5	S			≤0.12	S		
15		Escherichia coli	0.5	S			≤0.5	S			≤0.12	S		
16		Klebsiella pneumoniae	≤0.12	S			≤0.5	S			≤0.12	S		

Accuracy | Discrepancy Resolution | Reproducibility | Reproducibility Summary

Ertapenem Current Breakpoints (µg/ml)

Susc	Int	Res
≤0.5	1	≥2

= CDC modified original result

Reviewing Results

*Example: meropenem
Enterobacteriaceae

Current Breakpoints (µg/ml)		
Susc	Int	Res
≤1	2	≥4

AR Bank #	REF		cAST system		CA	Error?
1	4	R	8	R	yes	no
2	>8	R	>8	R	yes	no
8	2	I	4	R	no	Minor
10	1	S	0.5	S	yes	no
11	≤0.12	S	0.5	S	yes	no

*Enterobacteriaceae Carbapenem BP Panel (AR Bank Isolates)

Calculating % Errors

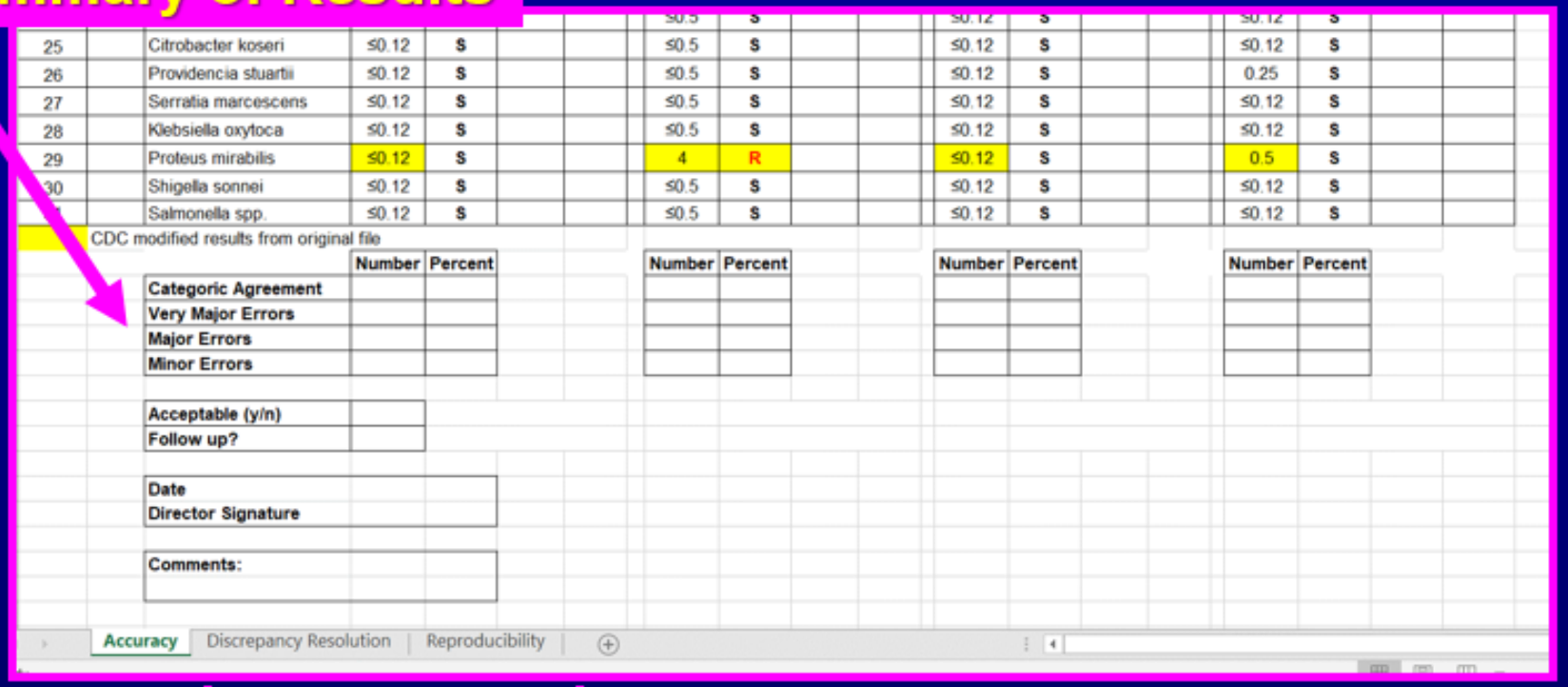
***Example: meropenem Enterobacteriaceae**

N	REF			Very Major		Major		Minor	
	# S	# I	# R	#	%	#	%	#	%
31	23	1	7	0/7	0	0/23	0	1/31	3.2

***Enterobacteriaceae Carbapenem Breakpoint Panel (AR Bank Isolates)**

Worksheet (editable)

Record Summary of Results



25		Citrobacter koseri	≤0.12	S			≤0.5	S			≤0.12	S			≤0.12	S		
26		Providencia stuartii	≤0.12	S			≤0.5	S			≤0.12	S			0.25	S		
27		Serratia marcescens	≤0.12	S			≤0.5	S			≤0.12	S			≤0.12	S		
28		Klebsiella oxytoca	≤0.12	S			≤0.5	S			≤0.12	S			≤0.12	S		
29		Proteus mirabilis	≤0.12	S			4	R			≤0.12	S			0.5	S		
30		Shigella sonnei	≤0.12	S			≤0.5	S			≤0.12	S			≤0.12	S		
		Salmonella spp.	≤0.12	S			≤0.5	S			≤0.12	S			≤0.12	S		

CDC modified results from original file

	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Categoric Agreement								
Very Major Errors								
Major Errors								
Minor Errors								

Acceptable (y/n)	
Follow up?	

Date
Director Signature

Comments:

Accuracy | Discrepancy Resolution | Reproducibility

Additional worksheets: discrepancy resolution; reproducibility

Additional CLSI Breakpoints Updated Since 2010

Appendix E –listing of additional MIC (µg/ml) BPs revised since 2010 for GNR

Enterobacteriaceae

Agent	Old			Current*		
	Susc	Int	Res	Susc	Int	Res
Cefazolin	≤8	16	≥32	≤1	2	≥4
Cefepime	≤8	16	≥32	≤2	4-8 (SDD)	≥16
Cefotaxime	≤8	16-32	≥64	≤1	2	≥4
Ceftazidime	≤8	16	≥32	≤4	8	≥16
Ceftizoxime	≤8	16-32	≥64	≤1	2	≥4
Ceftriaxone	≤8	16-32	≥64	≤1	2	≥4
Aztreonam	≤8	16	≥32	≤4	8	≥16

Note: BPs for fluoroquinolones (ciprofloxacin, levofloxacin) and *Salmonella* spp. were also revised

Pseudomonas aeruginosa

Agent	Old			Current*		
	Susc	Int	Res	Susc	Int	Res
Doripenem	None			≤2	4	≥8
Imipenem	≤4	8	≥16	≤2	4	≥8
Meropenem	≤4	8	≥16	≤2	4	≥8
Piperacillin	≤64	-	≥128	≤16	32-64	≥128
Piperacillin-tazobactam	≤64/4	-	≥128/4	≤16/4	32/4-64/4	≥128/4
Ticarcillin	≤64	-	≥128	≤16	32-64	≥128
Ticarcillin-clavulanate	≤64/2	-	≥128/2	≤16/2	32/2-64/2	≥128/2

***Acinetobacter* spp.**

Agent	Old			Current*		
	Susc	Int	Res	Susc	Int	Res
Doripenem	None			≤2	4	≥8
Imipenem	≤4	8	≥16	≤2	4	≥8
Meropenem	≤4	8	≥16	≤2	4	≥8

* CLSI M100, 28th edition. Performance standards for antimicrobial susceptibility testing; twenty-eighth informational supplement. Wayne, PA: Clinical Laboratory Standards Institute; 2018.

….from M100 Page xxix.

CLSI Breakpoint Additions/Revisions Since 2010

Antimicrobial Agent	Date of Addition/Revision* (M100 edition)	Comments
Enterobacteriaceae		
Azithromycin – *S.* Typhi only	January 2015 (M100-S25)	
Aztreonam	January 2010 (M100-S20)	
Cefazolin	January 2010 (M100-S20) January 2011 (M100-S21)	Breakpoints were revised twice since 2010.
	January 2014 (M100-S24) January 2016 (M100S, 26th ed.)	Breakpoints were revised to predict results for cefazolin when cefazolin is used for therapy of uncomplicated UTIs.
Cefepime	January 2014 (M100-S24)	
Cefotaxime	January 201	
Ceftaroline	January 201	
Ceftazidime	January 201	
Ceftazidime-avibactam	**January 201**	
Ceftizoxime	January 201	
Ceftolozane-tazobactam	January 201 **January 201**	
Ceftriaxone	January 201	
Ciprofloxacin – *Salmonella* spp. (including *S.* Typhi)	January 201	
Doripenem	June 2010 (M	
Ertapenem	June 2010 (M January 201	
Imipenem	June 2010 (M	
Levofloxacin – *Salmonella* spp. (including *S.* Typhi)	January 201	
Meropenem	June 2010 (M	
Ofloxacin – *Salmonella* spp. (including *S.* Typhi)	June 2013 (M	
Pefloxacin – *Salmonella* spp. (including *S.* Typhi)	January 201	

2_Checklist CBP Enterobacteriaceae BP Verif_D

cAST Systems Applying Outdated Breakpoints

Appendix F – listing of cAST systems marketed in the U.S. that apply out of date (pre-2010) FDA breakpoints

Organism Group	Antimicrobial Agent	BD Phoenix	Beckman Coulter MicroScan	bioMerieux Vitek 2	Sensititre
Enterobacteriaceae	aztreonam				
	cefazolin	x	x	x	x
	cefepime		x		
	cefotaxime	x			
	ceftazidime	x	x	x	
	doripenem				
	ertapenem				
	imipenem			x	
	meropenem		x	x	
Pseudomonas aeruginosa	doripenem				
	imipenem			x	
	meropenem			x	
	piperacillin-tazobactam		x	x	
Acinetobacter spp.	doripenem				
	imipenem			x	
	meropenem*				

* no FDA breakpoint

2_Checklist CBP Enterobacteriaceae BP Verif_D

Enterobacteriaceae Carbapenem Breakpoint Panel

Spreadsheet from CDC with Reference results

Results for other drugs (including cephalosporins)

5_BIT_ARBank_updated MJM07302018_D

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y
1	BANK #	Study ID	Organism	Amikacin	AN-MIC-Interpretation	Ampicillin	AMP-MIC-Interpretation	Ampicillin/ sulbactam	SAM-MIC-Interpretation	Aztreonam	AZT-MIC-Interpretation	Cefazolin	CZ-MIC-Interpretation	Cefepime	FEP-MIC-Interpretation	Cefotaxime	CTX-MIC-Interpretation	Cefotaxime/ clavulanic acid	CTX/CL-MIC-Interpretation	Cefoxitin	FOX-MIC-Interpretation	Ceftazidime	CAZ-MIC-Interpretation	Ceftazidime/ clavulanic acid	CAZ/CL-MIC-Interpretation	
2	0001	BIT-01	Escherichia coli	16	S	> 32	R	> 32	R	> 64	R	> 8	R	>32	R	>64	R	8	---	> 16	R	128	R	>64	---	>
3	0002	BIT-02	Enterobacter cloacae	2	S	> 32	R	> 32	R	> 64	R	> 8	R	>32	R	>64	R	>32	---	> 16	R	>128	R	>64	---	>
4	0003	BIT-03	Klebsiella pneumoniae	2	S	> 32	R	> 32	R	> 64	R	> 8	R	>32	R	>128	R	16	---	> 16	R	>128	R	>64	---	>
5	0004	BIT-04	Klebsiella pneumoniae	16	S	> 32	R	> 32	R	> 64	R	> 8	R	>32	R	>128	R	>64	---	> 16	R	>128	R	>64	---	>
6	0005	BIT-05	Klebsiella pneumoniae	32	I	> 32	R	> 32	R	> 64	R	> 8	R	>32	R	>128	R	32	---	> 16	R	>128	R	64	---	>
7	0006	BIT-06	Escherichia coli	16	S	> 32	R	> 32	R	> 64	R	> 8	R	>32	R	>128	R	>64	---	> 16	R	>128	R	>64	---	>
8	0007	BIT-07	Enterobacter aerogenes	4	S	> 32	R	> 32	R	64	R	> 8	R	>32	R	128	R	32	---	> 16	R	>128	R	>64	---	>
9	0008	BIT-08	Enterobacter cloacae	≤ 1	S	> 32	R	> 32	R	64	R	> 8	R	8	SDD	>128	R	>64	---	> 16	R	128	R	>64	---	3
10	0009	BIT-09	Enterobacter aerogenes	2	S	> 32	R	> 32	R	64	R	> 8	R	2	S	128	R	>64	---	> 16	R	128	R	>64	---	>
11	0010	BIT-10	Klebsiella pneumoniae	8	S	> 32	R	> 32	R	32	R	> 8	R	16	R	128	R	>64	---	> 16	R	>128	R	>64	---	>
12	0011	BIT-11	Escherichia coli	8	S	> 32	R	32	R	> 64	R	> 8	R	>32	R	>128	R	≤0.5	---	16	I	128	R	1	---	>
13	0012	BIT-12	Klebsiella pneumoniae	16	S	> 32	R	> 32	R	> 64	R	> 8	R	>32	R	>128	R	≤0.5	---	> 16	R	>128	R	4	---	>
14	0013	BIT-13	Escherichia coli	2	S	> 32	R	16	I	≤ 2	S	> 8	R	4	SDD	>64	R	≤0.5	---	≤ 2.0	S	≤1.0	S	≤0.5	---	>
15	0014	BIT-14	Escherichia coli	4	S	> 32	R	32	R	64	R	> 8	R	>32	R	>128	R	≤0.5	---	4	S	32	R	≤0.5	---	>
16	0015	BIT-15	Escherichia coli	16	S	> 32	R	> 32	R	> 64	R	> 8	R	>32	R	>128	R	≤0.5	---	> 16	R	64	R	1	---	>

BIT

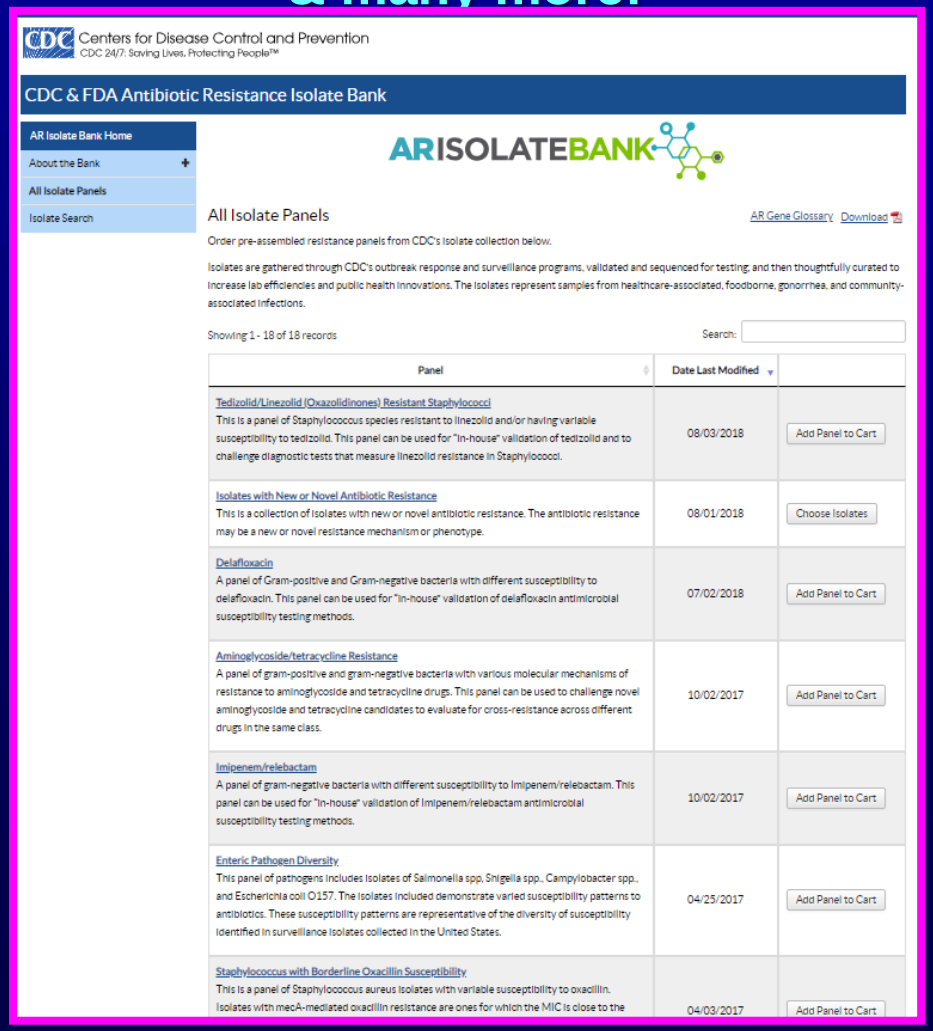
Other organism panels available from CDC including:

Acinetobacter baumannii

Pseudomonas aeruginosa

Gram negative carbapenemase detection

& many more!



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CDC & FDA Antibiotic Resistance Isolate Bank

AR Isolate Bank Home
About the Bank +
All Isolate Panels
Isolate Search

ARISOLATEBANK

All Isolate Panels

AR Gene Glossary Download

Order pre-assembled resistance panels from CDC's isolate collection below.

Isolates are gathered through CDC's outbreak response and surveillance programs, validated and sequenced for testing, and then thoughtfully curated to increase lab efficiencies and public health innovations. The isolates represent samples from healthcare-associated, foodborne, gonorrhea, and community-associated infections.

Showing 1 - 18 of 18 records Search:

Panel	Date Last Modified	
Tedizolid/Linezolid (Oxazolidinones) Resistant Staphylococci This is a panel of Staphylococcus species resistant to linezolid and/or having variable susceptibility to tedizolid. This panel can be used for "in-house" validation of tedizolid and to challenge diagnostic tests that measure linezolid resistance in Staphylococci.	08/03/2018	Add Panel to Cart
Isolates with New or Novel Antibiotic Resistance This is a collection of isolates with new or novel antibiotic resistance. The antibiotic resistance may be a new or novel resistance mechanism or phenotype.	08/01/2018	Choose Isolates
Delafloxacin A panel of Gram-positive and Gram-negative bacteria with different susceptibility to delafloxacin. This panel can be used for "in-house" validation of delafloxacin antimicrobial susceptibility testing methods.	07/02/2018	Add Panel to Cart
Aminoglycoside/tetracycline Resistance A panel of gram-positive and gram-negative bacteria with various molecular mechanisms of resistance to aminoglycoside and tetracycline drugs. This panel can be used to challenge novel aminoglycoside and tetracycline candidates to evaluate for cross-resistance across different drugs in the same class.	10/02/2017	Add Panel to Cart
Imipenem/relebactam A panel of gram-negative bacteria with different susceptibility to imipenem/relebactam. This panel can be used for "in-house" validation of imipenem/relebactam antimicrobial susceptibility testing methods.	10/02/2017	Add Panel to Cart
Enteric Pathogen Diversity This panel of pathogens includes isolates of Salmonella spp, Shigella spp., Campylobacter spp., and Escherichia coli O157. The isolates included demonstrate varied susceptibility patterns to antibiotics. These susceptibility patterns are representative of the diversity of susceptibility identified in surveillance isolates collected in the United States.	04/25/2017	Add Panel to Cart
Staphylococcus with Borderline Oxacillin Susceptibility This is a panel of Staphylococcus aureus isolates with variable susceptibility to oxacillin. Isolates with mecA-mediated oxacillin resistance are ones for which the MIC is close to the	04/03/2017	Add Panel to Cart

Harbor UCLA
Overview of Verification Study

- **Purpose:** Update to current CLSI / FDA breakpoints
- **Staffing:** CLS
- **Timeframe:** ~ 2 months (intermittent testing)
  - No dedicated staff for verification studies
  - CLS performed testing when staffing allowed
  - Tested over 10 days
- **AST Systems verified:** 2 Vitek 2 XL
- **Organism group:** Enterobacteriaceae
- **Antimicrobial agents:**
  - Meropenem
  - Cefazolin (urine breakpoints), ceftriaxone, ceftazidime, cefepime
  - Check MIC range on commercial system is low enough

Harbor UCLA
Overview of Verification Study

- Organism panels from CDC & FDA Antibiotic Resistance (AR) Isolate Bank
  - Enterobacteriaceae Carbapenem Breakpoint Panel
    - NOTE: AR-BANK #19 terminated on Vitek (poor growth?)
  - Gram-negative Carbapenemase Detection Panel
    - Provided 20 additional Enterobacteriaceae isolates
- 50 isolates tested between 2 Vitek instruments (25/instrument)
- Weekly QC for Vitek and KB – according to our IQCP
  - *P. aeruginosa* ATCC 27853
  - *E. coli* ATCC 25922
  - *E. coli* ATCC 35218
  - *K. pneumoniae* ATCC 700603

Harbor UCLA
Verification Study Acceptance Criteria

- Criteria for acceptable verification
  - ≥90% Categorical Agreement
  - 1 Major Error
  - No Very Major Error

See next slide…please

Harbor UCLA
Verification Study Results*

Meropenem
Enterobacteriaceae

N	REF			CA		Very Major		Major		Minor	
	# S	# I	# R	#	%	#	%	#	%	#	%
50	30	5	15	48/50	96	0/15	0	0/30	0	2/50	4

*** CDC & FDA AR Bank Isolates:**

Enterobacteriaceae Carbapenem Breakpoint Panel

Gram-Negative Carbapenamase Panels

Harbor UCLA
Verification Study Troubleshooting

AR Bank #	Organism	Antimicrobial	AR Bank Interpretation (MIC µg/ml)	Vitek Interpretation (MIC µg/ml)	Disk Diffusion Interpretation	Final Result
44	*Enterobacter aerogenes*	Meropenem	I (2)	R (4)	-	MiE
7	*Enterobacter cloacae*	Cefepime	R (≥32)	S (≤1)	S	OK
10	*K. pneumoniae*	Cefepime	R (16)	S (2)	SDD	MiE
8	*Enterobacter cloacae*	Cefepime	SDD (8)	S (≤1)	S	OK

Harbor UCLA
Verification Study
Troubleshooting

Harbor UCLA
Verification Study Post-Verification

- **Contact manufacturer** to assist with programming new breakpoints on instrument
  - Lab may have to hit “activate” button!
- **Conduct audit:** LIS reports
  - LIS is able to receive the new breakpoints/interpretations
  - Did not need to involve IT
- **Notify stakeholders:** Antimicrobial Stewardship, Infectious Diseases, Infection Control
- **Impact:** changes in antibiogram; resistance rates

Summary

- There is a clinical and public health need to accurately identify CRE.
- Failure to utilize updated carbapenem breakpoints for Enterobacteriaceae may result in missing 20% of CRE isolates.
- CADPH and LACDPH are available to assist clinical laboratories in updating breakpoints.
- Please stay tuned to learn more about other Public Health initiatives to assist clinical laboratories in confronting antimicrobial resistance and susceptibility testing challenges!

Thank You!

…and thank you to:

- **Sandeep Bhaurla**
- **Erin Epson, MD**
- **Nikki Green, PhD D(ABMM)**
- **Sam Horwich-Scholefield**
- **James McKinnell, MD**
- **Dawn Terashita, MD**

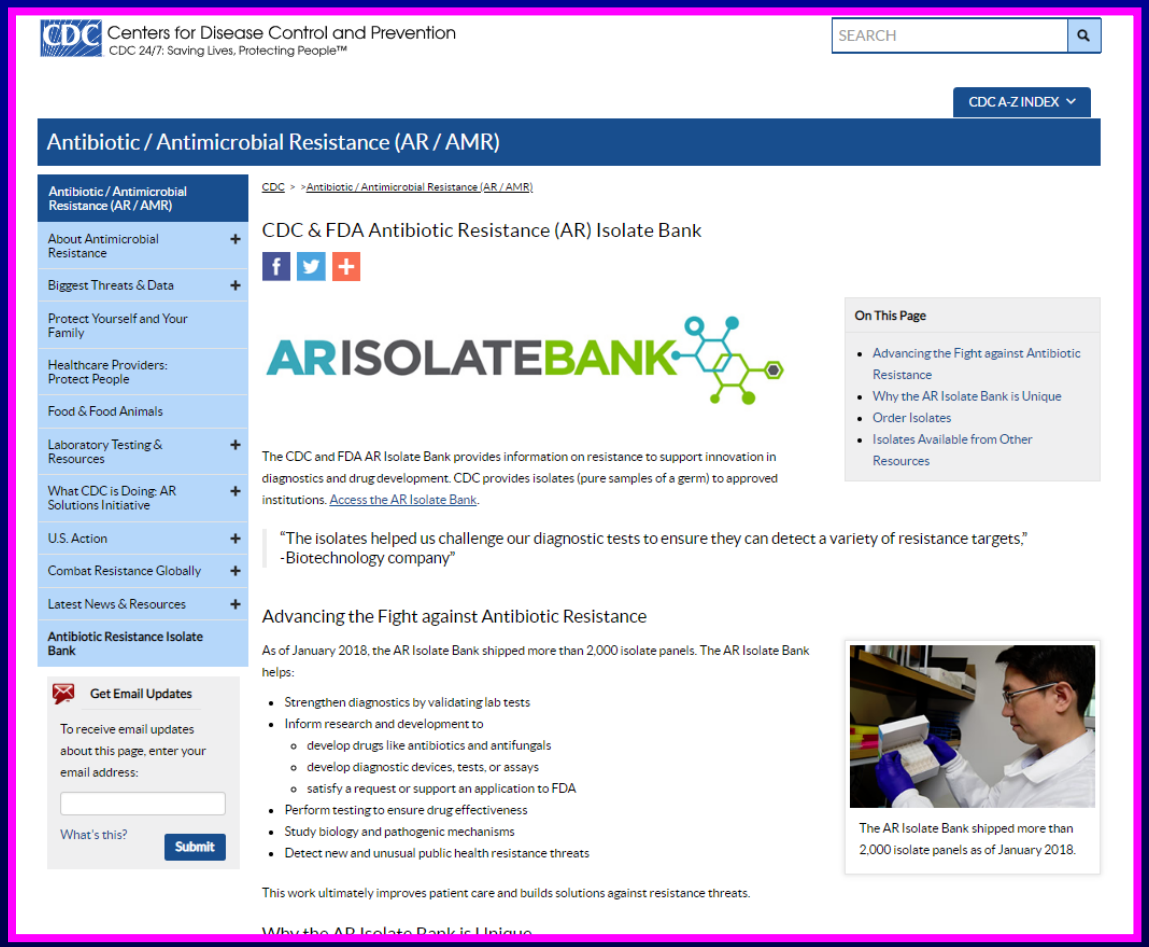
….and the rest of the teams!

Ordering Isolates from CDC & FDA AR Bank

- Ordering involves several steps but is not difficult.
- Refer to the following slides, if needed.
- If you experience problems, contact CDC staff to help you!

♦ Note: these slides were assembled 9/25/18. There was notice of a website update scheduled for 9/26/8. Some screens may have changed during that update.

Use AR Isolate Bank



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- U.S. Action +
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CDC > >Antibiotic / Antimicrobial Resistance (AR / AMR)

CDC & FDA Antibiotic Resistance (AR) Isolate Bank

AR ISOLATE BANK

On This Page

- Advancing the Fight against Antibiotic Resistance
- Why the AR Isolate Bank is Unique
- Order Isolates
- Isolates Available from Other Resources

The CDC and FDA AR Isolate Bank provides information on resistance to support innovation in diagnostics and drug development. CDC provides isolates (pure samples of a germ) to approved institutions. Access the AR Isolate Bank.

"The isolates helped us challenge our diagnostic tests to ensure they can detect a variety of resistance targets," -Biotechnology company"

Advancing the Fight against Antibiotic Resistance

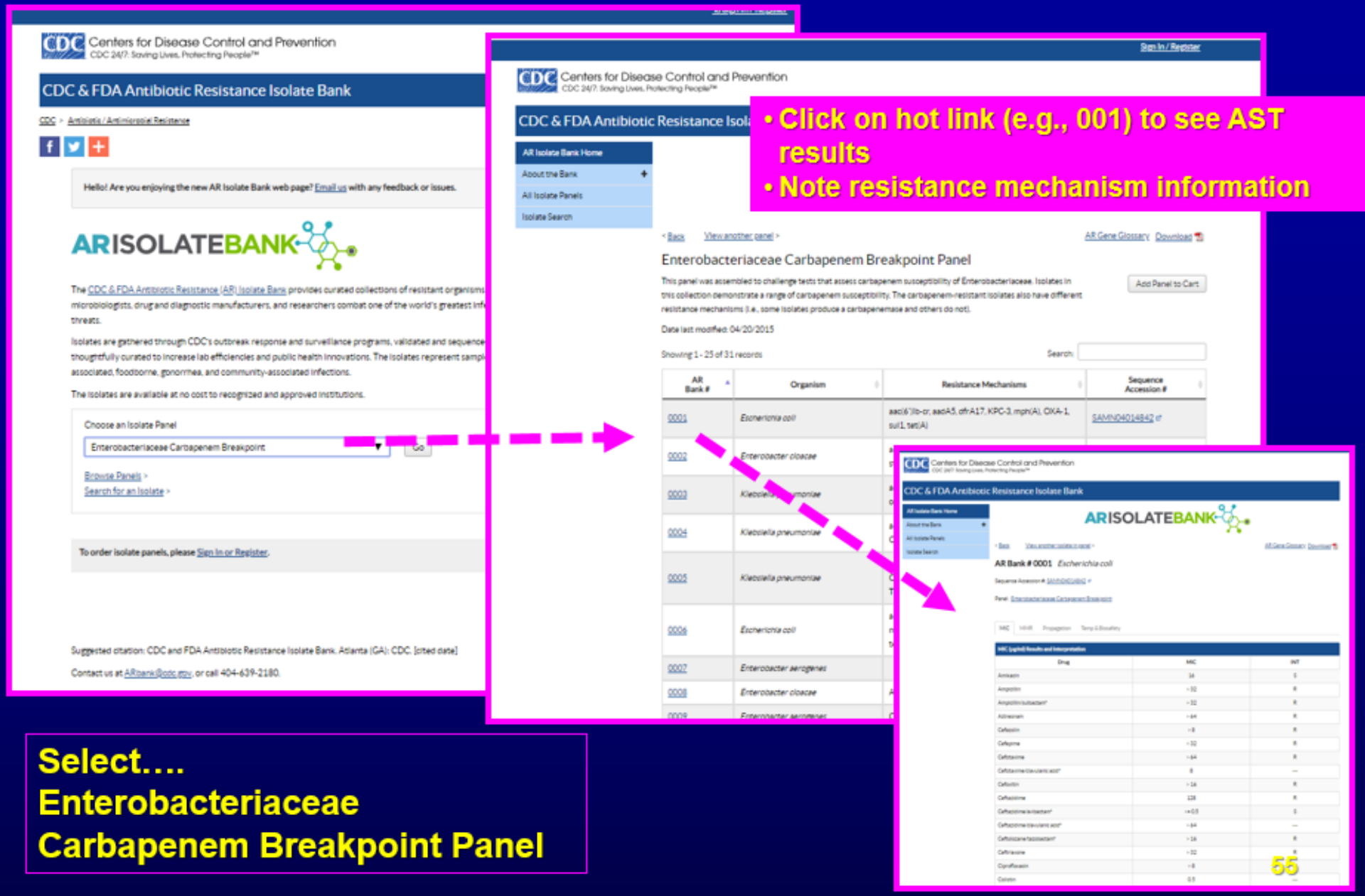
As of January 2018, the AR Isolate Bank shipped more than 2,000 isolate panels. The AR Isolate Bank helps:

- Strengthen diagnostics by validating lab tests
- Inform research and development to
  - develop drugs like antibiotics and antifungals
  - develop diagnostic devices, tests, or assays
  - satisfy a request or support an application to FDA
- Perform testing to ensure drug effectiveness
- Study biology and pathogenic mechanisms
- Detect new and unusual public health resistance threats

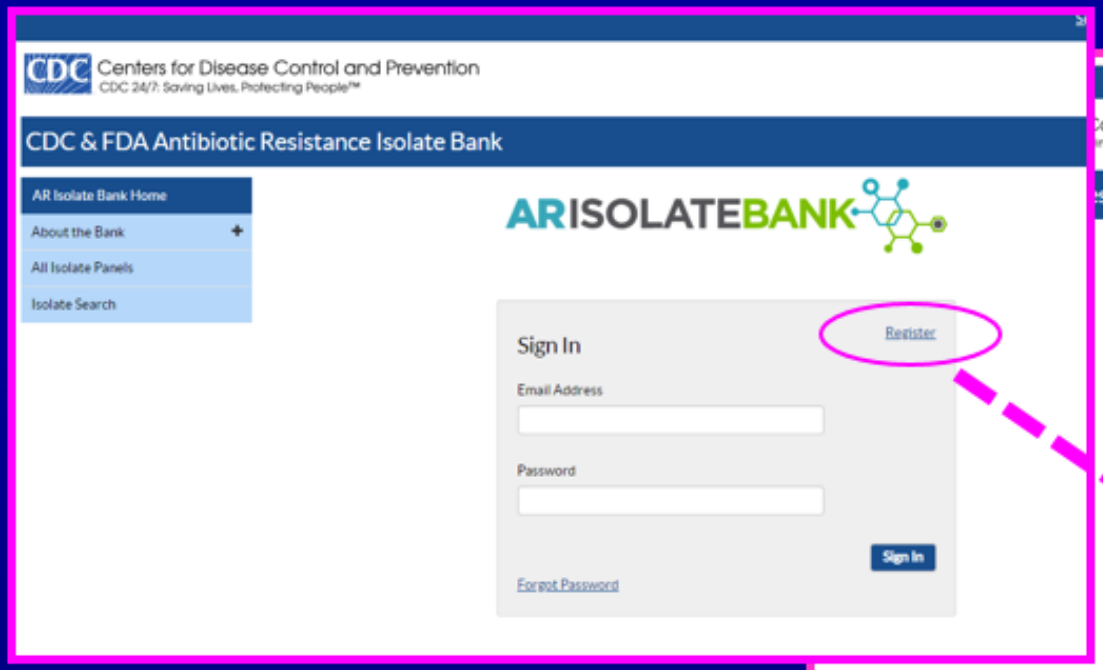
This work ultimately improves patient care and builds solutions against resistance threats.

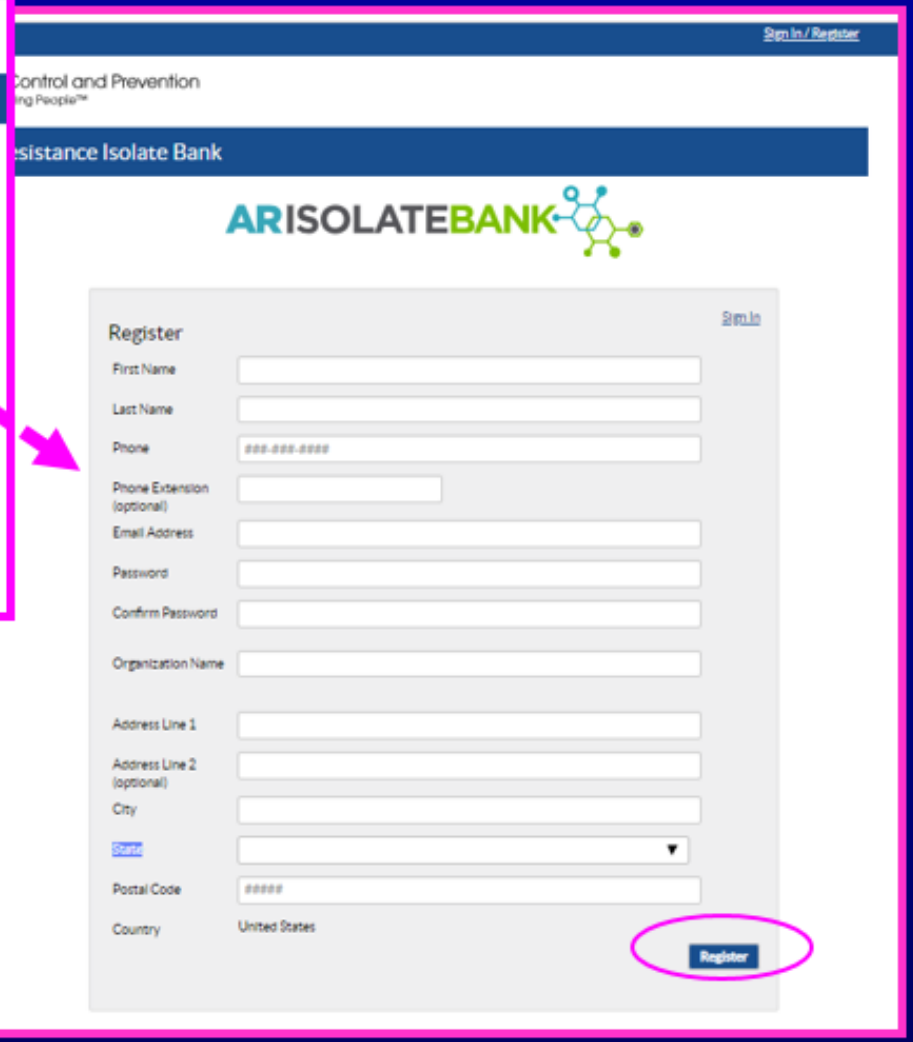
The AR Isolate Bank shipped more than 2,000 isolate panels as of January 2018.

Why the AR Isolate Bank is Unique

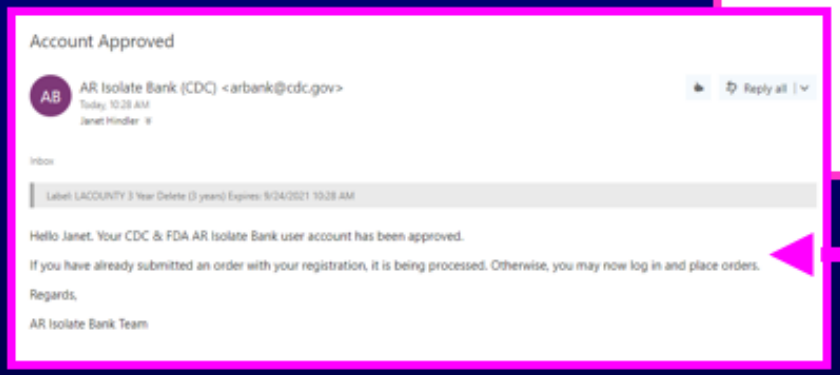


Select….
Enterobacteriaceae
Carbapenem Breakpoint Panel

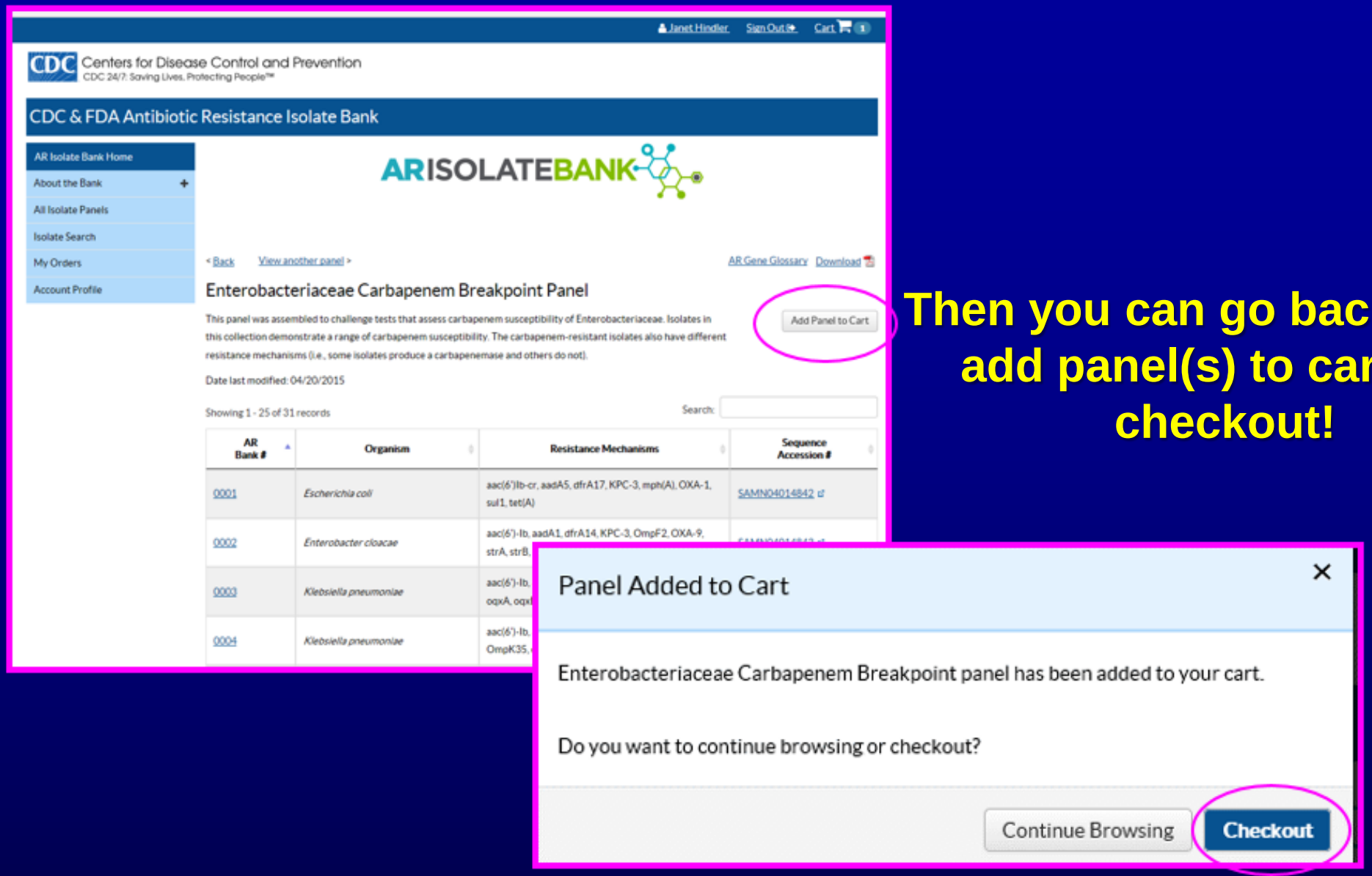




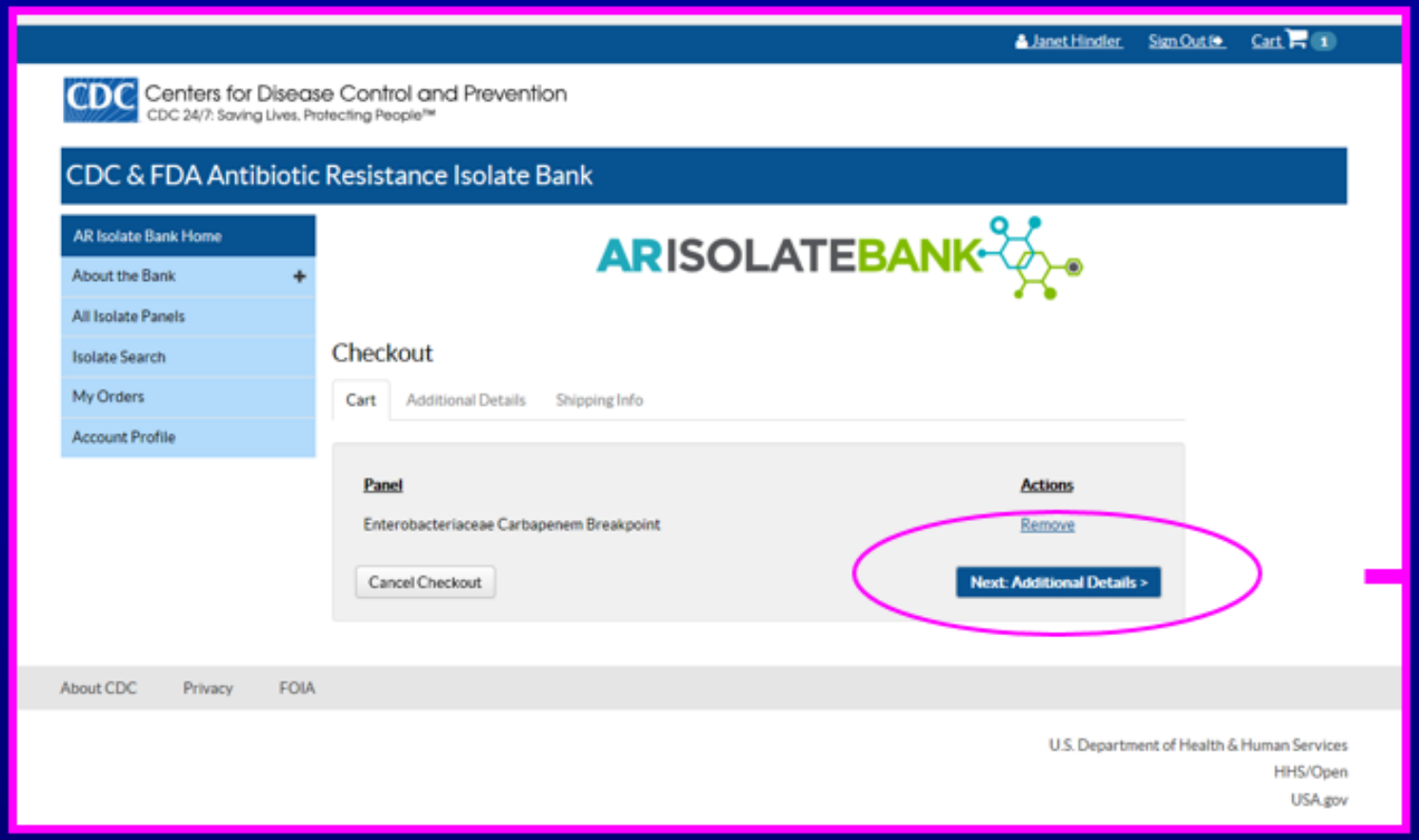
Must register to order isolates



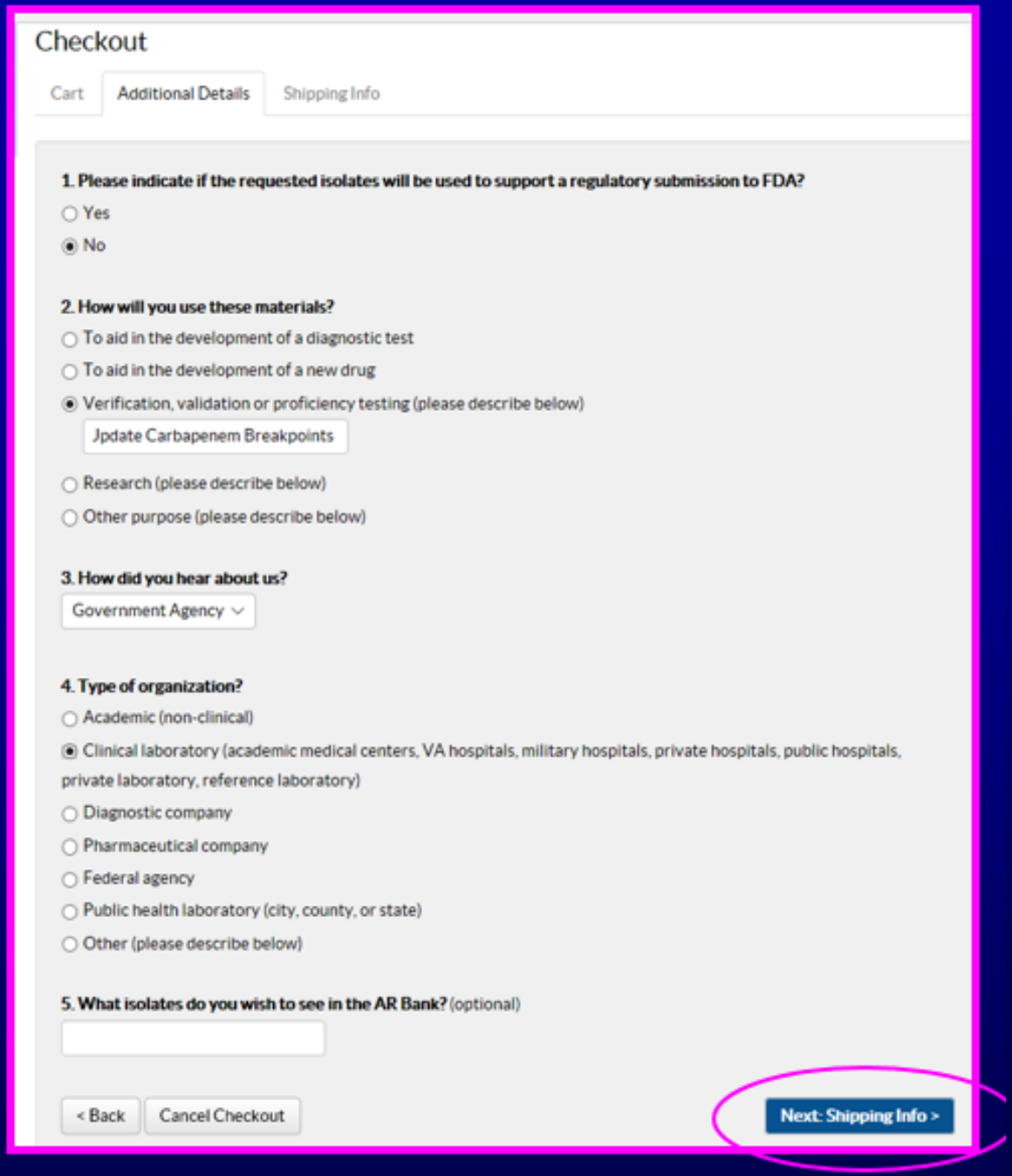
You will be notified once registration is complete.



Then you can go back in and add panel(s) to cart and checkout!



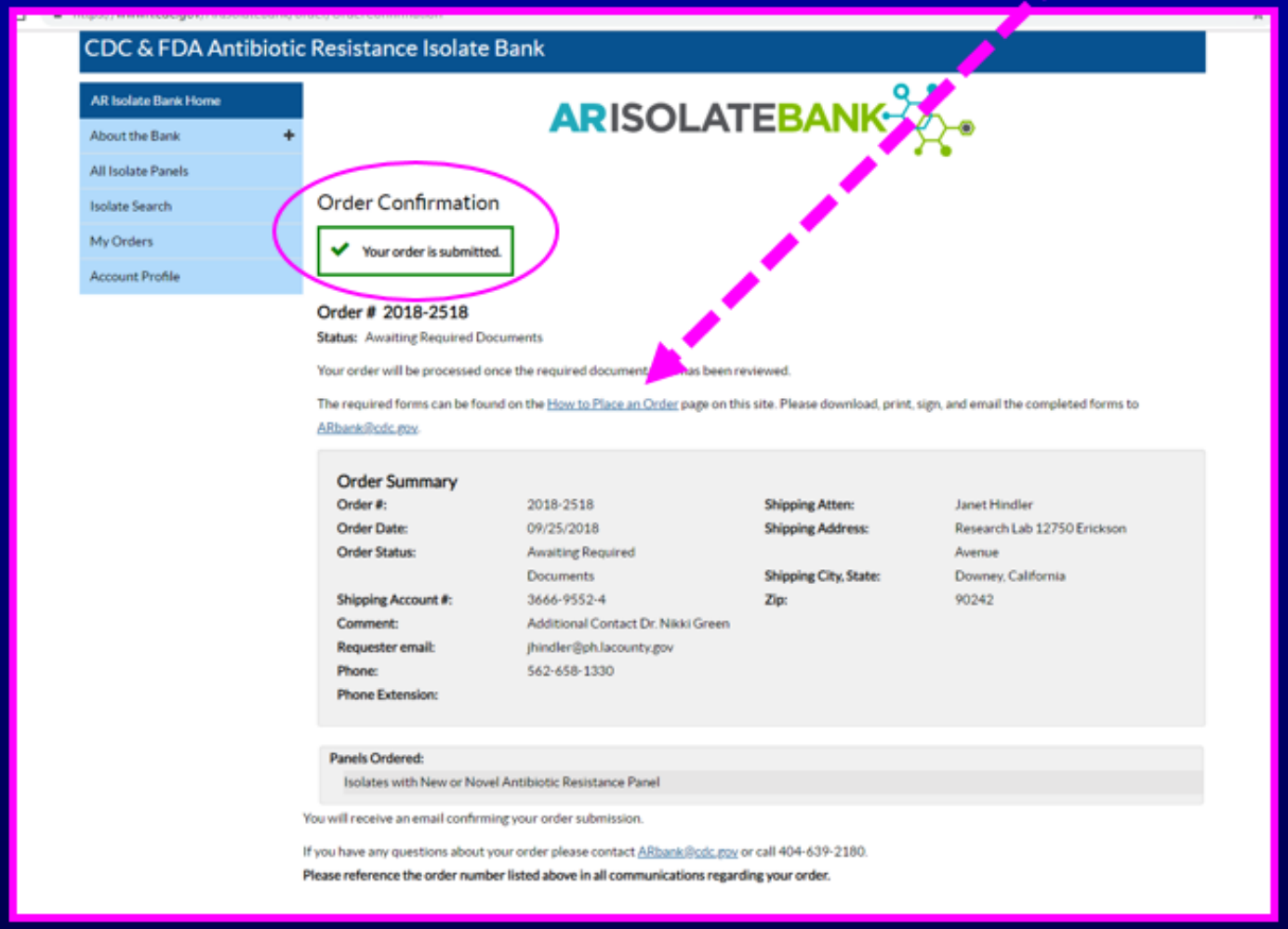
Provide additional information



How will you use the isolates?
(note answers filled out here are suggested for you)

You will need FedEx (or other shipping) account number
(you pay shipping fees)

..still need more forms
Click “How to Place an Order”



2 forms - click, print, complete, sign, submit (Fax) !

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CDC & FDA Antibiotic Resistance Isolate Bank

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- Contact Us
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- My Orders
- Account Profile

AR ISOLATE BANK

How to Place an Order

This page explains how users can browse through this public website and order curated isolate panels.

Customers may create an account and order isolate panels at no cost. All accounts and orders will be reviewed for approval prior to being shipped.

After placing an order, please download, print, and sign the forms provided below. Once these forms are completed, please scan and submit the forms to ARbank@cdc.gov for review.

Alternatively, forms may be mailed to:

AR Isolate Bank
1600 Clifton Rd.
Mail Stop: G-13
Atlanta, GA 30329-4027

Sign and Submit Forms Below to Complete Your Order	
SLA for Bacterial Bank	Simple Letter Agreement for requesting isolates from the CDC & FDA AR Isolate Bank. To be signed by recipient of the strains.
Biosafety Compliance Agreement	Letter of agreement to ensure compliance with biosafety guidelines for working with bacterial and fungal pathogens, like those in the CDC & FDA AR Isolate Bank. To be signed by a Biosafety Official. In the absence of a Biosafety Official, the Laboratory Director is eligible to sign.

You will receive email notifications as your order gets submitted, reviewed, approved, and shipped.

Note:

- These panels are the property of the CDC and are made available in collaboration with the FDA.
- Materials should not be reused for evaluation or development of other testing methods.
- Materials should not be redistributed.
- There is no cost for the panels, but requesters are required to pay shipping fees.

Searching Available Panels

Material Transfer Agreement (you cannot share isolates!)

The 2 forms…

Confirm compliance with Biosafety requirements

Simple Letter Agreement for Transfer of Non-Proprietary Biological Material v3

In response to the RECIPIENT's request for the MATERIAL, the PROVIDER asks that the RECIPIENT and the RECIPIENT SCIENTIST agree to the following before the RECIPIENT receives "MATERIAL" as described:

1. The selected MATERIAL is property in the PROVIDER's centralized repository of microbial pathogens with well-characterized resistance profiles.

2. THIS MATERIAL IS NOT FOR USE IN HUMAN SUBJECTS.

3. The MATERIAL will not be further distributed to any third party. The RECIPIENT shall refer any request for the MATERIAL to the PROVIDER. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agrees to make the MATERIAL available, under a separate Simple Letter Agreement to other scientists for teaching and/or internal research purposes only.

Select panel(s) below:
- ☐ Enterobacteriaceae Carbapenem Suceptibility
- ☒ Gram negative Carbapenemase Detection
- ☐ Enterobacteriaceae Carbapenemase Diversity
- ☐ Vancomycin Intermediate Resistance *Staphylococcus aureus*
- ☐ *Pseudomonas aeruginosa*
- ☐ *Neisseria gonorrhoeae*
- ☐ *Acinetobacter baumannii*
- ☐ Candida species
- ☐ Novel Antibiotic Resistance
- ☐ *Candida auris*
- ☐ Cefiolozane/tazobactam
- ☐ Ceftazidime/avibactam
- ☐ Enteric Pathogen Diversity
- ☐ *Staphylococcus aureus* with Borderline Oxacillin Susceptibility
- ☐ Imipenem/relebactam
- ☐ Aminoglycoside/tetracycline

4. The MATERIAL provided was not collected f r o m individuals specifically for the proposed research project. The PROVIDER will not, under any circumstances, provide the RECIPIENT with any personally identifiable information or the key linking the code to personally identifiable information associated with the MATERIAL."

5. The MATERIAL will be used for teaching and/or internal research purposes only. The MATERIAL will not be used in research projects:
   i. in which the RECIPIENT or the RECIPIENT SCIENTIST is obligated to assign inventions containing the MATERIAL or offer an exclusive license to inventions containing the MATERIAL to an organization other than the RECIPIENT or a contractor of the RECIPIENT that manages the RECIPIENT's inventions on behalf of the RECIPIENT; or
   ii. in which the MATERIAL is incorporated into a commercial product.

6. The RECIPIENT will acknowledge the PROVIDER of the MATERIAL in any publications or public disclosures. The original name given to the MATERIAL by the PROVIDER shall be maintained. In all publications related to the MATERIAL, its origin and the name given by the PROVIDER must be indicated.

7. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK

CDC & FDA AR Isolate Bank Biosafety Compliance Agreement

Version 1

Purpose In the setting of quality management system practices, this biosafety compliance agreement is to ensure that the requester agrees and complies with the biosafety guidelines for working with bacterial and fungal pathogens provided by the FDA-CDC Antimicrobial Resistance Bank (AR Bank).

An authorized representative of the requester laboratory must authorize this agreement and send it by fax or email to ARBank@cdc.gov before isolates from the AR Bank will be shipped to the requester. The requester will be notified if isolates cannot be shipped. Please call 404-639-2180 if you have any questions.

Recommended Laboratory Facilities, Equipment and Practices

Manipulations of viable strains of AR Bank isolates must be performed in a Biosafety Level 2 (BSL-2) laboratory that meets the following criteria outlined in the "Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition" (https://www.cdc.gov/biosafety/publications/bmbl5/ , see Section IV—Laboratory Biosafety Level Criteria).

Note: The AR Bank isolates may be resistant to multiple drugs that are commonly used to treat infectious caused by the bacterial or fungal strain. The increased difficulty in treating an infection should be a consideration when performing the risk assessment and deciding which precautions are most appropriate for your laboratory work.

The BSL-2 requirements include, but are not limited to, the following:

- Facility and Equipment:
  - Access to the laboratory is restricted when work is being conducted.
  - Laboratory doors are self-closing and have locks in accordance with the institutional policies.
  - All laboratory surfaces can be easily cleaned and decontaminated.
  - A sink is available for hand washing.
  - An eyewash station is readily available.
  - A method for decontaminating all laboratory wastes is available in the facility, preferably within the laboratory (e.g., autoclave, chemical disinfection or other validated decontamination method).

- Practices appropriate for AR Bank isolates:

Isolates will come frozen in about 1-2 weeks!

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- Order Isolates
- Isolates Available from Other Resources

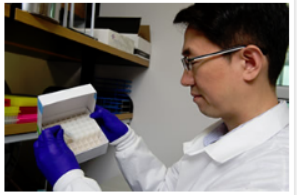
The CDC and FDA AR Isolate Bank provides information on resistance to support innovation in diagnostics and drug development. CDC provides isolates (pure samples of a germ) to approved institutions. Access the AR Isolate Bank.

> "The isolates helped us challenge our diagnostic tests to ensure they can detect a variety of resistance targets," -Biotechnology company"

Advancing the Fight against Antibiotic Resistance

As of January 2018, the AR Isolate Bank shipped more than 2,000 isolate panels. The AR Isolate Bank helps:

- Strengthen diagnostics by validating lab tests
- Inform research and development to
  - develop drugs like antibiotics and antifungals
  - develop diagnostic devices, tests, or assays
  - satisfy a request or support an application to FDA
- Perform testing to ensure drug effectiveness
- Study biology and pathogenic mechanisms
- Detect new and unusual public health resistance threats



The AR Isolate Bank shipped more than 2,000 isolate panels as of January 2018.

This work ultimately improves patient care and builds solutions against resistance threats.

Why the AR Isolate Bank is Unique

The End!